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): March 17, 2021

EVELO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38473**	**46-5594527**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

620 Memorial Drive
Cambridge, Massachusetts 02139
(Address of principal executive offices) (Zip Code)

(617) 577-0300
(Registrant's telephone number, including area code)

N/A
(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
Common Stock, $0.001 par value per share	EVLO	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 March 17, 2021, Evelo Biosciences, Inc. (the "*Company*") entered into a commercialization and license agreement (the "*ALJ Agreement*") with Meddist Company Limited ("*ALJ*"). Pursuant to the ALJ Agreement, the Company granted to ALJ an exclusive, non-transferable (except as permitted), sublicensable license under certain of the Company's know-how and patent rights relating to the Company's product candidate EDP1815 (together with any replacement or second products of the Company described below, the "*Products*") solely (i) to conduct development activities relating to the Products allocated to ALJ in a development plan agreed with the Company, (ii) to conduct manufacturing activities relating to the Products in all therapeutic uses in humans (the "*Field*") throughout the world, subject to certain conditions and requirements, and (iii) to commercialize the Products in the Field in all countries of Africa and the Middle East-Turkey excluding certain restricted countries (the "*Territory*"). If the Company ceases all development of EDP1815 prior to receipt of regulatory approval required for commercialization of EDP1815 in any one of the United States, the United Kingdom, France, Germany, Spain, Italy, China or Japan, then ALJ will have the right to designate another product candidate of the Company as a replacement to EDP1815 or terminate the ALJ Agreement, subject to certain conditions and requirements. Further, for the first two years of the term, ALJ will have the right to negotiate in good faith to add a second product candidate of the Company at a comparable stage of development to the ALJ Agreement, subject to certain conditions and requirements, including an additional fee (not to exceed $7.5 million) to be paid to the Company in consideration for ALJ's rights to such second product candidate. Under the ALJ Agreement, neither party is permitted to exploit any competitive product of the Products in the Field in the Territory, other than to develop or manufacture such competitive products in the Territory solely for purposes of exploiting such competitive products outside the Territory. However, the Company retains rights to (i) practice the licensed know-how and patents and exploit the Products (a) outside the Territory for any and all purposes and (b) outside the Field anywhere in the world in the Company's sole discretion, (ii) practice the licensed know-how and patents and exploit the Products in the Field in the Territory to the extent necessary to perform its obligations under the ALJ Agreement, (iii) manufacture the Products worldwide, and (iv) exploit any competitive products outside the Territory.

Pursuant to the ALJ Agreement, the Company is obligated to use commercially reasonable efforts to develop EDP1815 in order to obtain regulatory approval required for commercialization of EDP1815 in at least one of the United States, the United Kingdom, France, Germany, Spain, Italy, China and Japan. Both parties will (i) use commercially reasonable efforts to perform all activities allocated to the party in the development plan and a regulatory plan agreed by the parties and (ii) share eligible development expenses equally (50:50). Additionally, ALJ will be responsible for undertaking all regulatory activities in the Territory in accordance with the regulatory plan. Finally, ALJ will use commercially reasonable efforts to commercialize the Products in the Territory in accordance with a commercialization plan agreed by the parties and the parties will share eligible commercialization expenses equally (50:50).

In consideration for the rights the Company granted under the ALJ Agreement, ALJ paid to the Company a one-time, upfront payment of $7.5 million. Furthermore, ALJ Health Care & Life Sciences Company Limited purchased $7.5 million of the Company's common stock in a stand-alone transaction at the then-current fair market value on February 2, 2021. The parties will also share the operating profits and losses for all Products in the Territory equally (50:50).

Under the ALJ Agreement, the Company has the sole right and authority to file, prosecute and maintain the licensed patents, as well as the initial right, but not the obligation, to initiate an infringement or other appropriate suit relating to the licensed patents. Further, the Company will have the sole right, but not the obligation, to defend against actions challenging any claims within the licensed patents.

The ALJ Agreement will remain in effect until it is terminated pursuant to the terms thereunder. ALJ may terminate the ALJ Agreement, in its entirety or on a product-by-product basis, for convenience upon prior written notice. Additionally, ALJ may terminate the ALJ Agreement (i) in its entirety (or, if following ALJ's designation of a second product, only with respect to EDP1815) upon written notice if the Company ceases all development of EDP1815 prior to regulatory approval required for commercialization of EDP1815 in the specified countries triggering ALJ's right to a replacement product and ALJ chooses not to replace EDP1815, or (ii) on a product-by-product basis, upon written notice if regulatory authorities in five of the specified major market countries within the Territory provide written notice that they will not grant any regulatory approval required for commercialization in such countries for such Product. The Company may terminate the ALJ Agreement upon prior written notice, on a product-by-product basis, if ALJ does not conduct any material regulatory or commercialization activities with respect to a Product in any of the specified major market countries within the Territory for a continuous period of time, subject to certain conditions. Either party may terminate the ALJ Agreement upon written notice in the event of the other party's (x) material breach that is not cured after 90 days after written notice thereof or (y) bankruptcy or insolvency.

Upon termination of the ALJ Agreement for any reason (whether in whole or in part), (i) all licenses, sublicenses, and all other rights granted to ALJ thereunder will terminate for any terminated product in any terminated country, (ii) the Company will have a worldwide, exclusive, fully-paid, royalty-free, perpetual, irrevocable, sublicensable (through multiple tiers) license under ALJ's rights in any know-how or patents that relate to the Products that are owned and controlled by ALJ and are

necessary to exploit any terminated Products in terminated countries, (iii) ALJ will assign to the Company any third-party agreement entered into pursuant to which ALJ then controls any know-how or patents from a third party relating exclusively to terminated Products in terminated countries and that are necessary or reasonably useful to exploit such Products in such countries, if permitted under such third-party agreement, or, if such third-party know-how or patents cannot be assigned to the Company, then ALJ will maintain such third-party agreements and the Company will pay to ALJ 100% of all payments due thereunder in consideration of the sublicense to the Company and the Company's exploitation of such third-party know-how or patents, (iv) ALJ, to the extent requested by the Company, will assign and transfer to the Company all of its rights, title and interests in and to all regulatory submissions and approvals for terminated Products in the terminated countries, (v) ALJ, upon the Company's request, will provide copies of all material documentation relating to terminated Products, including material non-clinical, preclinical and clinical data, and (vi) ALJ, to the extent requested by the Company, will promptly assign and transfer to the Company all of ALJ's or its affiliates', sublicensees' or subcontractors' rights, title and interests in and to all clinical trial agreements, manufacturing agreements, supply agreements, distribution agreements, confidentiality and other agreements, data and other know-how in ALJ's or its affiliates', sublicensees' or subcontractors' control, in each case, relating exclusively to terminated Products in terminated countries. In addition, upon termination of the ALJ Agreement in part, if ALJ controls any know-how or patents from a third party that non-exclusively relate to terminated Products in terminated countries that are necessary or reasonably useful to exploit such Products, ALJ will maintain such third-party agreements and the Company will pay to ALJ 100% of all payments due thereunder in consideration of the sublicense to the Company and the Company's exploitation of such third-party know-how or patents.

The foregoing description of the Agreement is not complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which is filed as Exhibit 1.1 to this Current Report on form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
1.1	Commercialization and License Agreement dated March 17, 2021 by and among Evelo Biosciences, Inc. and Meddist Company Limited
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

EVELO BIOSCIENCES, INC.

Date: March 23, 2021

By: /s/ Daniel S. Char
Daniel S. Char
General Counsel & Secretary

Certain information marked as [***] has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 1.1

COMMERCIALIZATION AND LICENSE AGREEMENT

BETWEEN

EVELO BIOSCIENCES, INC.

AND

MEDDIST COMPANY LIMITED

Dated 17 March 2021

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COMMERCIALIZATION AND LICENSE AGREEMENT

THIS COMMERCIALIZATION AND LICENSE AGREEMENT (this "**Agreement**") is entered into as of 17 March 2021 (the "**Effective Date**") by and between EVELO BIOSCIENCES, INC., a corporation organized and existing under the laws of Delaware ("**Evelo**"), and MEDDIST COMPANY LIMITED, a company organized and existing under the laws of Jersey ("**ALJ**"). Evelo and ALJ are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Evelo is in the business of developing, manufacturing, and commercializing biologic therapeutic products, including the Products;

WHEREAS, Evelo is seeking a partner to Commercialize Products in the Territory, and ALJ desires to acquire rights to Commercialize Products in the Territory, in each case, upon the terms and conditions set forth herein; and

WHEREAS, Evelo desires to grant to ALJ, and ALJ desires to receive from Evelo, an exclusive right and license under the Licensed Technology to Commercialize Products in the Field in the Territory.

NOW, **THEREFORE**, the Parties agree as follows:

1. DEFINITIONS

1.1 "**Accounting Standards**" means International Financial Reporting Standards (IFRS) or U.S. Generally Accepted Accounting Principles (GAAP), as generally and consistently applied in compliance with Applicable Laws throughout a Party's organization at the relevant time.

1.2 "**Acquirer**" means, collectively, with respect to the acquisition of a Party by a Third Party, a Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates (determined as of immediately prior to the closing of such Change of Control).

1.3 "**Additional Cure Period**" has the meaning set forth in Section 14.2.1(c) (Disputes Regarding Material Breach).

1.4 "**Adverse Event**" has the meaning set forth in U.S. Federal Regulation 21 C.F.R. § 312.32 and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An Adverse Event does not necessarily have a causal relationship with a product, that is, an Adverse Event can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.5 "**Affiliate**" of a Person means any other Person that (directly or indirectly) is controlled by, controls, or is under common control with such Person, but only for so long as such control continues. For the purposes of this definition, the term "**control**" (including, with correlative meanings, the terms "**controlled by**" and "**under common control with**") as used with respect to a Person, will mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and "**control**" will be presumed to exist if either of the following conditions is met: (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least 50% of the votes in the election of directors; or (b) in the case of a non-corporate entity, direct or indirect ownership of at least 50% of the equity interests with the power to direct the management and policies of such entity. For purposes of this Agreement, neither Evelo nor any of its Affiliates will be considered an Affiliate of ALJ, and neither ALJ nor any of its Affiliates will be considered an Affiliate of Evelo.

1.6 "**ALJ Exclusive Identified Rights**" has the meaning set forth in Section 15.2.1(c) (Licenses).

1.7 "**ALJ Housemarks**" means (a) the corporate logo of ALJ or any of its Affiliates, (b) the trademarks "ALJ", "AJ" and "Abdul Latif Jameel" (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "ALJ", "AJ" or "Abdul Latif Jameel" (d) any other corporate logo or trademark used by ALJ to identify ALJ or its Affiliates, (e) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (f) all goodwill associated with any and all of the foregoing in subsections (a) through (e).

1.8 "**ALJ Indemnified Party**" has the meaning set forth in Section 13.1 (Indemnification by Evelo).

1.9 "**ALJ Manufacturing Activities**" means activities directed to fill and finish of a Product for the Territory.

1.10 "**ALJ Non-Exclusive Identified Rights**" has the meaning set forth in Section 15.2.1(d) (Licenses).

1.11 "**ALJ Sales Personnel**" has the meaning set forth in Section 6.7.1 (Approval and Branding of Training Materials).

1.12 "**Alliance Manager**" has the meaning set forth in Section 3.6.1 (Alliance Managers).

1.13 "**Allowable Overruns**" means any amount that is up to [***] above the total budgeted or approved amounts for a Calendar Year on a quarterly basis set forth in any Shared Expenses Budget for such Calendar Year to the extent such amount is not attributable to a Party's action or inaction that constitutes a breach or default under this Agreement.

1.14 "**API**" means, in respect of a Product, the active pharmaceutical ingredient for that Product.

1.15 "**Applicable Law**" means applicable laws, statutes, rules, regulations, and other pronouncements having the effect of law of any Governmental Authority in the Territory that may be in effect from time to time, including any applicable rules, regulations, guidance, and other requirements of any Regulatory Authority that may be in effect from time to time.

1.16 "**Approved Labeling**" means, with respect to each Product in a country in the Territory: (a) the Regulatory Authority-approved full prescribing information for such Product in such country; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Product in such country.

1.17 "**Approved Subcontractor**" has the meaning set forth in Section 2.2 (Sublicensing and Subcontracting by ALJ).

1.18 "**Audited Party**" has the meaning set forth in Section 9.7.1 (Record Retention; Audits).

1.19 "**Auditing Party**" has the meaning set forth in Section 9.7.1 (Record Retention; Audits).

1.20 "**BLA**" means (a) in the United States, a Biologics License Application, as defined in the United States Public Health Service Act (42 U.S.C. § 262), and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application, and (b) in any other country, the relevant equivalent to the foregoing.

1.21 "**Business Day**" means any day other than a Friday, Saturday, Sunday, or bank or other public holiday in Boston, Massachusetts, Dubai, United Arab Emirates or Jeddah, the Kingdom of Saudi Arabia.

1.22 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, or December 31 in any Calendar Year.

1.23 "**Calendar Year**" means any calendar year beginning on January 1 and ending on December 31.

1.24 "**Change of Control**" means, with respect to a Party, (a) a merger, consolidation, recapitalization, or reorganization of such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies for purposes of management voting on matters as directed by beneficial owners) of the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to hold beneficial ownership of more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger, consolidation, recapitalization, or reorganization, (b) a transaction or series of related transactions in

which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets.

1.25 "**Clinical Trial**" means: (a) a Phase I Clinical Trial, (b) a Phase II Clinical Trial, or (c) a Phase III Clinical Trial.

1.26 "**Co-Funded Expense Report**" has the meaning set forth in Schedule 9.3 (Profit and Loss Share).

1.27 "**Commercialization**," "**Commercializing**," or "**Commercialize**" means any and all activities directed to the marketing, promotion, distribution, offering for sale, sale, having sold, importing, having imported, exporting, having exported, or other commercialization of a pharmaceutical or biological product, but excluding activities directed to Manufacturing, Medical Affairs, or Development. "**Commercialized**" will be construed accordingly.

1.28 "**Commercialization Budget**" has the meaning set forth in Section 6.1 (Commercialization Plan).

1.29 "**Commercialization Plan**" has the meaning set forth in Section 6.1 (Commercialization Plan).

1.30 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended with respect to any objective or activity hereunder by a Party, such reasonable, diligent, good faith efforts to accomplish such objective or activity as a similarly situated (with respect to size, stage of development of products, and assets) company would normally use to accomplish such objective or activity with respect to a pharmaceutical or biologic product of similar market potential (without taking into account payments under this Agreement) and at a similar stage of its product life, based on conditions then prevailing and taking into account efficacy, safety, Approved Labeling, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, the likelihood of receiving regulatory approval given the regulatory structure involved, profitability, and other relevant factors. For clarity, Commercially Reasonable Efforts is be determined on a country-by-country and Product-by-Product basis and it is anticipated that the level of effort may be different for different countries in which the relevant activity is conducted and may change over time, reflecting changes in the status of the relevant Product and the countries involved.

1.31 "**Competing Infringement**" has the meaning set forth in Section 10.4.1 (Third Party Infringement).

1.32 "**Competitive Product**" means any orally administered, pharmaceutical preparation containing the bacteria *Prevotella histicola* for treatment or prevention of inflammatory disease, other than a Product.

1.33 "**Confidential Information**" means (a) the terms of this Agreement, and (b) with respect to each Party, all Know-How or other proprietary information, including information and materials (whether or not patentable) regarding or embodying such Party's technology, products, business information, or objectives, that is communicated: (i) in writing and marked as confidential (including information disclosed in writing and marked as confidential prior to the Effective Date pursuant to the Confidentiality Agreement); (ii) orally or in any other intangible form, and reduced to writing and marked as confidential within 20 days of such initial communication; or (iii) at a PCC meeting in accordance with Section 3.1.2, in each case by or on behalf of such Party to the other Party.

1.34 "**Confidentiality Agreement**" means that certain Confidentiality Agreement effective as of [***], by and between [***] and Evelo.

1.35 "**Control**" or "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other Intellectual Property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other Intellectual Property on the terms set forth herein, or (c) with respect to a product or component thereof, the legal authority or right to grant to the other Party a license, sublicense, access, or right to use (as applicable) under Patent Rights that Cover, or proprietary Know-How that is incorporated in or embodies, such product or component on the terms set forth herein, in each case (subsections (a), (b), and (c)), (i) without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense, or (ii) without incurring any additional payment obligations to a Third Party that are not subject to an agreed allocation between the Parties. Notwithstanding any provision to the contrary set forth in this Agreement, a Party will be deemed not to Control any Know-How (tangible or intangible), Patent Rights, Regulatory Approvals, Regulatory Submissions, or other Intellectual Property that are owned or in-licensed by an Acquirer.

1.36 "**Cover**," "**Covering**," or "**Covered**" means, with respect to a product, composition of matter, technology, process, method, or mode of administration that, in the absence of ownership of or a license granted under a particular patent, the manufacture, use, offer for sale, sale, or importation of such product or composition of matter or the practice of such technology, process, method, or mode of administration would infringe such patent or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue and become an issued patent.

1.37 "**Data Package**" means, with respect to any Eligible Replacement Product or Eligible Second Product, as applicable: (a) a summary of all the relevant data from any Clinical Trial, including all resultant data analyses; (b) any regulatory submissions made to any Regulatory Authority by or on behalf of Evelo; and (c) subject to any existing Third Party confidentiality obligations, protocols for any ongoing Clinical Trials and proposed designs for any planned and budgeted Clinical Trials, in each case, in the same format provided to Regulatory Authorities, if available, and otherwise in the format then-existing within Evelo's records, at the time at which Evelo provides ALJ with the identity of such Eligible Replacement Product or Eligible Second Product in accordance with Section 2.4.1 (Evelo Cessation) or Section 2.4.2 (Second Product), as applicable.

1.38 "**Defaulting Party**" has the meaning set forth in Section 14.2.1(c) (Disputes regarding Material Breach).

1.39 "**Develop**" or "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, toxicology, non-clinical and preclinical testing and activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain or maintain Regulatory Approval of a pharmaceutical or biologic product, and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but expressly excluding activities directed to Manufacturing, Medical Affairs, or Commercialization. "**Developing**" and "**Developed**" will be construed accordingly.

1.40 "**Development Budget**" has the meaning set forth in Section 4.2 (Development Plan).

1.41 "**Development Plan**" has the meaning set forth in Section 4.2 (Development Plan).

1.42 "**Development Report**" has the meaning set forth in Section 4.5 (Development Reports).

1.43 "**Disclosing Party**" has the meaning set forth in Section 11.2 (Non-Disclosure and Non-Use Obligation).

1.44 "**Distribution Costs**" means the FTE Costs and Out-of-Pocket Expenses incurred by ALJ or its Affiliates that are directly attributable to the distribution of the Product(s) for the Territory, including storage and distribution activities, packaging and labelling of the Products (to the extent not included in Manufacturing Costs), customer services, collection of data about sales to hospitals and other end users, order entry, billing, credit, and credit and collection services and other such activities, but for clarity, excluding any such amounts to the extent included as a deduction in calculating Net Sales. Distribution Costs will be recognized and calculated in accordance with the applicable Accounting Standards.

1.45 "**Dollar**" means the U.S. dollar, and "**$**" will be interpreted accordingly.

1.46 "**EDP1815**" means a pharmaceutical preparation comprising bacteria from a single strain of *Prevotella histicola*, which strain has NRRL accession number [***].

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

1.48 "**Eligible Commercialization Expenses**" means the FTE Costs and Out-of-Pocket Expenses incurred by or on behalf of a Party or its Affiliates that are directly attributable or reasonably allocable to Commercialization activities for the Products described in the applicable Commercialization Plan:

(a) Manufacturing Costs for Products used for Commercialization (including for inventory build);

(b) Distribution Costs;

(c) FTE Costs and Out-of-Pocket Expenses associated with (i) the development of the Commercialization Plan and each update or amendment thereto, (ii) marketing of such Product, (iii) marketing (including telemarketing), promotion, advertising, professional education, symposia and opinion leader development, and Promotional Materials (including the development thereof), (iv) activities related to obtaining reimbursement from payers and costs of sales and marketing data, and (v) market research and strategic planning activities for such Product;

(d) to the extent provided in Section 13.3 (Certain Indemnified Losses), Liabilities from Third Party claims arising from the Commercialization (or Manufacture in support of Commercialization) of the Products for the Territory; and

(e) FTE Costs and Out-of-Pocket Expenses that are attributable to the establishment and maintenance of sales personnel (including a field-based sales force and regional managers) to the extent such personnel are, or will be, assigned to selling such Product,

in each case, to the extent such costs and expenses (as applicable) are included in the applicable Commercialization Budget, plus applicable Allowable Overruns and costs or expenses otherwise approved by the PCC, but expressly excluding Overhead Costs and capital expenditures.

If any FTE Cost or Out-of-Pocket Expense is directly attributable or reasonably allocable to more than one Commercialization cost category set forth above, then such cost or expense will only be counted once (i.e., as an Eligible Commercialization Expense with respect to only one such category). Eligible Commercialization Expenses specifically exclude (i) the cost of activities that promote a Party's, its Affiliates' or Sublicensees' business as a whole without being specific to the Commercialization of any Product, and (ii) any costs or expenses incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party or its Affiliates' or Sublicensees' action or omission that constitutes a breach of or default under this Agreement by or on behalf of such Party. No FTE Cost

or Out-of-Pocket Expense included as an Eligible Commercialization Expense will also be included as an Eligible Development Expense, an Eligible Medical Affairs Expense or an Other Operating Expense. Eligible Commercialization Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

1.49 "**Eligible Development Cost Share Ratio**" has the meaning set forth in Section 4.4 (Development Costs).

1.50 "**Eligible Development Expenses**" means all FTE Costs and Out-of-Pocket Expenses to the extent relating to the Territory (1) incurred by or on behalf of a Party or its Affiliates that are directly attributable or reasonably allocable to (x) Development activities in accordance with the Development Plan and Development Budget or (y) regulatory activities in accordance with the Regulatory Plan and Regulatory Budget, or (2) otherwise approved by the PCC, including the following:

(a) Manufacturing Costs for Products required to perform such activities;

(b) FTE Costs and Out-of-Pocket Expenses incurred in the performance of the Development activities to the extent in accordance with the Development Plan and Development Budget plus Allowable Overruns and other FTE Costs and Out-of-Pocket Expenses otherwise approved by the PCC, but expressly excluding Overhead Costs and capital expenditures;

(c) to the extent provided in Section 13.3 (Certain Indemnified Losses), Liabilities from Third Party claims arising from the Development (or Manufacture in support of Development) of the Products for the Territory; and

(d) FTE Costs and Out-of-Pocket Expenses related to preparing, filing, obtaining, and maintaining Regulatory Approval or other submissions to Regulatory Authorities (including associated filing and other Regulatory Authority fees, translation expenses, and legal and other professional services fees), and performing other regulatory activities for the Products for the Territory, in each case, to the extent in accordance with the Regulatory Plan and Regulatory Budget plus Allowable Overruns and other FTE Costs and Out-of-Pocket Expenses otherwise approved by the PCC, but expressly excluding Overhead Costs and capital expenditures.

If any cost or expense (as applicable) is specifically identifiable or reasonably allocable to more than one Development cost category above, then such cost or expense will only be counted once. Eligible Development Expenses specifically exclude any costs or expenses incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party's or its Affiliates' or Sublicensees' action or omission that constitutes a breach of or default under this Agreement by or on behalf of such Party. No expense included as an Eligible Development Expense will also be included as an Eligible Shared Expense. Eligible Development Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

1.51 "**Eligible Development Expenses Report**" has the meaning set forth in Section 4.4 (Development Costs).

1.52 "**Eligible Medical Affairs Expenses**" means all FTE Costs or Out-of-Pocket Expenses incurred by or on behalf of a Party or its Affiliates (a) that are directly attributable or reasonably allocable to the Medical Affairs activities and any other activities related to patient advocacy or health economics and outcomes research, in each case, for the Products for the Territory in accordance with the Medical Affairs Plan and Medical Affairs Budget, plus applicable Allowable Overruns and other FTE Costs and Out-of-Pocket Expenses otherwise approved by the PCC, but expressly excluding Overhead Costs and capital expenditures, and (b) to the extent provided in Section 13.3 (Certain Indemnified Losses), Liabilities from Third Party claims arising from the performance of Medical Affairs for the Products for the Territory. Eligible Medical Affairs Expenses specifically exclude any costs or expenses incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party or its Affiliates' action or omission that constitutes a breach of or default under this Agreement by or on behalf of such Party. No expense included as an Eligible Medical Affairs Expense will also be included as an Eligible Development Expense, Eligible Commercialization Expense, or Other Operating Expense. Eligible Medical Affairs Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

1.53 "**Eligible Replacement Product**" has the meaning set forth in Section 2.4.1(b) (Evelo Cessation).

1.54 "**Eligible Shared Expenses**" means the Eligible Commercialization Expenses, Eligible Medical Affairs Expenses, and Other Operating Expenses.

1.55 "**Evelo Housemarks**" means (a) the corporate logo of Evelo, (b) the trademarks "EVELO," and "Squiggle," (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "Evelo," (d) any trademark, trade name, or service mark (whether registered or unregistered) used as the name of any Clinical Trial for any Product, (e) any other corporate logo or trademark of Evelo used by Evelo to identify Evelo or its Affiliates, (f) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (g) all goodwill associated with any and all of the foregoing in subsections (a) through (f).

1.56 "**Evelo Indemnified Party**" has the meaning set forth in Section 13.2 (Indemnification by ALJ).

1.57 "**Executive Officers**" has the meaning set forth in Section 3.3.2 (Decisions of the PCC).

1.58 "**Exploit**" means to Develop, have Developed, make, have made, use, have used, perform Medical Affairs, have performed Medical Affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Commercialize, have Commercialized, or otherwise exploit. "**Exploitation**" and "**Exploiting**" will be construed accordingly.

1.59 "**FDA**" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.60 "**Field**" means all therapeutic uses in humans.

1.61 "**Financing**" has the meaning set forth in Section 9.2 (Equity Investment).

1.63 "**Finished Form**" means a Product supplied in finished form in any presentation, ready for distribution in the applicable country in the Territory in compliance with all Applicable Law in such country at the relevant time, including all applicable Packaging and Labeling of such Product for sale or use in the applicable country in the Territory, including the Approved Labeling and all other Packaging and Labeling for such Product in the applicable country.

1.64 "**First Commercial Sale**" means, with respect to a Product in a country in the Territory, the first sale of such Product by ALJ or its Affiliates or Sublicensees to a Third Party (other than a Sublicensee) for distribution, use, or consumption by an end user in such country. For the avoidance of doubt, First Commercial Sale excludes any transfers of a Product to Third Parties for Clinical Trial purposes.

1.65 "**Force Majeure**" has the meaning set forth in Section 16.10 (Force Majeure).

1.66 "**Foreign Partnership**" has the meaning set forth in Section 9.6.2 (Foreign Partnership).

1.67 "**FTE**" means the equivalent of a fulltime person's work time, carried out by an appropriately qualified employee of a Party or its Affiliates, on the performance of Development, Manufacturing, Commercialization, or Medical Affairs activities, based on [***] per year, pro-rated as necessary. Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (e.g., timeandahalf or double time) toward the number of hours that are used to calculate the contribution. Indirect personnel (including support functions such as managerial, financial, legal, or business development) will not constitute FTEs.

1.68 "**FTE Costs**" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

1.69 "**FTE Rate**" means all actual direct and indirect costs of the performing Party's FTE, [***], including personnel and travel expenses. The initial FTE Rate for each Party will be determined by the PCC in accordance with Section 3.2.2 (Responsibilities). The FTE Rates for either Party may be adjusted as set forth in Section 3.2.3 (Responsibilities).

1.70 "**Global Commercialization Plan**" has the meaning set forth in Section 6.1 (Commercialization Plan).

1.71 "**Global Trade Control Laws**" means the U.S. Export Administration Regulations ("**EAR**"); the U.S. International Traffic in Arms Regulations ("**ITAR**"); the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign

Assets Control (including the Export Administration Act); European Union ("**EU**") Council Regulations on export controls, including Nos. 428/2009 and 267/2012; other EU Council sanctions regulations, as implemented in EU Member States; United Nations sanctions policies; all relevant regulations and legislative instruments made under any of the above; other relevant economic sanctions, export and import control laws, and other laws, regulations, legislation, orders, and requirements imposed by a relevant Governmental Authority.

1.72 "**GMP**" means all applicable current good manufacturing practices, including, as applicable, the principles detailed in (a) the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.

1.73 "**Governmental Authority**" means any court, tribunal, arbitrator, agency, commission, department, ministry, official, authority, or other instrumentality of any national, state, county, city, or other political subdivision.

1.74 "**Government Official**" means: (a) any Person employed by or acting on behalf of a Governmental Authority; (b) any political party, party official, or candidate; (c) any Person who holds or performs the duties of an appointment, office, or position created by custom or convention; or (d) any Person who holds himself out to be the authorized intermediary of any of the foregoing.

1.75 "**Housemarks**" means the Evelo Housemarks and the ALJ Housemarks.

1.76 "**IND**" means an Investigational New Drug application required pursuant to U.S. Federal Regulation 21 C.F.R. Part 312 or any comparable filings outside of the United States to commence Clinical Trials in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

1.77 "**Indemnified Party**" has the meaning set forth in Section 13.4 (Procedure).

1.78 "**Indemnifying Party**" has the meaning set forth in Section 13.4 (Procedure).

1.79 "**Infringement**" has the meaning set forth in Section 10.4.1 (Third Party Infringement).

1.80 "**Infringement Action**" has the meaning set forth in Section 10.4.2 (Evelo's Rights).

1.81 "**Intellectual Property**" means all Patent Rights, rights to Inventions, copyrights, design rights, trademarks, trade secrets, Know-How, and all other intellectual property rights (whether registered or unregistered) and all applications and rights to apply for any of the foregoing, anywhere in the world.

1.82 "**Invention**" means any process, method, utility, formulation, composition of matter, article of manufacture, material, creation, discovery or finding, or any improvement

thereof, that is made, conceived, discovered, or otherwise generated, whether patentable or not.

1.82 "**Know-How**" means any (a) proprietary information or materials, including records, improvements, modifications, techniques, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, processes, marketing, pricing and distribution costs, Inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, other know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) physical embodiments of any of the foregoing.

1.83 "**Knowledge**" means the actual knowledge of Evelo's officers as defined under Rule 16a-1(f) of the Securities Exchange Act of 1934 (or amendment thereto or replacement or successor law), having made reasonable inquiries, as of the Effective Date.

1.84 "**Liabilities**" has the meaning set forth in Section 13.1 (Indemnification by Evelo).

1.85 "**Licensed Know-How**" means any and all Know-How that is: (a) Controlled by Evelo or any of its Affiliates during the Term; and (b) necessary or reasonably useful for ALJ to Commercialize or perform any permitted ALJ Manufacturing Activities with respect to the Products in the Territory.

1.86 "**Licensed Patent Rights**" means any and all Patent Rights that are: (a) Controlled by Evelo or any of its Affiliates during the Term; and (b) necessary or reasonably useful for ALJ to Commercialize or perform any permitted ALJ Manufacturing Activities with respect to the Products in the Territory.

1.87 "**Licensed Technology**" means all Licensed Know-How and Licensed Patent Rights.

1.88 "**Major Market**" means all Major Market Countries taken together.

1.89 "**Major Market Country**" means [***].

1.90 "**Manufacture**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.91 "**Manufacturing Costs**" means, with respect to the Products, the consolidated fully burdened Manufacturing costs in accordance with the applicable Accounting Standards, which will be the sum of:

(a) if and to the extent such Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a contract manufacturing organization (including process development or other Manufacturing services), (i) the actual amount paid or payable to a Third Party by the supplying Party, including the costs of raw materials (including any costs incurred by such supplying Party for time spent by such Party's personnel to draft authorization letters or other documentation necessary for the other Party to obtain such raw materials, at the FTE Rate), intermediates and components, reference materials, or standards required for release testing, materials necessary to support stability studies (including methods, reference materials, and consumables), drug substance and drug product Manufacturing, regulatory matters required to comply with Applicable Law, quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, technology access charge, insurance, storage and freight, shipping, tariffs, sales and excise taxes imposed thereon, customs and duty and charges levied by Governmental Authorities (including export fees) and all costs of packaging and labeling, plus (ii) any reasonable internal costs (at the applicable FTE Rate) incurred by such supplying Party in connection with and attributable to such Manufacturing, including for process development, project management, Manufacturing oversight (including at the applicable FTE Rate for any person-in-plant of such supplying Party), and quality control and assurance; and

(b) if and to the extent such Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Party or its Affiliate, the actual, fully burdened costs that are attributable to and reasonably allocated to such Manufacturing, including the cost of raw materials and any costs incurred by such supplying Party for time spent by such Party's personnel to draft authorization letters or other documentation necessary for the other Party to obtain such raw materials, at the applicable FTE Rate, direct labor and benefits, a proportionate share of indirect Manufacturing costs, including idle plant capacity reserved specifically for such Product to the extent the foregoing are allocable to the Manufacture of such Product, as applicable (based on anticipated product volumes), intellectual property acquisition and licensing costs (including royalties, upfront fees, etc.) paid by such supplying Party with respect to the Manufacture of the Product (as applicable), and actual utilization for such product in a particular Calendar Year as compared to the actual working days during such Calendar Year, and all other reasonable and customary Manufacturing-related costs for such Product, including, to the extent incurred during the Term, actual product inventory write-offs, factory, plant, or equipment start-up or start-up amortization costs (but not any capital expenses), scale-up expenses, failed lots, regulatory matters required

to comply with Applicable Law, quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, insurance, storage and freight, shipping, tariffs, customs and duty and charges levied by Governmental Authorities (including export fees), and all costs of packaging and labeling. Such costs will be recognized and calculated in accordance with the applicable Accounting Standards, consistently applied.

1.92 "**Manufacturing Tech Transfer Plan**" has the meaning set forth in Section 8.3 (ALJ Manufacturing Option; Technology Transfer).

1.93 "**Mark**" means any trademark, trade name, service mark, service name, product name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.94 "**Medical Affairs**" means activities conducted by a Party's medical affairs departments in relation to a Product (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, and activities related to the generation of other data, including real world clinical data, to support a pharmaceutical or biologic product following receipt of Regulatory Approval therefor required for Commercialization, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and conducted by a Party's medical affairs (or equivalent) departments and do not involve the promotion, marketing, sale, or other Commercialization of the Products.

1.95 "**Medical Affairs Budget**" has the meaning set forth in Section 7.1 (Medical Affairs Plan).

1.96 "**Medical Affairs Plan**" has the meaning set forth in Section 7.1 (Medical Affairs Plan).

1.97 "**Medical Education Materials**" means all written medical education materials relating to any condition treated with a Product, and other printed, graphic, electronic, audio, video, or other media and materials used to educate the public regarding a Product or any indication treated with a Product.

1.98 "**Net Sales**" means, with respect to a Product, the gross amount invoiced in a country in the Territory by or on behalf of ALJ or its Affiliates or Sublicensees (each of the foregoing Persons, a "**Selling Party**") for the sale or other disposition of such Product in such country to Third Parties (including Third Party Distributors), less the following deductions:

(a) sales returns and allowances actually paid, granted or accrued on such Product, including trade, quantity, prompt pay and cash discounts, and any other

adjustments, including those granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return, or wastage replacement of such Product or for rebates or retroactive price reductions (including government health insurance programs, copay assistance, managed care, patient services, and similar types of rebates and chargebacks);

(c) (i) taxes, duties, or other governmental charges levied on or measured by the billing amount for such Product, as adjusted for rebates and refunds, (ii) other excise, sales, use, stamp, transfer, property taxes, (iii) value added, goods and services taxes that are not offset by any credits or refunds, and (iv) non-net income withholding taxes, but which, in each case, will not include any tax, duty, or other charge imposed on or measured by net income (however denominated) or any franchise taxes, branch profits taxes, or similar tax; and

(d) charges for freight, customs, and insurance related to the distribution of such Product and wholesaler and distributor administration fees.

Such amounts will be determined in accordance with such Selling Party's Accounting Standards as consistently applied.

Notwithstanding any provision to the contrary set forth in this Agreement, Net Sales will not be imputed to transfers of Product to Third Parties as part of Clinical Trials if such sale or disposition is at or below costs of goods therefor.

Sale or transfer of Products between any of the Selling Parties will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or disposition of a Product to a non-Selling Party, Net Sales will be calculated based on the average price charged for such Product, as applicable, during the preceding Calendar Quarter, or in the absence of such sales, based on the fair market value of the Products, as determined by the Parties in good faith.

In the case of discounts on "bundles" of products that include a Product, ALJ may, with notice to Evelo, discount (or permit the discounting by an Affiliate or Sublicensee of ALJ) the *bona fide* list price of any Product in such "bundle" by the average percentage discount of all products in a particular "bundle," calculated as follows: average percentage discount on a particular "bundle" = [1 - (A/B)] x 100; where A equals the total discounted price of a particular "bundle" of products, and B equals the sum of the undiscounted *bona fide* list prices of each unit of every product in such "bundle" (including the Products). Concurrently with each quarterly Co-Funded Expense Report submitted by ALJ pursuant to Schedule 9.3 (Profit and Loss Share), ALJ will provide to Evelo reasonable documentation establishing such average discount with respect to each "bundle." If ALJ cannot so establish the average discount of a "bundle," then Net Sales will be based on the undiscounted list price of the Product in the "bundle."

If a Product in a "bundle" is not sold separately, and no *bona fide* list price exists for such the Product, then the Parties will agree (such agreement not to be unreasonably withheld, conditioned or delayed by either Party) an imputed list price for the Product and the Net Sales with respect thereto will be based on such imputed list price.

1.99 "**Non-Defaulting Party**" has the meaning set forth in Section 14.2.1(c) (Disputes Regarding Material Breach).

1.100 "**Operating Profits or Losses**" means, for all Products in the Territory, the profits or losses calculated in accordance with Schedule 9.3 (Profit and Loss Share).

1.101 "**Other Operating Expenses**" means the following items, to the extent directly attributable or reasonably allocable to the Exploitation of the Products for the Territory:

(a) FTE Costs and Out-of-Pocket Expenses incurred conducting any recall (subject to Section 5.5) or other similar market withdrawal or other action for any Product for the Territory pursuant to Section 8.1 (Supply Agreement);

(b) any other categories of expenses included in the Commercialization Budget or Medical Affairs Budget for activities performed pursuant to the applicable Commercialization Plan or Medical Affairs Plan for such Product but not accounted for in the definitions Eligible Commercialization Expenses or Eligible Medical Affairs Expenses;

(c) all FTE Costs and Out-of-Pocket Expenses incurred in the performance of any activities under the Manufacturing Tech Transfer Plan;

(d) costs and expenses incurred in connection with selection, filing, maintenance, enforcement, and defense of the Product Marks for the Territory;

(e) costs and expenses incurred in connection with prosecution, maintenance, enforcement, and defense of the Licensed Patent Rights for the Territory; and

(f) other FTE Costs and Out-of-Pocket Expenses incurred by a Party or its Affiliates in connection with the Exploitation of such Products approved by the PCC as Other Operating Expenses.

No expense included as an Eligible Development Expense, an Eligible Commercialization Expense, or an Eligible Medical Affairs Expense will also be included as an Other Operating Expense. Other Operating Expenses specifically exclude any costs or expenses incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party or its Affiliates' or Sublicensees' action or omission that constitutes a breach of or default under this Agreement by or on behalf of such Party. Other Operating Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

1.102 "**Out-of-Pocket Expenses**" means, with respect to certain activities for a Product hereunder, specifically identifiable expenses paid or payable by a Party or its Affiliates to Third Parties to conduct such activities, including payments to contract personnel (including contractors, consultants, and Subcontractors).

1.103 "**Overhead Costs**" means costs incurred by a Party or for its account that are attributable to the performing Party's supervisory or support services and functions, occupancy costs, corporate bonus (to the extent not charged directly to department), and its payroll, information systems, human relations or purchasing functions, and, in each case, that are allocated to company departments based on space occupied or headcount or other activity-based method in accordance with applicable Accounting Standards, as consistently applied by such Party, including any costs attributed to general corporate activities including, by way of example, executive management, investor relations, business development, legal affairs, and finance.

1.104 "**P&L Share**" means the Parties' equal sharing of the Operating Profits or Losses for Products pursuant to Section 9.3 (Profit and Loss Share).

1.105 "**Packaging and Labeling**" means primary, secondary, or tertiary packaging and labeling of a Product (in its commercial packaging presentation) for sale or use in the Territory, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying a Product and any brand security or anti-counterfeiting measures included in the packaging elements for a Product considered to be part of the finished packaged Product, and all testing and release thereof.

1.106 "**Patent Rights**" means any and all (a) patents, (b) patent applications, including all provisional and non-provisional applications, patent cooperation treaty applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patent rights granted thereon, (c) patents-of-addition, reissues, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates and equivalents thereof, (d) inventor's certificates, letters patent, or (e) other substantially equivalent form of government issued right substantially similar to any of the foregoing described in subsections (a) through (d) above, anywhere in the world.

1.107 "**PCC**" has the meaning set forth in Section 3.1 (Product Commercialization Committee).

1.108 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association, or other entity.

1.109 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.4 (Pharmacovigilance Agreement).

1.110 "**Phase I Clinical Trial**" means a clinical trial (or any arm thereof) of an investigational product that satisfies the requirements of U.S. Federal Regulation 21 C.F.R. § 312.21(a)

and its successor regulation or an equivalent clinical trial prescribed by the relevant Regulatory Authority in a country other than the United States.

1.111 "**Phase II Clinical Trial**" means a clinical trial (or any arm thereof) of an investigational product that satisfies the requirements of U.S. Federal Regulation 21 C.F.R. § 312.21(b) and its successor regulation or an equivalent clinical trial prescribed by the relevant Regulatory Authority in a country other than the United States.

1.112 "**Phase III Clinical Trial**" means a clinical trial (or any arm thereof) of an investigational product that satisfies the requirements of U.S. Federal Regulation 21 C.F.R. § 312.21(c) and its successor regulation or an equivalent clinical trial prescribed by the relevant Regulatory Authority in a country other than the United States.

1.113 "**Product Marks**" means any Mark (whether registered or unregistered) selected by Evelo for use on, with, or to refer to a Product (other than any Housemarks, as applicable) or used with patient support or other information or services or Product Materials associated with a Product in the Territory during the Term, and all Intellectual Property rights and goodwill associated with the foregoing.

1.114 "**Products**" means (a) either (i) EDP1815 or (ii) any Replacement Product added to this Agreement in accordance with Section 2.4.1 (Evelo Cessation), and (b) any Second Product added to this Agreement in accordance with Section 2.4.2 (Second Product), including in each case (subsections (a) and (b)), all oral dosage forms, presentations, strengths, and formulations.

1.115 "**Product Materials**" means any and all Promotional Materials, Training Materials, Medical Education Materials, Packaging and Labeling, and all other literature or other information related to a Product for the Territory.

1.116 "**Professional Requirements**" means (a) the codes and standards of The Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO), (b) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), (c) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI), and (d) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory, as any of the foregoing may be amended from time-to-time.

1.117 "**Promotional Materials**" means all written sales, promotion, and advertising materials relating to the Products for the Territory, and other printed, graphic, electronic, audio, video, or other media and materials used to promote the Products in the Territory.

1.118 "**Receiving Party**" has the meaning set forth in Section 11.2 (Non-Disclosure and Non-Use Obligation).

1.119 "**Regulatory Approval**" means all technical, medical, and scientific licenses, registrations, authorizations and approvals (including supplements and amendments, pre- and post- approvals and labeling approvals) of any Regulatory Authority, necessary for the Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical or biologic product in a given country, including Reimbursement Approvals.

1.120 "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a given country, and any corresponding national or regional regulatory authorities.

1.121 "**Regulatory Budget**" has the meaning set forth in Section 5.1 (Regulatory Plan).

1.122 "**Regulatory Plan**" has the meaning set forth in Section 5.1 (Regulatory Plan).

1.123 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of the Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical or biologic product (including to obtain or maintain Regulatory Approval from that Regulatory Authority), and all written or electronic correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, BLAs, and other applications for Regulatory Approval and their equivalents.

1.124 "**Reimbursement Approval**" means any approval, agreement, determination, or other decision by the applicable Governmental Authority in a given country that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in such country or any other approvals related to pricing, reimbursement, or access to a pharmaceutical or biologic product (including all activities related to tenders and contracts).

1.125 "**Replacement Event**" has the meaning set forth in Section 2.4.1 (Evelo Cessation).

1.126 "**Replacement Product**" has the meaning set forth in Section 2.4.1(b) (Evelo Cessation).

1.127 "**Restricted Countries**" means Iran, Sudan, Syria, and any other country that, during the Term, is the subject of restrictions, embargoes, or sanctions by any Governmental Authority in the United States of America, the United Kingdom of Great Britain and Northern Ireland, or the European Union, or pursuant to any Global Trade Control Laws, in each case, that prohibit Commercialization of products similar to the Product in such country by or on behalf of, or at the instruction of, a Party.

1.128 "**Restricted Person**" means any individual or entity on one or more of the Restricted Person Lists.

1.129 "**Restricted Person Lists**" means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the consolidated list of Persons, Groups and Entities Subject to EU Financial Sanctions, as implemented by the EU Common Foreign & Security Policy; the List of Excluded Individuals / Entities, as published by the U.S. Health and Human Services – Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of persons and entities suspended or debarred from contracting with the U.S. government; and, to the extent applicable to the activities under this Agreement, similar lists of restricted parties maintained by the Governmental Authorities of the jurisdictions of import and export.

1.130 "**Restricted Person Screening**" means the comparison of any individual or entity directly or indirectly involved in activities under this Agreement, against the relevant Restricted Person Lists.

1.131 "**Right of Negotiation Period**" has the meaning set forth in Section 2.4.2 (Second Product).

1.132 "**Second Product**" has the meaning set forth in Section 2.4.2 (Second Product).

1.133 "**Second Product Notice**" has the meaning set forth in Section 2.4.2 (Second Product).

1.134 "**Selling Party**" has the meaning set forth in Section 1.98 (Net Sales).

1.135 "**Shared Expenses Budget**" means any of the Development Budget, Regulatory Budget, Commercialization Budget, or Medical Affairs Budget.

1.136 "**Stock Purchase Agreement**" has the meaning set forth in Section 9.2 (Equity Investment).

1.137 "**Subcontractor**" means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights on behalf of such Party under this Agreement (including all Third Party Distributors, contract research organizations, and contract manufacturing organizations).

1.138 "**Sublicensees**" means any Third Party (including any Approved Subcontractor) to whom ALJ or any of its Affiliates grants a sublicense of the rights granted to it hereunder in accordance with Section 2.2 (Sublicensing and Subcontracting by ALJ).

1.139 "**Supply Agreement**" has the meaning set forth in Section 8.1 (Supply Agreement).

1.140 "**Suspension Cure Period**" has the meaning set forth in Section 14.2.4(b) (Termination for Cessation of Commercialization in the Major Market).

1.141 "**Suspension Period**" has the meaning set forth in Section 14.2.4(a) (Termination for Cessation of Commercialization in all the Major Market).

1.142 "**Term**" has the meaning set forth in Section 14.1 (Term).

1.143 "**Terminated Country**" means with respect to a particular Product, (a) any country in the Territory with respect to which this Agreement is terminated in relation to that Product pursuant to Article 14 (Term and Termination), and (b) in the event of termination of this Agreement either in its entirety or with respect to that Product throughout the Territory, all countries in the Territory.

1.144 "**Terminated Product**" means (a) any Product with respect to which this Agreement is terminated pursuant to Article 14 (Term and Termination), and (b) in the event of termination of this Agreement in its entirety, all Products.

1.145 "**Territory**" means all the countries of Africa and the Middle East-Turkey as detailed in Schedule 1.145 (Territory), expressly excluding any country that is a Restricted Country as of the Effective Date, or that becomes a Restricted Country at any time during the Term, subject to Section 2.5 (Removal of Restricted Countries from Territory; Inclusion of Previously Restricted Countries).

1.146 "**Third Party**" means any Person other than ALJ or Evelo or their respective Affiliates.

1.147 "**Third Party Distributor**" means, with respect to a country in the Territory, any Third Party that purchases Products from ALJ or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market, and resell such Product in such country.

1.148 "**Third Party Exclusive IP Agreement**" has the meaning set forth in Section 15.2.1(c) (Licenses).

1.149 "**Third Party Non-Exclusive IP Agreement**" has the meaning set forth in Section 15.2.1(d) (Licenses).

1.150 "**Training Materials**" means the materials (which may include written or other recorded, videotaped, or web-based training materials or online training programs) to be used in the training of ALJ's trainers, sales representatives, sales managers, and other representatives with respect to the Products and the detailing thereof in the Territory.

1.151 "**Transaction Document**" means this Agreement, the Confidentiality Agreement, any Supply Agreement, any Pharmacovigilance Agreement, and any Stock Purchase Agreement.

1.152 "**Transferee Party**" has the meaning set forth in Section 16.1 (Assignment).

1.153 "**Upfront Payment**" has the meaning set forth in Section 9.1 (Upfront Payment).

1.154 "**VAT**" means: (a) any tax imposed in compliance with the Council Directive of 28 November 2006 on the common system of value added tax (EC Directive 2006/112); and (b) any other tax of a similar nature, whether imposed in a member state of the European Union in substitution for, or levied in addition to, such tax referred to in (a), or imposed elsewhere.

2. LICENSE GRANTS; EXCLUSIVITY

2.1 **License Grant to ALJ**. Subject to the terms of this Agreement, including Section 2.3 (No Implied Licenses; Retained Rights), Evelo hereby grants and agrees to grant to ALJ an exclusive, royalty-free (subject to Section 9.3 (Profit and Loss Share)), non-transferable (except as provided in Section 16.1 (Assignment)) license, with the right to sublicense solely in accordance with the applicable provisions of Section 2.2 (Sublicensing and Subcontracting by ALJ), under the Licensed Technology: (a) solely to conduct those Development activities with respect to the Products for which ALJ is responsible in accordance with the Development Plan and Regulatory Plan, (b) conduct ALJ Manufacturing Activities with respect to the Products (solely in accordance with Section 8.3 (ALJ Manufacturing Option; Technology Transfer)) in the Field anywhere in the world, and (c) to Commercialize the Products in the Field in the Territory.

2.2 **Sublicensing and Subcontracting by ALJ**. Schedule 2.2 sets forth the minimum requirements that any Third Party that ALJ or its Affiliates wishes to engage to perform any of ALJ's obligations under this Agreement must satisfy. Following the Effective Date, the PCC may amend or add additional commercially reasonable requirements that must be satisfied by any Third Party that ALJ or its Affiliates wishes to engage to perform any of ALJ's obligations under this Agreement. ALJ may engage as a Subcontractor (a) any Third Party that the PCC determines satisfies such requirements, or (b) subject to Evelo's prior written approval, not to be unreasonably withheld, conditioned, or delayed, any other Third Party (collectively, "**Approved Subcontractors**"). ALJ may grant sublicenses of the rights granted to ALJ under Section 2.1 (License Grant to ALJ) or Section 6.14.3 (Mark Licenses) to any Affiliate of ALJ or any Approved Subcontractor to perform the obligations or exercise the rights granted to ALJ under this Agreement; provided that no Sublicensee may grant further sublicenses without Evelo's prior written approval (which may be withheld in its sole discretion). Any such sublicense will be consistent with the terms of this Agreement, will expressly prohibit any further sublicensing without Evelo's prior written approval (which may be withheld in its sole discretion), and will include confidentiality, non-disclosure, non-use, and indemnification provisions at least as restrictive or protective of the Parties as those set forth in this Agreement. ALJ will promptly provide Evelo with a copy of each such sublicense (which may be reasonably redacted to remove personal data, information concerning products other than the Products, and, to the extent not necessary to determine compliance with the terms of this Agreement, any other financial or commercially sensitive data). Notwithstanding any sublicense or engagement of a Subcontractor, ALJ

will remain liable to Evelo for the performance of all of its obligations under, and ALJ's compliance with all provisions of, this Agreement, and for the performance of all obligations of its Affiliates, Sublicensees, and Subcontractors as required under this Agreement.

2.3 **No Implied Licenses; Retained Rights**. Except as expressly provided in this Agreement, neither Party will be deemed to have granted the other Party any license or other right with respect to any Intellectual Property owned, Controlled, or held for use by such Party, whether by implication, estoppel, reliance, or otherwise. Any rights not expressly granted by Evelo under this Agreement are hereby retained by Evelo, including the right to practice the Licensed Technology and Exploit the Products (i) outside the Territory for any and all purposes, and (ii) outside the Field anywhere in the world in its sole discretion. Notwithstanding the exclusive nature of the rights granted to ALJ under Section 2.1 (License Grant to ALJ) to the contrary, Evelo expressly retains the rights to (i) practice the Licensed Technology and Exploit the Products in the Field in the Territory to the extent necessary to perform its obligations under this Agreement and (ii) Manufacture Products worldwide, in each case, whether directly or through its Affiliates, Third Party licensees, or subcontractors. In addition, Evelo expressly retains the right to Exploit any Competitive Product outside the Territory.

2.4 **Inclusion of Additional Products**.

2.4.1 **Evelo Cessation**.

(a) If, prior to receipt of approval of a BLA for EDP1815 in any one of the United States of America, the United Kingdom of Great Britain and Northern Ireland, France, Germany, Spain, Italy, China, or Japan, Evelo ceases all Development of EDP1815 (a "**Replacement Event**"), then Evelo will provide written notice to ALJ of such Replacement Event. Evelo shall (a) use reasonable efforts to provide such written notice at least 45 days prior to the Replacement Event (unless cessation of Development must occur sooner due to an urgent regulatory or safety reason, in which case notice must be given promptly upon Evelo becoming aware that Development must cease), and (b) include in such written notice the reason for such cessation.

(b) As soon as practicable after the Replacement Event (and in any event, no later than [***] thereafter), Evelo will provide ALJ with the identity of all products Controlled by Evelo or its Affiliates (i) that are the subject of a Phase I Clinical Trial or Phase II Clinical Trial (prior to database lock for any such Phase II Clinical Trial) conducted by Evelo or its Affiliates at such time, (ii) that are equivalent in value to the value of EDP1815 as at the Effective Date and (iii) with respect to which (A) Evelo has not granted any Development, Commercialization, or other rights or options to any Third Party with respect to the Territory that, in each case, would conflict with the inclusion of such product as a Product for purposes of

this Agreement, (B) Evelo is not at that time in ongoing negotiations being conducted pursuant to a signed non-disclosure agreement with any Third Party with respect to the grant of Development or Commercialization rights or any other rights with respect to the Territory that, in each case, would conflict with the inclusion of such product as a Product for purposes of this Agreement, and (C) such product is not otherwise encumbered by Third Party rights that would conflict with the inclusion of such Product in this Agreement (each an "**Eligible Replacement Product**"), together with a Data Package for each Eligible Replacement Product. ALJ will have the right (in its sole discretion and, subject to Section 2.4.1(d)(iii), without prejudice to its other rights and remedies), exercisable by providing written notice of such election to Evelo no later than [***] after ALJ's receipt of the Data Packages, to: (i) designate one of the Eligible Replacement Products as a Product for purposes of this Agreement (the "**Replacement Product**"); or (ii) terminate this Agreement in accordance with Section 14.2.3. Evelo shall have no obligation to generate or provide ALJ with any information or materials for any product in order to provide any Data Packages or in addition to the Data Packages.

(c) If ALJ elects not to designate a Replacement Product in accordance with Section 2.4.1(b), then Evelo shall repeat the process in Section 2.4.1(b) at least [***] until the earlier of: (i) ALJ electing to designate a Replacement Product; or (ii) termination of this Agreement; provided that, Evelo will only be required to provide such information and materials for the applicable Eligible Replacement Products as are Controlled by Evelo at the time such process is repeated and have not previously been provided as part of a Data Package.

(d) If ALJ elects to designate a Replacement Product, then (i) such Replacement Product will automatically become a Product for all purposes under this Agreement, and the Parties shall enter into a written amendment to this Agreement revising the Competitive Product definition to reflect the API of the Replacement Product, (ii) EDP1815 will automatically become a Terminated Product for all purposes under this Agreement and the effects of Article 15 (Effects of Termination) will apply to EDP1815 as a Terminated Product, and (iii) all other rights and remedies of ALJ with respect to a Replacement Event shall terminate.

2.4.2 **Second Product**. During the period commencing as of the Effective Date and ending two years thereafter (the "**Right of Negotiation Period**"), ALJ will have the right to negotiate with Evelo in good faith the terms on which the Parties might include a second product Controlled by Evelo as a Product under this Agreement (the "**Second Product**"). If, during the Right of Negotiation Period, ALJ wishes to include a Second Product under this Agreement, then ALJ will

provide written notice thereof to Evelo (a "**Second Product Notice**") and Evelo will provide ALJ with the identity of all products Controlled by Evelo or its Affiliates (i) that are the subject of a Phase I Clinical Trial or Phase II Clinical Trial (prior to database lock for any such Phase II Clinical Trial) conducted by Evelo or its Affiliates at such time, and (ii) with respect to which (A) Evelo has not granted any Development, Commercialization or other rights or options to any Third Party with respect to the Territory that would, in each case, conflict with the inclusion of such product as a Product for purposes of this Agreement, (B) Evelo is not at that time in ongoing negotiations being conducted pursuant to a signed non-disclosure agreement with any Third Party with respect to the grant of Development or Commercialization rights or any other rights with respect to the Territory that would, in each case, conflict with the inclusion of such product as a Product for purposes of this Agreement, and (C) such product is not otherwise encumbered by Third Party rights that would conflict with the inclusion of such Product in this Agreement (each an "**Eligible Second Product**"), together with a Data Package for each such product. ALJ will have the right, exercisable by providing written notice of such election to Evelo no later than [***] after ALJ's receipt of the Data Packages, to designate one Eligible Second Product as a Product for purposes of this Agreement, if during such [***] period (or such other period agreed between the Parties), (1) the Parties, each acting reasonably and in good faith, agree on the additional amount to be paid to Evelo in consideration for ALJ's rights to such Second Product which shall not exceed $7,500,000 (the "**Second Product Fee**") and (2) ALJ pays such Second Product Fee to Evelo. For clarity, Evelo shall have no obligation to generate or provide ALJ with any information or materials for any product in order to provide the applicable Data Packages or in addition to the Data Packages. No such product will become a Second Product for purposes of this Agreement unless and until ALJ pays to Evelo the Second Product Fee. During the Right of Negotiation Period, ALJ may submit multiple Second Product Notices to Evelo until a product becomes a Second Product; provided that (i) ALJ shall not submit a Second Product Notice within [***] of the date on which the previous Second Product Notice was submitted, (ii) Evelo will only be required to provide such information and materials for the applicable Eligible Second Products as are Controlled by Evelo at the time Evelo receives the applicable Second Product Notice and have not previously been provided as part of a Data Package, and (iii) ALJ's right to submit Second Product Notices shall lapse upon any product becoming a Second Product for purposes of this Agreement.

2.5 **Removal of Restricted Countries from Territory; Inclusion of Previously Restricted Countries into the Territory.** Either Party may notify the PCC during the Term of any country in Africa or the Middle East-Turkey that ceases to be a Restricted Country, and the PCC may agree to add such country to the Territory for all purposes under this Agreement for so long as such country is not a Restricted Country. In addition, if any country included in the Territory as of the Effective Date or added to the Territory in accordance with this Section 2.5 (Removal of Restricted Countries from Territory;

Inclusion of Previously Restricted Countries into the Territory) becomes a Restricted Country, then upon notice thereof from one Party to the other Party, such country will automatically be excluded from the Territory. Without limitation to the foregoing, if trade between Israel and the United Arab Emirates becomes prohibited by Applicable Law, then upon notice thereof from one Party to the other Party, Israel will automatically be excluded from the Territory and the Parties shall immediately cease Development and Commercialization of the Products in Israel.

2.6 **Exclusivity and Restrictions**.

2.6.1 **Exclusivity Covenants**. Subject to Section 2.6.3 (Acquisitions by or of Third Parties), except as expressly permitted under this Agreement, during the Term, neither Party will, and will ensure that its Affiliates do not, independently or for or with any Third Party (including any licensee or sublicensee), Exploit any Competitive Product in the Field in the Territory, other than to Develop or Manufacture Competitive Products in the Territory solely for purposes of Exploiting such Competitive Products outside of the Territory, (the "**Competitive Activities**"). To the extent a Replacement Product or a Second Product are selected, the Parties will, each acting reasonably and in good faith, discuss and agree appropriate amendments to the definition of Competitive Activities to contemplate Products other than EDP1815.

2.6.2 **Stipulation of the Parties**. Each Party stipulates and agrees that (a) Section 2.6.1 (Exclusivity Covenants) has been negotiated by the Parties, (b) the geographical and time limitations on activities set forth in Section 2.6.1 (Exclusivity Covenants) are reasonable, valid, and necessary in light of the Parties' circumstances and are necessary for the adequate protection of the business of the Products in the Territory, and (c) neither Party would have entered into this Agreement without the protection afforded it by this Section 2.6.1 (Exclusivity Covenants). If, notwithstanding the foregoing, an arbitral tribunal or a court of competent jurisdiction or other Governmental Authority determines that the restrictions set forth in Section 2.6.1 (Exclusivity Covenants) are too broad or otherwise unreasonable under Applicable Law, including with respect to duration, geographic scope, or space, then such arbitral tribunal, court or other Governmental Authority is hereby requested and authorized by the Parties to revise Section 2.6.1 (Exclusivity Covenants) to include the maximum restrictions allowable under Applicable Law.

2.6.3 **Acquisitions by or of Third Parties**.

(a) **Acquisitions by Third Parties**. Neither Party will be in breach of the restrictions set forth in Section 2.6.1 (Exclusivity Covenants) if that Party undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "**Acquired Party**") that is (either directly or through an Affiliate, or in collaboration with the Third Party)

performing Competitive Activities with respect to one or more Competitive Products at the closing of the Change of Control transaction, and such Acquired Party may continue to perform, or commence the performance of, the applicable Competitive Activities with respect to such Competitive Products after such Change of Control transaction; as long as (a) no Licensed Technology is used by or on behalf of such Acquired Party or its Affiliates in more than a *de minimis* fashion in connection with any subsequent performance of Competitive Activities with respect to such Competitive Products, and (b) such Acquired Party institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (a) are met, including by creating "firewalls" between the personnel working on such Competitive Products and the personnel teams charged with working on any Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

(b) **Acquisitions of Third Parties**.

Options. If a Party or any of its Affiliates anticipates that it will merge or consolidate with, or otherwise acquire a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation, or similar transaction) (the "**Acquisition Party**") and at such time such Third Party or any of its Affiliates is performing Competitive Activities with respect to one or more Competitive Products or is engaged in activities that would, upon the closing of such acquisition transaction, otherwise constitute a breach of Section 2.6.1 (Exclusivity Covenants), then the Acquisition Party will provide the other Party with as much advance notice prior to the consummation of such acquisition transaction as is practicable and as permitted under Applicable Law. If the Acquisition Party subsequently undergoes such an acquisition transaction, then, (1) unless the Party that is not the Acquisition Party agrees otherwise in writing, the Acquisition Party will take one of the following actions set forth below in clauses (A) or (B), and (2) no later than [***] following the date of consummation of the relevant acquisition transaction, the Acquisition Party will notify the other Party of which of the actions in the following clauses (A) or (B) that it has elected to take:

(A) divest, or cause its relevant Affiliates to divest, whether by license or otherwise, its interest in such Competitive Products; or

(B) terminate, or cause its relevant Affiliates to terminate, any further Competitive Activities with respect to such Competitive Products.

Time Periods. If the Acquisition Party notifies the other Party in writing that it intends to divest the applicable Competitive Products or terminate the performance of further Competitive Activities with respect to such

Competitive Products as provided in Section 2.6.3(b)(A) (Acquisitions of Third Parties; Options), then the Acquisition Party or its relevant Affiliate will effect (i) the consummation of such divestiture within [***] or such other period as may be required to comply with Applicable Law, or (ii) effect such termination of the applicable Competitive Activities with respect to the Competitive Product within [***], in each case, after the closing of the relevant transaction and will confirm to the other Party in writing when it completes such divestiture pursuant to clause (i) or termination pursuant to clause (ii). The Acquisition Party will keep the other Party reasonably informed of its efforts and progress in effecting such divesture or termination until the Acquisition Party completes the same.

(c) **Protective Provisions**. Notwithstanding anything to the contrary set forth in this Agreement, (a) no Licensed Technology may be used by or on behalf of such Acquisition Party or its Affiliates in more than a *de minimis* fashion in connection with any performance of Competitive Activities with respect to such Competitive Products, and (b) the Acquisition Party will institute commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (a) are met, including by creating "firewalls" between the personnel working on such Competitive Products and the personnel teams charged with working on any Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

3. GOVERNANCE

3.1 **Product Commercialization Committee**. Within 30 days after the Effective Date, the Parties will establish a product commercialization committee (the "**PCC**") to facilitate communications between the Parties and oversee, review, and share information regarding the Commercialization of the Products in and for the Territory as follows:

3.1.1 **Composition of the PCC**. The PCC will comprise of three (or more, as the Parties may agree in writing) representatives of each of ALJ and Evelo, one of which will be of vice president-level (or above) and each of whom will be fluent in English and will have the appropriate experience, decision-making authority, and expertise to perform their respective responsibilities on the PCC at the applicable time. Evelo's initial representatives to the PCC will include [***], and ALJ's initial representatives to the PCC will include [***]. Each Party may change its representatives to the PCC from time to time in its sole discretion, effective upon notice to the other Party of such change. If agreed by the PCC on a case-by-case basis, the PCC may invite non-members to participate in the discussions and meetings of the PCC, provided that any such non-member participants will have no voting authority at the PCC and are bound by written obligations of confidentiality, non-disclosure, and non-use provisions at least as

restrictive or protective of the Parties as those set forth in this Agreement. Each Party's Alliance Manager may, but is not required, to be a member of the PCC, but the Alliance Managers or suitable designees will attend all meetings of the PCC. Each Party will bear its own expenses related to the attendance of such meetings by its representatives.

3.1.2 **Meetings**. Unless otherwise agreed by the Parties, the PCC will meet at least once each Calendar Quarter during each Calendar Year (i.e., four times per Calendar Year), in each case by teleconference, videoconference, or in person, as agreed to by the Parties and, where possible, at least two meetings per Calendar Year will be in person. Specific meeting dates will be determined by agreement of the Parties. Either Party may also call a special meeting of the PCC (by videoconference or teleconference) upon prior written notice to, and agreement by, the other Party, if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled PCC meeting. The first meeting of the PCC shall be held at a mutually agreeable time no later than 90 days after the Effective Date. Evelo will host the first in person meeting of the PCC at a mutually agreeable place. The Alliance Manager of each Party will alternate holding responsibility, on behalf of the PCC, for setting the agenda for meetings of the PCC with input from the other members and for conducting the meetings of the PCC. The applicable then-responsible Alliance Manager will prepare and disseminate agendas and presentations no less than five Business Days in advance of each PCC meeting unless otherwise agreed to by the Parties in writing. No later than 10 Business Days after each PCC meeting, the Alliance Managers will jointly prepare and circulate draft minutes from each PCC meeting that shall reference, reflect and summarize any Confidential Information shared (by way of example only and without limitation to the generality of the foregoing, if a confidential formula is disclosed orally at a meeting of the PCC, then the minutes of the PCC meeting should record that the formula was disclosed, provide a description of the nature and purpose of the formula, and note that the formula is to be treated as the disclosing Party's Confidential Information, but the formula itself would not need to be written in the minutes), decisions made, and action items identified at such meetings and will prepare and circulate final minutes for each PCC meeting for review and approval no later than five Business Days after circulation of the draft minutes from each such meeting. The Alliance Managers will ensure that such minutes are reviewed and approved by their respective companies no later than five Business Days after circulation of the draft minutes or such circulated minutes will be deemed final.

3.2 **Responsibilities**. The PCC will monitor the progress of activities for the Products in and for the Territory conducted by or on behalf of the Parties as set forth in this Agreement. Subject to Section 3.3 (Decision-Making), Section 3.4 (Resolution of Disputes) and Section 3.5 (Limits on PCC Decision-Making Authority), the PCC will:

3.2.1 review, discuss, and determine whether to approve (i) any additional FTE Costs, or Out-of-Pocket Expenses to be included as Eligible Commercialization Expenses, as described in Section 1.48 (Eligible Commercialization Expenses), as Eligible Development Expenses, as described in Section 1.50 (Eligible Development Expenses), as Eligible Medical Affairs Expenses, as described in Section 1.52 (Eligible Medical Affairs Expenses), or as Other Operating Expenses, as described in Section 1.101 (Other Operating Expenses), respectively, so long as any such approved additional costs or expenses are not inconsistent with the applicable definitions (i.e., the PCC will not have the right to approve capital expenditure as Eligible Commercialization Expenses), and (ii) any Eligible Development Expenses or Eligible Shared Expenses in excess of the applicable Shared Expenses Budget, respectively and in each case plus Allowable Overruns, in respect of a Calendar Year;

3.2.2 prior to initiation by the Parties of any regulatory, Commercialization, or Medical Affairs activities for the Products for which the Parties will share the costs under Section 4.4 (Development Costs) or Section 9.3 (Profit and Loss Share), determine the FTE Rate that will be used for each Party;

3.2.3 determine whether to adjust the FTE Rate for either Party on an annual basis as part of an update to the Development Plan under Section 4.2 (Development Plan), the Regulatory Plan under Section 5.1 (Regulatory Plan), the Commercialization Plan under Section 6.1 (Commercialization Plan), or the Medical Affairs Plan under Section 7.1 (Medical Affairs Plan);

3.2.4 review, discuss, and determine whether to approve the requirements that any Third Party that ALJ or its Affiliates wishes to engage to perform any of ALJ's obligations under this Agreement must satisfy (and any proposed updates thereto), and determine whether any proposed Subcontractor satisfies such requirements, in each case, as described in Section 2.2 (Sublicensing and Subcontracting by ALJ);

3.2.5 review, discuss, and determine whether to approve any additional countries for inclusion in the Territory in accordance with Section 2.5;

3.2.6 discuss and resolve disputes and issues identified by the Alliance Managers, as described in Section 3.6.2 (Roles and Responsibilities);

3.2.7 review, discuss, and determine whether to approve the Development Plan, and any proposed amendments or updates to the Development Plan (including any amendments to the Development Budget), as described in Section 4.2 (Development Plan);

3.2.8 review, discuss, and determine whether to approve the Regulatory Plan, and any proposed amendments or updates to the Regulatory Plan (including any amendments to the Regulatory Budget), as described in Section 5.1 (Regulatory Plan);

3.2.9 review, discuss, and determine whether to approve all BLAs, applications for Reimbursement Approval, and other Regulatory Submissions for any Product in the Territory to be submitted, as described in Section 5.2.2 (Regulatory Filings);

3.2.10 review, discuss, and determine whether to approve the Commercialization Plan, and any amendment or updates thereto (including any amendments to the Commercialization Budget), as described in Section 6.1 (Commercialization Plan);

3.2.11 review, discuss, and determine whether to approve all Training Materials for use in the Territory and all substantive updates thereto, as described in Section 6.7.1 (Approval and Branding of Training Materials);

3.2.12 review, discuss, and determine whether to approve all Territory Product Materials for use in the Territory and all substantive updates thereto, as described in Section 6.8.1 (Review);

3.2.13 review, discuss, and determine whether to obtain or maintain a trademark registration for a Product Mark in respect of each Product in a country in the Territory, as described in Section 6.14.1 (Product Marks);

3.2.14 review, discuss, and determine whether to approve the Medical Affairs Plan, including any amendments or updates thereto (including any amendments to the Medical Affairs Budget), as described in Section 7.1 (Medical Affairs Plan);

3.2.15 review, discuss, and determine whether to approve all Training Materials for use in the Territory and all substantive updates thereto, as described in Section 7.3 (Medical Education Materials);

3.2.16 determine whether ALJ has established the capabilities to perform the ALJ Manufacturing Activities for the Territory in accordance with GMP standards, and whether ALJ will be permitted to perform the ALJ Manufacturing Activities, for purposes of Section 2.1 (License Grant to ALJ) and Section 8.3 (ALJ Manufacturing Option; Technology Transfer);

3.2.17 review, discuss, and determine any changes to minimum insurance coverage requirements in accordance with Section 13.5 (Insurance);

3.2.18 form such other sub-committees as the PCC may deem appropriate; and

3.2.19 perform such other functions as expressly set forth in this Agreement or allocated to the PCC by the written agreement of the Parties.

3.3 **Decision-Making**.

3.3.1 **Authority to Make Decisions**. The Alliance Managers will provide written notice of each PCC meeting to each Party no less than ten days in advance of the

date of such meeting. A quorum for a meeting of the PCC will require the presence of at least one PCC representative from each of ALJ and Evelo or a suitable delegate of either Party's representatives and each Party will take reasonable efforts to ensure that all its representatives attend each PCC meeting. Any decisions by the PCC will require consensus, with each Party having one vote collectively through its representative members of the PCC, *provided* that a quorum must be present for any decision to be made by the PCC. Without limiting the Parties' responsibilities under Section 3.1.2 (Meetings) with respect to recording minutes from each PCC meeting, the Alliance Managers will promptly document in the minutes of each PCC meeting all decisions made at each meeting of the PCC and a duly authorized representative to the PCC for each Party will sign such minutes to approve such decisions. Except as otherwise expressly set forth in this Agreement, the phrase "determine," "designate," "confirm," "resolve," "approve," or "determine whether to approve" by the PCC and similar phrases used in this Agreement will mean approval in accordance with this Section 3.3 (Decision-Making), including the escalation and tie breaking provisions herein.

3.3.2 **Decisions of the PCC**. The PCC will use good faith efforts, in compliance with this Section 3.3.2 (Decisions of the PCC), to promptly resolve any such matter for which it has authority. Subject to the terms of this Agreement, including Section 3.5 (Limits on PCC Decision-Making Authority), if the PCC cannot or does not, after reasonable efforts, reach agreement on an issue with respect to which it has authority within the scope of the PCC's authority pursuant to Section 3.2 (Responsibilities) within a period of 30 days following the initial discussion thereof by the PCC, then a Party may refer such matter for resolution in accordance with Section 3.4.1 (Referral to Executive Officers) to the Chief Executive Officer of ALJ Health (or an executive officer of ALJ designated by the Chief Executive Officer of ALJ Health who has the power and authority to resolve such matter) and the Chief Executive Officer of Evelo (or an executive officer of Evelo designated by the Chief Executive Officer of Evelo who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**"); provided that if both Parties' Executive Officers are appointed PCC representatives during the period of initial discussion of such matter by the PCC, then such matter will not be subject to Section 3.4.1 (Referral to Executive Officers), but instead will be determined in accordance with Section 3.4.2 (Final Decision-Making Authority).

3.4 **Resolution of Disputes**.

3.4.1 **Referral to Executive Officers**. If a Party makes an election under Section 3.3.2 (Decisions of the PCC) to refer a matter on which the PCC cannot reach a consensus decision for resolution by the Executive Officers, then the PCC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve

any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.4.2 **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter referred to them within 15 Business Days after such matter being so referred (or such longer period as the Executive Officers may agree upon), then:

(a) **No Decision**. Neither Party will have final decision-making authority with respect to: (i) approval of the Development Plan, Regulatory Plan, Commercialization Plan, or Medical Affairs Plan; (ii) any amendment or update to any Development Plan, Regulatory Plan, Commercialization Plan, or Medical Affairs Plan (including any Shared Expenses Budget set forth therein); (iii) approval of any additional FTE Costs, or Out-of-Pocket Expenses to be included as Eligible Commercialization Expenses, Eligible Development Expenses, Eligible Medical Affairs Expenses, or as Other Operating Expenses, (iv) any BLA, application for Reimbursement Approval, or other Regulatory Submission for any Product in the Territory to be submitted by or on behalf of either Party; (v) the initial FTE Rate for either Party or any adjustment to the FTE Rate for either Party; (vi) adding a previously Restricted Country to the Territory; (vii) approval of support for ALJ's Commercialization activities to the extent such support is not set out in the Commercialization Plan and is requested by ALJ in accordance with Section 6.3; (viii) whether ALJ shall have the right to assume responsibility for the prosecution and maintenance of a Licensed Patent Right in accordance with Section 10.2.2; (x) whether ALJ or its designee may initiate an Infringement Action in accordance with Section 10.4.3; (xi) a determination not to obtain or maintain trademark registrations for a Product Mark in respect of each Product in a country in the Territory; or (xii) changes to minimum insurance coverage requirements in accordance with Section 13.5 (Insurance).

(b) **Evelo Final Decision-Making Authority**. Evelo will have final decision-making authority with respect to (i) any determination as to whether ALJ has established the capabilities to perform the ALJ Manufacturing Activities for the Territory in accordance with GMP standards, and whether ALJ will be permitted to perform the ALJ Manufacturing Activities, for purposes of Section 2.1 (License Grants to ALJ) and Section 8.3 (ALJ Manufacturing Option; Technology Transfer), (ii) establishing the commercially reasonable requirements that any Third Party that ALJ or its Affiliates wishes to engage to perform any of ALJ's obligations under this Agreement must satisfy, and any determination as to whether any proposed Subcontractor satisfies such requirements, in accordance with Section 2.2 (Sublicensing and Subcontracting by ALJ),

(iii) the approval of all Training Materials for use in the Territory and substantive updates thereto, (iv) the approval of all Territory Product Materials and all substantive updates thereto, and (v) the approval of all Medical Education Materials and all substantive updates thereto.

(c) **ALJ Final Decision-Making Authority**. To the extent not specified in Section 3.4.2(a) (No Decision) or Section 3.4.2(b) (Evelo Final Decision-Making Authority), ALJ will have final decision-making authority with respect to all operational decisions relating to Medical Affairs or Commercialization of the Product(s) in the Territory; provided that ALJ may not exercise its final decision-making authority in a manner that could adversely impact the Exploitation of any Product outside of the Territory or that is inconsistent with Evelo's global regulatory strategy for the Products or the Global Commercialization Plan.

3.5 **Limits on the PCC Decision-Making Authority**. Notwithstanding any provision to the contrary set forth in this Agreement, and except as explicitly required by any Regulatory Authority to obtain or maintain Regulatory Approval for any Product for the Territory (or otherwise required by any Regulatory Authority in the Territory), or to address any requirements under Applicable Law or changes thereto, without each Party's prior written consent, no decision of the PCC, Evelo, or ALJ (in the exercise of such Party's final decision-making authority on any such matters as set forth in this Agreement) in each case, may (a) result in a material increase in the scope of activities required to be performed by the other Party under this Agreement, including under any Development Plan, Regulatory Plan, Commercialization Plan, or Medical Affairs Plan, (b) require a Party to take or decline to take any action that would be reasonably likely to result in a violation of any Applicable Law, the requirements of any Regulatory Authority, or any agreement between a Party and any Third Party or that would be reasonably likely to result in the infringement, misappropriation, or other violation of any Intellectual Property of any Third Party; provided that such Party provides a copy of any such agreement to the other Party, or (c) conflict with this Agreement or the Supply Agreement. Each Party shall ensure that (i) in making any decision at the PCC and (ii) in exercising its final decision-making authority on any matters set forth in this Agreement, it shall (and shall procure that its representatives on the PCC shall) act in good faith and in a commercially reasonable manner.

3.6 **Alliance Management**.

3.6.1 **Alliance Managers**. Each Party will appoint an employee who will oversee interactions between the Parties for all matters related to this Agreement or, to the extent related to the Products, the Supply Agreement (each an "**Alliance Manager**"). Such persons will endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and will serve as a single point of contact for any matters arising under this Agreement or, to the extent related to the Products, the Supply Agreement. The

Alliance Managers may bring to the attention of the PCC (or any applicable sub-committee of the PCC) any matters or issues either Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may agree in writing. Each Party may change its Alliance Manager by notice in writing to the other Party.

3.6.2 **Roles and Responsibilities**. The Alliance Managers will have the responsibility of creating and maintaining a constructive work environment between the Parties with respect to the activities contemplated under this Agreement and, to the extent related to the Products, the Supply Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(a) identify and bring disputes and issues that may result in disputes to the attention of the PCC in a timely manner and function as the point of first referral in all matters of conflict resolution;

(b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;

(c) plan and coordinate between the Parties cooperative efforts, internal communications, and external communications with respect to this Agreement and, to the extent related to the Products, the Supply Agreement; and

(d) take responsibility for ensuring that meetings and the production of meeting agendas and minutes, in each case, occur as set forth in this Agreement and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

3.6.3 **Key Personnel**. If ALJ or ALJ Health ceases to employ [***] within two years after the Effective Date, ALJ will (a) as soon as reasonably practicable after becoming aware of the cessation of his employment, provide Evelo with a reasonable opportunity to review a shortlist of candidates selected by ALJ to replace [***], (b) consult with Evelo in relation to the candidates on that shortlist, and (c) have due regard to any reasonable comments made by Evelo in relation to that shortlist and the suitability of each candidate. For the avoidance of doubt, subject to ALJ's compliance with the foregoing requirements, the appointment of any replacement [***] shall be within ALJ's sole discretion.

4. DEVELOPMENT

4.1 **Development Responsibility**. Except as expressly allocated to ALJ under the Development Plan, Regulatory Plan, or Article 5 (Regulatory Matters), Evelo will have sole control over all activities required to file for and obtain and maintain Regulatory Approvals for all Products.

4.2 **Development Plan**. No later than [***] following Evelo notifying ALJ in writing that the first dose in the first patient of any Phase III Clinical Trial for a Product has occurred anywhere in the world, Evelo will prepare: (a) a reasonably detailed written plan of the Development activities for the Products that are specific to the Territory and submit such plan to the PCC to review, discuss, and determine whether to approve (as such plan may be updated pursuant to this Section 4.2 (Development Plan), the "**Development Plan**"), and (b) a budget of the expected FTE Costs, Out-of-Pocket Expenses, and Manufacturing Costs to be incurred by or on behalf of Evelo in the performance of such activities on a Calendar Year basis (as may be updated pursuant to this Section 4.2 (Development Plan), the "**Development Budget**"). It is the intent of the Parties that the initial Development Plan will include all Development activities necessary to file for and to obtain and maintain Regulatory Approval for EDP1815 in the Major Market Countries. All Development of the Products that is specific to the Territory (other than regulatory-related activities) will be performed in accordance with the Development Plan. Evelo may provide to ALJ an update to the then-current Development Plan from time to time, including in the event additional Development activities are required to file for and obtain and maintain Regulatory Approvals for a Product in any country in the Territory, and the PCC will review and discuss, and determine whether to approve any proposed amendment or updates to the Development Plan (including any amendments to the Development Budget) in accordance with Section 3.3 (Decision-Making).

4.3 **Development Diligence Obligations**. Evelo will use Commercially Reasonable Efforts to Develop EDP1815 in order to obtain approval of a BLA for EDP1815 in at least one of the United States of America, the United Kingdom of Great Britain and Northern Ireland, France, Germany, Spain, Italy, China, and Japan. Each Party will use Commercially Reasonable Efforts to perform all activities allocated to it in the Development Plan and will not take any action that conflicts with the Development Plan. ALJ will not perform any Development activities for the Products other than in accordance with the Development Plan.

4.4 **Development Costs**. During each Calendar Quarter during the Term, the Parties will share all Eligible Development Expenses at a ratio of 50:50 (ALJ:Evelo) (the "**Eligible Development Cost Share Ratio**") in accordance with the procedures set forth in this Section 4.4 (Development Costs). No later than 20 days after the end of each Calendar Quarter, each Party will prepare and deliver to the other Party a report detailing the Eligible Development Expenses incurred by or on behalf of such Party during such past Calendar Quarter (each such report, an "**Eligible Development Expenses Report**"). No later than [***] after the end of each Calendar Quarter, one Party will make a balancing payment to the other Party such that for each Calendar Quarter each Party bears the Eligible Development Cost Share Ratio of the total undisputed aggregate costs and expenses set forth in each Eligible Development Expenses Report for such Calendar Quarter (and any disputed amounts within [***] following resolution of the applicable dispute).

4.5 **Development Reports**. On a quarterly basis during the performance of any Development activities within 30 days following the end of each Calendar Quarter, Evelo will prepare and provide a summary to update the PCC on the status of the material Development activities performed by or on behalf of Evelo during the applicable Calendar Quarter (each, a "**Development Report**"). The PCC will review and discuss each quarterly Development Report.

5. REGULATORY MATTERS

5.1 **Regulatory Plan**. No later than [***] following Evelo notifying ALJ in writing that the first dose in the first patient of any Phase III Clinical Trial for a Product has occurred anywhere in the world, Evelo will prepare a reasonably detailed written plan of the regulatory activities for the Products that are specific to the Territory and submit such plan to the PCC to review, discuss, and determine whether to approve (as such plan may be updated pursuant to this Section 5.1 (Regulatory Plan), the "**Regulatory Plan**"), including a detailed, written budget of the FTE Costs and Out-of-Pocket Expenses expected to be incurred by each Party in the performance of such activities on a Calendar Year basis (as may be updated pursuant to this Section 5.1 (Regulatory Plan), the "**Regulatory Budget**"). The Regulatory Plan will include all regulatory activities and anticipated meetings and other communications and correspondence with applicable Regulatory Authorities in the Territory regarding obtaining and maintaining Regulatory Approvals and Reimbursement Approvals (including preparation and submission of all BLAs for all Products in each country in the Territory) to be undertaken by each Party for the Products in the Territory and an allocation between the Parties for all such activities. The Regulatory Plan will include a longstop date for each country in the Territory by which Regulatory Approval to Commercialize a Product is expected to be achieved in that country. At least once each Calendar Year, ALJ will provide to the PCC an update to the then-current Regulatory Plan, and may provide additional updates thereto from time to time, and the PCC will review, discuss, and determine whether to approve any proposed amendment or updates to the Regulatory Plan (including any amendments to the Regulatory Budget) in accordance with Section 3.3 (Decision-Making). All updates to the Regulatory Plan must be consistent with Evelo's global plan for obtaining and maintaining Regulatory Approvals for the Products throughout the world (as provided to ALJ by Evelo in writing from time to time). ALJ will not perform any activities related to obtaining or maintaining any Regulatory Approval or Reimbursement Approval, or any other regulatory activities, in each case, for the Products for the Territory other than in accordance with the Regulatory Plan.

5.2 **Regulatory Activities**.

5.2.1 **Regulatory Diligence Obligations**. Each Party will use Commercially Reasonable Efforts to perform all activities allocated to it in the Regulatory Plan in accordance with the timeframes set forth therein. Without limiting the foregoing, ALJ will use Commercially Reasonable Efforts to obtain and maintain

all Regulatory Approvals and Reimbursement Approvals necessary or useful to Commercialize the Products in each country in the Territory.

5.2.2 **Regulatory Filings**. Except as prohibited by Applicable Law or otherwise set forth in the Regulatory Plan, ALJ will be responsible for undertaking all regulatory activities and interactions with Regulatory Authorities in the Territory for the Products, including preparing and submitting, in accordance with the Regulatory Plan, all Regulatory Submissions necessary or desirable for obtaining (in its name), supporting, or maintaining all Regulatory Approvals for the Products in each country in the Territory (for each country in the Territory, ALJ or, solely to the extent required by Applicable Law in a particular country in the Territory or as set forth in the Regulatory Plan, Evelo, the "**Responsible Party**"). The Party that is not the Responsible Party for a country in the Territory will take all actions reasonably requested by the Responsible Party in furtherance of obtaining or maintaining Regulatory Approvals to Commercialize the Products in that country. The Responsible Party for each country in the Territory will provide the other Party (through the PCC) with an opportunity to review and comment on all Regulatory Submissions to be submitted to any Regulatory Authority in the Territory by or on behalf of the Responsible Party with respect to each Product in the applicable country reasonably in advance of the date such Regulatory Submissions are to be finalized to allow for the other Party's review and comment. The Responsible Party for each country in the Territory will, and will cause its Affiliates and, in the case of ALJ as the Responsible Party, Sublicensees, and Subcontractors to, consider in good faith and implement all comments from the other Party thereon that are provided by the other Party in a timely manner so as to meet the applicable submission or response deadline for such Regulatory Submission. All BLAs, applications for Reimbursement Approval, and other Regulatory Submissions for any Product in the Territory to be submitted by or on behalf of the Responsible Party in each country in the Territory must be submitted to the PCC to review, discuss, and determine whether to approve, and may not be submitted unless and until approved by the PCC.

5.2.3 **Correspondence with Authorities**. Unless prohibited by Applicable Law in a particular country in the Territory, the Responsible Party will have the right to conduct all communications with Regulatory Authorities in the Territory related to the Products, including all written or electronic correspondence and meetings, conferences, and discussions (including advisory committee meetings). Without limiting Section 5.2.2 (Regulatory Filings), no later than five Business Days following receipt thereof each Responsible Party will provide the PCC with (a) access to or copies of all substantive written or electronic correspondence and communications received by that Responsible Party (or its Affiliates, Sublicensees, or Subcontractors) from, or forwarded by that Responsible Party (or its Affiliates, Sublicensees, or Subcontractors) to, the Regulatory Authorities in the Territory, and (b) copies of all meeting minutes and summaries of all meetings, conferences, and discussions held by that Responsible Party (or its

Affiliates, Sublicensees, or Subcontractors) with the Regulatory Authorities in the Territory, including copies of all contact reports produced by that Responsible Party (or its Affiliates, Sublicensees, or Subcontractors), in each case (subsections (a) and (b)), relating to the Products in the Territory. If such written or electronic correspondence received from any such Regulatory Authority relates to the prohibition or suspension of the supply of a Product, or the initiation of any investigation, review, or inquiry by such Regulatory Authority concerning the safety of a Product, then the Responsible Party will notify the other Party and provide the other Party with copies of such written or electronic correspondence as soon as practicable and, in any event, within two Business Days after receipt of such correspondence. Without limiting the foregoing, the Responsible Party for each country in the Territory will provide the other Party with a reasonable opportunity to review and comment on all substantive written or electronic correspondence and communications to be submitted to any Regulatory Authority in the Territory by or on behalf of the Responsible Party with respect to each Product in the applicable country reasonably in advance of the date such correspondence is to be finalized to allow for the other Party's review and comment. The Responsible Party for each country in the Territory will, and will cause its Affiliates (and, in the case of ALJ as the Responsible Party, Sublicensees, and Subcontractors) to, consider in good faith and, following review and discussion between the Parties, implement all reasonable comments from the other Party thereon that are provided by the other Party in a timely manner so as to meet the applicable submission or response deadline for such correspondence.

5.2.4 **Meetings with Regulatory Authorities**. The Responsible Party for each country in the Territory will provide the other Party with prior written notice of any scheduled material meeting, conference, or discussion (including any advisory committee meeting, pre-submission meetings, product development meetings or oral arguments) with a Regulatory Authority in any country in the Territory relating to any Product as soon as practicable after such Responsible Party or its Affiliate first receives notice of the scheduling of such meeting, conference, or discussion (and, in any event, in sufficient time as may be necessary in order to give the other Party a reasonable opportunity to attend such meeting, conference, or discussion). Each Party will provide to the other Party copies of any correspondence relating to such meetings, conferences, or discussions, including meeting requests, briefing materials or questions no later than five Business Days after the other Party's receipt thereof and in any event prior to the applicable meeting, conference, or discussion. Unless prohibited by Applicable Law in a particular country in the Territory, the Responsible Party will permit the other Party to attend as an observer (or, if reasonably requested by the other Party, participate) in all such meetings, conferences, and discussions. In addition, the Responsible Party will provide to the other Party reasonable prior written notice of any meeting held by such Responsible Party to prepare for any of the foregoing meetings, conferences, or discussions, and the other Party will have the right to

attend and participate in any and all such preparatory meetings. The Responsible Party for a particular country in the Territory shall, upon the other Party's reasonable request, permit and will use good faith efforts to cause any applicable representative of the other Party to be permitted to attend and participate in any meeting, conference, or discussion with a Regulatory Authority in such country relating to any Product. If a Party elects not to attend or is prohibited from attending such meeting or discussion, then the Responsible Party will provide to the other Party a written summary thereof in English promptly following such meeting or discussion.

5.2.5 **Ownership of Regulatory Approvals**. Subject to Section 15.3, ALJ will own any and all Regulatory Approvals for the Products in the Territory, unless prohibited by Applicable Law in a particular country in the Territory, in which case Evelo will file and own all Regulatory Approvals for each Product in such country in the Territory in Evelo's own name.

5.3 **Right of Reference**.

5.3.1 **Grant to ALJ**. From and after the Effective Date, Evelo hereby grants to ALJ a "Right of Reference," as that term is defined in U.S. Federal Regulation 21 C.F.R. § 314.3(b) (or any successor rule), and corresponding rights under the foreign equivalents of 21 C.F.R. § 314.3(b) in the applicable countries in the Territory, and a right to copy, access, reference, and otherwise use (at no cost to ALJ or any of its Affiliates), any and all Regulatory Approvals for all Products Controlled by Evelo or its Affiliates or licensees solely in connection with obtaining, supporting, or maintaining any Regulatory Approvals for the Products in the Territory.

5.3.2 **Grant to Evelo**. From and after the Effective Date, ALJ hereby grants to Evelo a "Right of Reference," as that term is defined in U.S. Federal Regulation 21 C.F.R. § 314.3(b) (or any successor rule), and corresponding rights under the foreign equivalents of 21 C.F.R. § 314.3(b) in the applicable countries in the Territory, and a right to copy, access, reference, and otherwise use (at no cost to Evelo or any of its Affiliates), any and all Regulatory Approvals for all Products Controlled by ALJ or its Affiliates or licensees solely in connection with obtaining, supporting, or maintaining any Regulatory Approvals for the Products.

5.3.3 **Further Actions**. Each Party will provide to the other Party a signed statement to the effect of Section 5.3.1 (Grant to ALJ) and Section 5.3.2 (Grant to Evelo), as applicable, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or foreign equivalent) and will take such actions as may be reasonably requested by such Party to give effect to the intent of this Section 5.3 (Right of Reference) and to give such Party the benefit of such Regulatory Approvals as provided in this Section 5.3 (Right of Reference). Such actions may include providing any underlying raw data or information submitted by the applicable Party to any Regulatory Authority with respect to any Regulatory Submissions or Regulatory Approval Controlled by such Party or its Affiliates that relates to any Product.

5.4 **Pharmacovigilance Agreement**. No later than [***] following the first dose of the first patient in any Phase III Clinical Trial for a Product anywhere in the world, the Parties will use good faith efforts to negotiate and execute a pharmacovigilance agreement, on reasonable and customary terms that will provide, among other things, guidelines and responsibilities for (a) the receipt, investigation, recording, review, communication, reporting, and exchange between the Parties of Adverse Event reports and other safety information relating to the Products, (b) appropriate reconciliation procedures to ensure adequate and compliant exchange of safety data, (c) contact with Regulatory Authorities with respect to the foregoing, and (d) the maintenance of a global safety database with respect to the Products (which in any event will be owed by Evelo), in each case (subsections (a) through (d)), in accordance with Applicable Law (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement will contain terms no less stringent than those required by ICH and other applicable guidelines in order to allow the Parties to meet the applicable regulatory and legal requirements regarding the management of safety data in their respective territories. Pending entry into such Pharmacovigilance Agreement, the Parties will, if necessary, within 30 days of the Effective Date, implement an interim procedure for exchange of any and all information concerning all Adverse Events related to use of the Product.

5.5 **Recalls**. Each Party will promptly notify the other Party upon its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market withdrawal, or stock recovery of a Product in the Territory (but in no event later than 48 hours and in all cases prior to the execution of such recall, market withdrawal, or stock recovery). For all such recalls, the Parties will reasonably consult with each other with respect to the actions to be taken to address such recall. Subject to the foregoing, the Responsible Party will have sole control over and decision-making authority with respect to all recalls, market withdrawals, and stock recoveries that are taken in the Territory, and the other Party will take such actions as reasonably requested by the Responsible Party in connection therewith and otherwise reasonably cooperate in all such efforts. All costs and expenses incurred in connection with any recall (including expenses for notification, destruction, and return of the affected Product and any refund to customers of amounts paid for such Product) in the Territory will treated as Other Operating Expenses (unless caused by a breach of this Agreement or the Supply Agreement by a Party, in which case such costs and expenses will be payable by the Party in breach).

5.6 **Regulatory Audits**.

5.6.1 Upon reasonable notification and no more than [***] (or more frequently as reasonably required for cause), each Party (or its representatives) will be entitled (at its own cost and expense) to conduct reasonable audits of safety and regulatory systems, procedures, or practices of the other Party relating to this Agreement.

5.6.2 With respect to any inspection of ALJ or its Affiliates, Sublicensees, or Subcontractors by any Governmental Authority relating to any Product, ALJ will notify Evelo of such inspection (a) no later than two Business Days after ALJ

receives notice of such inspection (or with as much advanced notice as is possible prior to such inspection if ALJ receives notice thereof less than two Business Days in advance of the inspection) or (b) within two Business Days after the completion of any such inspection of which ALJ did not receive prior notice, and in each case will promptly provide the Evelo with all information related to any such inspection. Following any such regulatory inspection related to a Product, ALJ will provide Evelo with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to a Product) within two Business Days of receiving the same, and (ii) a written summary in English of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to a Product) within five Business Days after receiving the same. Any costs and expenses incurred by ALJ in relation to any such inspection by a Governmental Authority shall be included as an Eligible Development Expense, unless any such inspection conducted for cause by a Governmental Authority is caused by a Party's action or inaction under this Agreement (in which case, that Party will be solely responsible for costs and expenses incurred).

5.7 **No Harmful Actions**. If Evelo believes that ALJ is taking or intends to take any action with respect to a Product in the Territory that could have a material adverse impact upon the regulatory status of any Product outside of the Territory, then Evelo will have the right to bring the matter to the attention of the PCC and the PCC will discuss in good faith a resolution to such concern. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth in this Agreement or the Regulatory Plan), neither Party will communicate with any Regulatory Authority having jurisdiction outside of its respective territory with respect to any Product, unless for the purpose of seeking Regulatory Approval or so ordered by such Regulatory Authority, in which case, such Party will immediately notify the other Party of such order.

5.8 **Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of a Party relating to any Product in the Territory, then that Party will notify the other Party of such contact, inspection, or notice or action within two Business Days after receipt of such notice (or, if action is taken without notice, within two Business Days of that Party becoming aware of such action). The Responsible Party for a country in the Territory will have the final decision-making authority with respect to the content of any responses to Regulatory Authorities that solely relate to a Product in that country and the Responsible Party will consider the other Party's reasonable comments to such responses.

5.9 **Notice of Other Actions**. Each Party will promptly notify the other Party of any information that it receives regarding any threatened or pending action, inspection, or communication by or from a Third Party that would reasonably be expected to materially affect the Development of any Product in the Territory.

6. COMMERCIALIZATION

6.1 **Commercialization Plan**. No later than [***] following Evelo notifying ALJ in writing that the first dose in the first patient of any Phase III Clinical Trial for a Product has occurred anywhere in the world after the Effective Date, ALJ will prepare: (a) a reasonably detailed written plan of the Commercialization activities for such Product in the Territory and submit such plan to the PCC to review, discuss, and determine whether to approve (as such plan may be updated as set forth below in this Section 6.1 (Commercialization Plan), a "**Commercialization Plan**"); and (b) a detailed, written budget of the Distribution Costs and other FTE Costs, Out-of-Pocket Expenses, Manufacturing Costs, and Other Operating Expenses expected to be incurred by or on behalf of each Party in the performance of such Commercialization activities on a Calendar Year basis (as may be updated pursuant to this Section 6.1 (Commercialization Plan), the "**Commercialization Budget**"). The Commercialization Plan will include all Commercialization activities to be undertaken by each Party for the Products in the Territory and an allocation between the Parties for all such activities (including, in the case of Evelo, manufacturing of the API for each Product). At least once each Calendar Year, ALJ will provide to the PCC an update to the then-current Commercialization Plan and Commercialization Budget, and may provide additional updates thereto from time to time, and the PCC will review, discuss, and determine whether to approve any proposed amendments or updates to the Commercialization Plan (including any amendments to the Commercialization Budget) in accordance with Section 3.3 (Decision-Making). If an amendment to the Commercialization Budget is required for the completion of a Commercialization activity already contemplated in the Commercialization Plan, and the PCC does not agree to such amendment to the Commercialization Budget for such Commercialization activity, each Party shall be relieved of its obligations under Section 6.2 to the extent directly relating to the specific Commercialization activity or portion of such Commercialization activity for which the increased budget was required. The Commercialization Plan for a Product (including each update thereto) must be consistent with Evelo's global brand strategy and global key messaging for such Product (each, a "**Global Commercialization Plan**"), if and as provided to ALJ in writing by Evelo from time to time during the Term. ALJ will not perform any Commercialization activities for the Products for the Territory other than in accordance with the Commercialization Plan.

6.2 **Commercialization Diligence**. ALJ will use Commercially Reasonable Efforts to perform the Commercialization activities under the Commercialization Plan and to otherwise Commercialize the Products in the Territory. Without limiting the generality of the foregoing, unless otherwise provided in the Commercialization Plan, ALJ will use Commercially Reasonable Efforts to, as soon as reasonably practicable after receiving Regulatory Approval required for Commercialization for a Product in a particular country in the Territory, achieve the First Commercial Sale for such Product in such country.

6.3 **Commercialization Support**. Evelo will provide support for ALJ's Commercialization activities to the extent such support is either (a) set out in the Commercialization Plan or (b) otherwise requested by ALJ and approved by the PCC.

6.4 **Shared Expenses**. The Parties will share the Eligible Commercialization Expenses for all Products for the Territory as set forth in Section 9.3 (Profit and Loss Share).

6.5 **Commercialization Reports**. Within [***] after the end of each Calendar Quarter in which ALJ is Commercializing one or more Products in the Territory, ALJ will provide to Evelo a written high-level summary in English of ALJ's Commercialization Activities related to such Products in the Territory during such Calendar Quarter and planned to be conducted during the upcoming Calendar Year.

6.6 **Diversion**. ALJ agrees that it will not, and will ensure that its Affiliates, Sublicensees, and Subcontractors will not, either directly or indirectly, promote, market, distribute, export, have exported, sell, or have sold any Products to any Third Party or to any address or Internet Protocol address or the like in any country or jurisdiction outside the Territory, or any country or jurisdiction inside the Territory for which all Regulatory Approvals required to Commercialize such Product have not been received, in each case, including via the Internet or mail order. ALJ will not engage, nor permit its Affiliates, Sublicensees, or Subcontractors to (a) engage, in any advertising or promotional activities relating to any Products for use directed primarily to customers or other buyers or users of the Products located in any country or jurisdiction outside the Territory or located in any country or jurisdiction inside the Territory for which all Regulatory Approvals required to Commercialize such Product have not been received, or (b) solicit orders from any prospective purchaser located in any country or jurisdiction outside the Territory or located in any country or jurisdiction inside the Territory for which all Regulatory Approvals required to Commercialize such Product have not been received. If ALJ or its Affiliates, Sublicensees, or Subcontractors receive any order for any Products from a prospective purchaser located in a country or jurisdiction outside the Territory or any country or jurisdiction inside the Territory for which all Regulatory Approvals required to Commercialize such Product have not been received, then ALJ will immediately refer that order to Evelo and will not accept any such orders. ALJ will not, and will not permit its Affiliates, Sublicensees, or Subcontractors to, deliver or tender (or cause to be delivered or tendered) any Products to Third Parties for use in such country or territory.

6.7 **Training**.

6.7.1 **Approval and Branding of Training Materials**. Evelo, in collaboration with ALJ, will prepare and produce all Training Materials for use in the Territory and will provide English-language proof copies of initial versions of all Training Materials and all substantive updates to such Training Materials to the PCC to review, discuss, and determine whether to approve prior to any use of such materials in training any of ALJ's trainers, sales representatives, sales managers, or other sales personnel ("**ALJ Sales Personnel**"). In addition, ALJ may propose new or modified Training Materials at any time and submit such materials to the PCC to review, discuss, and determine whether to approve. ALJ will not use any Training Materials that have not been approved by the PCC. All Training Materials will be in compliance with all Applicable Laws, Professional

Requirements, and the Approved Labeling. In addition, to the extent permitted under Applicable Law within the Territory, and to the extent bearing any Housemarks, the Training Materials will include the Evelo Housemarks and the ALJ Housemarks with equal prominence. Each Party will provide to the other Party proof copies of the applicable Evelo Housemarks and ALJ Housemarks (as applicable) to be included in connection with all cobranding described in this Section 6.7.1 (Approval and Branding of Training Materials) in the manner and format as may be reasonably specified by a Party from time-to-time.

6.7.2 **Evelo's Training Obligations**. Evelo will provide the Training Materials approved in accordance with Section 6.7.1 (Approval and Branding of Training Materials) to ALJ for ALJ and its Affiliates, as applicable, to use in the training of ALJ's or ALJ's Affiliates' trainers and all other ALJ Sales Personnel. Evelo may provide to ALJ, and ALJ may use in the conduct of its training pursuant to Section 6.7.3 (ALJ's Training Obligations), information regarding (i) the use of such Training Materials, (ii) any new information pertaining to the Products that may periodically arise, and (iii) the conduct of any further training to be provided by ALJ's trainers to the applicable ALJ Sales Personnel.

6.7.3 **ALJ's Training Obligations**. ALJ will be responsible for preparing and delivering training to its trainers and all ALJ Sales Personnel using only the Training Materials approved by the PCC and provided by Evelo in accordance with Section 6.7.2 (Evelo's Training Obligations). ALJ will ensure that training of all ALJ Sales Personnel occurs (a) prior to the provision by such ALJ Sales Personnel of any detailing of the Products in the Territory under this Agreement, and (b) periodically thereafter in each country in the Territory during the Term as set forth in the Commercialization Plan, or as may be reasonably requested by Evelo.

6.8 **Territory Product Materials**.

6.8.1 **Review**. Evelo, in collaboration with ALJ, will prepare and produce all Packaging and Labeling, Promotional Materials, and Product Materials for use in the Territory (collectively, "**Territory Product Materials**") and will provide English-language proof copies of initial versions of all Territory Product Materials and all substantive updates to such Territory Product Materials to the PCC to review, discuss, and determine whether to approve prior to any use by either Party; provided that ALJ will be responsible for providing to the PCC localized versions of all Approved Labeling satisfactory for use in each country in the Territory in compliance will Applicable Law in each such country. In addition, ALJ may propose new or modified Territory Product Materials at any time and submit such materials to the PCC to review, discuss, and determine whether to approve. All Territory Product Materials will be in compliance with all Applicable Laws, Professional Requirements, and Approved Labeling and

otherwise consistent the applicable terms of this Section 6.8.1 (Review). ALJ will not use any Territory Product Materials that have not been approved by the PCC.

6.8.2 **Branding**. The Parties agree that, to the extent permitted under Applicable Law within the Territory, to the extent bearing any Housemarks, the Territory Product Materials will include the Evelo Housemarks and the ALJ Housemarks with equal prominence. At Evelo's request, Territory Product Materials will include an acknowledgement that the Products are being sold under a license from its developer, Evelo Biosciences. In addition, each Party will use reasonable efforts in the Territory to cobrand all sponsorships, booths, and similar activities, to the extent the same are solely related to the Products and such cobranding is permitted under Applicable Law, and otherwise in accordance with the terms of Section 6.8.1 (Review). Each Party will provide to the other Party proof copies of the applicable Evelo Housemarks and ALJ Housemarks (as applicable) to be included in connection with all cobranding described in this Section 6.8 (Territory Product Materials) in the manner and format as may be reasonably specified by a Party from time-to-time.

6.9 **Dissemination of Product Materials**. ALJ will, directly or through its Affiliates, have full responsibility for the dissemination of all applicable Territory Product Materials to all ALJ Sales Personnel and other representatives who need such information to perform ALJ's activities under this Agreement or the Commercialization Plan.

6.10 **Ownership of Product Materials**. Evelo will own all rights, title, and interests in and to all Product Materials worldwide in perpetuity (including all Product Marks, copyright, and other Intellectual Property rights relating thereto), except that ALJ will retain all rights to any ALJ Housemarks that may be included on any Product Materials. Except with respect to the incorporation of any ALJ Housemarks therein, ALJ's use of the Product Materials pursuant to rights granted in this Agreement is for Evelo's benefit and will inure to Evelo, and ALJ will not acquire any rights in any of them by such use.

6.11 **Restrictions on Use of Territory Product Materials**. ALJ will and will cause its Affiliates, Sublicensees, Subcontractors, and its and their respective representatives, including all ALJ Sales Personnel, to use all Territory Product Materials solely in connection with the performance of ALJ's and its Affiliates' activities under this Agreement and the Commercialization Plan and the Medical Affairs Plan. In addition, without the prior approval of the PCC, ALJ will not, and will cause its Affiliates, Sublicensees, and Subcontractors not to, (a) create, distribute, or use sales, promotion, or any other material relating to the Products other than the Territory Product Materials approved by the PCC, (b) add to, delete from, or modify any Territory Product Materials in any material manner after approval by the PCC, or (c) otherwise make any other changes to any Territory Product Materials after approval by the PCC. If the PCC determines that any Training Materials or other Territory Product Materials are inaccurate or non-compliant or if the PCC (or Evelo in accordance with its final decision-making authority in Section 3.4.2(b) (Evelo Final Decision-Making Authority)) determines that

any Training Materials or other Territory Product Materials must otherwise cease to be used, then ALJ will promptly cease to use such Training Materials or other Territory Product Materials and will collect and destroy any such materials from its Affiliates, Sublicensees, Subcontractors, and its and their respective representatives.

6.12 **Communications with Sales Representatives**. Any information or written communication disseminated by ALJ or its Affiliates to any ALJ Sales Personnel concerning the promotion of the Products will be based on and consistent with information set forth in the Territory Product Materials approved by the PCC, the Training Materials approved by the PCC, or otherwise provided by Evelo to ALJ (to the extent that Evelo has provided to ALJ information relevant to such information or written communication).

6.13 **Standards of Conduct; Compliance**. Each Party will perform, or will ensure that each of its Affiliates, Sublicensees, and Subcontractors perform, all Commercialization activities in the Territory for which it is responsible pursuant to this Agreement in a professional and ethical business manner and in compliance with Applicable Law, Professional Requirements, the Approved Labeling, and the Commercialization Plan. Without limiting the foregoing:

6.13.1 **Personnel Conduct and Policies**. (a) Each Party will instruct its personnel not to, and will ensure that its personnel do not, make any representation, statement, warranty, or guaranty, whether oral or written, with respect to any Product that is inconsistent with the then-current Approved Labeling of such Product, Applicable Laws, or the applicable approved Territory Product Materials, in each case, in the Territory; or that is deceptive or misleading in any way; or take any action that disparages or may jeopardize the good name, goodwill, or reputation of any of the Products or of a Party or its Affiliates; and (b) ALJ will maintain and enforce a corporate compliance program consistent with Applicable Law in each country in the Territory in which it is Commercializing the Product. Without limiting the foregoing, ALJ's comprehensive corporate compliance program will also include, and ALJ will carry out, a broad training program in ethics and compliance with Applicable Law in each country in the Territory in which it is Commercializing the Product, in addition to Product training.

6.13.2 **Compliance Program Changes**. ALJ will promptly notify Evelo of any changes to its compliance program (including applicable policies and procedures) that relate to or may affect ALJ's performance of its Commercialization or other activities under this Agreement.

6.13.3 **Notification of Non-Compliance; Reporting**. ALJ will immediately notify Evelo of any claim, demand, communication, investigation, or inquiry of any type related to this Agreement or a Product in the Territory, or otherwise impacting the Products in the Territory, including any subpoena, civil investigative demand, or congressional inquiry letter, from any Governmental Authority. In addition, ALJ will give notice to Evelo of the substance of any report relating to non-compliance

with Applicable Laws or Professional Requirements by ALJ's personnel in connection with ALJ's activities under this Agreement within a reasonable time (but in no event later than three days) after such report is received. In addition, ALJ will provide Evelo with a quarterly written report summarizing the substance of any investigation by ALJ relating to any ALJ Sales Personnel's alleged violation of Applicable Laws or Professional Requirements in connection with such Party's promotion of a Product.

6.14 **Marks and International Non-Proprietary Name**.

6.14.1 **Product Marks**. Evelo will select the global brand name for each Product and the applicable Product Marks for each such Product and, unless otherwise agreed by the PCC, shall use Commercially Reasonable Efforts to obtain and maintain trademark registrations for the applicable Product Marks in respect of each Product, in: (a) the Major Market Countries; and (b) other countries in the Territory where the Regulatory Approval required for the Commercialization of that Product has been obtained. ALJ will Commercialize each Product in the Territory under the Product Marks. ALJ will monitor the Product Marks against infringing uses relating to the Products in the Territory and will promptly notify Evelo of any infringement or threatened infringement of any of the Product Marks of which it becomes aware.

6.14.2 **Required Use and Compliance**.

(a) **Housemarks**. ALJ will promote the Products only under the applicable Product Marks and each Party's Housemarks as set forth herein, and no other Marks.

(b) **Ownership; Use**. ALJ will and will cause its Affiliates, Sublicensees, and Subcontractors to: (i) ensure that each use of the Product Marks and all Evelo Housemarks is accompanied by an acknowledgement that such Product Marks and Evelo Housemarks are owned by Evelo; (ii) not use such Product Marks or the Evelo Housemarks in a way that could prejudice their distinctiveness or validity or the goodwill of Evelo therein and includes the trademark registration symbol ® or ™ as appropriate; and (iii) not use any trademarks or trade names so resembling any of such Product Marks or the Evelo Housemarks as to be likely to cause confusion or deception.

6.14.3 **Mark Licenses**.

(a) **Product Marks**. Subject to the terms and conditions of this Agreement, Evelo hereby grants and will grant to ALJ a co-exclusive (with Evelo), royalty-free with the right to grant sublicenses (solely in accordance with Section 2.2 (Sublicensing and Subcontracting by ALJ)), license to use the Product Marks solely to perform Medical Affairs activities with respect to

and Commercialize, the Products in the Territory pursuant to this Agreement, the Medical Affairs Plan, and the Commercialization Plan. ALJ will assure at all times that the quality of the Product Marks is of a standard of quality consistent with pharmaceutical industry standards.

(b) **Evelo Housemarks**. Subject to the terms and conditions of this Agreement, Evelo hereby grants and will grant to ALJ a non-exclusive, royalty-free, with the right to grant sublicenses (solely in accordance with Section 2.2 (Sublicensing and Subcontracting by ALJ)), license to use the Evelo Housemarks solely as set forth in the Territory Product Materials and other materials provided to it by Evelo, and solely to perform Medical Affairs activities with respect to and Commercialize the Products in the Territory in accordance with this Agreement.

6.14.4 **Mark Responsibility**. Evelo will have sole control over and decision-making authority with respect to (a) registering, prosecuting, and enforcing the Product Marks in the Territory, (b) preparing any guidelines applicable to the use of Product Marks in the Territory, and (c) investigating and defending any infringement or threatened infringement relating to any Product Marks. ALJ will cooperate and assist Evelo with any of the foregoing activities with respect to all Product Marks, including, if reasonably requested by Evelo, providing any specifications, affidavits, declarations, or other documents necessary for Evelo to submit to appropriate Regulatory Authorities in order to register and prosecute Product Marks. Evelo will own and be responsible for securing any Internet domain names associated with the Product Marks. ALJ will not obtain or hold any such domain name in its own name.

6.14.5 **Respect of Product Marks and Evelo Housemarks**. ALJ will not and will cause its Affiliates, Sublicensees, and Subcontractors to not: (a) attack, challenge, oppose, petition to cancel, or initiate legal action or proceedings in connection with any Product Mark or the Evelo Housemarks, or challenge the registration of any Product Marks or Evelo Housemark in any country; (b) file, register, or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Mark (other than for a Product) or Evelo Housemarks, in any country without the express prior written consent of Evelo; or (c) authorize or assist any Third Party to do the foregoing. ALJ will not have, assert, or acquire any rights, title, or interests in or to any Evelo Housemarks or the goodwill pertaining thereto. ALJ will maintain the quality standards of Evelo with respect to use of Product Marks and the Evelo Housemarks pursuant to the licenses granted under Section 2.1 (License Grant to ALJ) or Section 6.14.3 (Mark Licenses), as applicable, and with respect to the goods it sells and the services it provides in connection with the Product Marks and the Evelo Housemarks hereunder. ALJ will comply with all written trademark usage guidelines provided by Evelo from time to time. Upon Evelo's reasonable request from time to time, ALJ will provide to Evelo for its review all materials that include any Product

Marks or Evelo Housemarks, provided that all subsequent uses of any materials already provided to Evelo for review may be used without additional review. ALJ recognizes and agrees that no ownership rights are vested or created by the limited licenses granted pursuant to Section 2.1 (License Grant to ALJ) and Section 6.14.3 (Mark Licenses) and that all goodwill developed by virtue of the use by ALJ of the Product Marks and the Evelo Housemarks inures to the benefit of Evelo.

6.15 **International Non-Proprietary Name**. Evelo will have sole control over and decisionmaking authority with respect to the selection and filing of the international non-proprietary name for each Product with the World Health Organization and any Regulatory Authorities in the Territory, which ALJ will have the right to reference.

7. MEDICAL AFFAIRS

7.1 **Medical Affairs Plan**. Evelo has developed a global Medical Affairs strategy (including a strategy for managing communications with key opinion leaders), and no later than one year following the Effective Date, in collaboration with Evelo through the PCC, ALJ will prepare a reasonably detailed medical affairs plan for the Territory that will be consistent with Evelo's global Medical Affairs strategy (the "**Medical Affairs Plan**"). The PCC will review, discuss, and determine whether to approve the initial Medical Affairs Plan so submitted by ALJ. The Medical Affairs Plan will be compliant with all Applicable Laws and each Party's written compliance policies and procedures, and each Medical Affairs Plan will include:

7.1.1 the Medical Affairs activities to be undertaken by each Party for the Products in the Territory and an allocation between the Parties for all such activities;

7.1.2 the qualification requirements for each Party's medical science liaisons;

7.1.3 medical science liaison resource planning; and

7.1.4 a written budget of the expected FTE Costs and Out-of-Pocket Expenses for all activities under the Medical Affairs Plan on a Calendar Year basis for the subsequent Calendar Year (as may be updated pursuant to this Section 7.1 (Medical Affairs Plan), the "**Medical Affairs Budget**").

At least once each Calendar Year, ALJ will provide to the PCC an update to the then-current Medical Affairs Plan and Medical Affairs Budget, and may provide additional updates thereto from time to time, and the PCC will review, discuss, and determine whether to approve any proposed amendment or updates to the Medical Affairs Plan (including any amendments to the Medical Affairs Budget) in accordance with Section 3.3 (Decision-Making). ALJ will not perform any Medical Affairs activities for the Products for the Territory that is not in accordance with the Medical Affairs Plan.

7.2 **Products Medical Affairs Expenses**. The Parties will share the Eligible Medical Affairs Expenses for all Products for the Territory as set forth in Section 9.3 (Profit and Loss Share).

7.3 **Medical Education Materials**. Evelo will prepare and produce all Medical Education Materials for use in the Territory and will provide English-language proof copies of initial versions of all Medical Education Materials for use in the Territory and all substantive updates to such Medical Education Materials to the PCC to review, discuss, and determine whether to approve. In addition, ALJ may propose new or modified Medical Education Materials for use in the Territory at any time and submit such materials to the PCC to review, discuss, and determine whether to approve. ALJ will not use Medical Education Materials that have not been approved by the PCC, including any presentation by any key opinion leaders in the Territory (unless otherwise approved in writing by Evelo). All Medical Education Materials will be compliant with Applicable Laws and the Medical Affairs Plan. In addition, to the extent permitted under Applicable Laws within the Territory, and to the extent bearing any Housemarks, the Medical Education Materials to be distributed in such countries by each Party's respective medical affairs personnel will include the Evelo Housemarks and the ALJ Housemarks with equal prominence. Each Party will provide to the other Party proof copies of the Evelo Housemarks and ALJ Housemarks (as applicable) to be included in connection with all cobranding described in this Section 7.3 (Medical Education Materials) in the manner and format as may be reasonably specified by a Party from time-to-time. Each Party will, directly or through its Affiliates, have full responsibility for the dissemination of all applicable Medical Education Materials to its medical affairs personnel and other representatives who need such materials to perform such Party's Medical Affairs under this Agreement or the Medical Affairs Plan.

8. MANUFACTURING AND SUPPLY

8.1 **Supply Agreement**. Within [***] following Evelo notifying ALJ in writing that the first dose in the first patient of any Phase III Clinical Trial for a Product has occurred anywhere in the world after the Effective Date, the Parties will (acting reasonably and in good faith) discuss and execute a supply agreement that includes the terms set forth in Schedule 8.1 (Supply Terms) (the "**Supply Agreement**"), which Supply Agreement will be consistent with the terms of the agreements between Evelo and all applicable Third Parties for the Manufacture of the Product for the Territory. Pursuant to the terms of the Supply Agreement, Evelo will (itself or through one or more Affiliates or Third Party contract manufacturers) Manufacture and supply ALJ's requirements of each Product in Finished Form for a specific presentation by or on behalf of ALJ in the Territory and in any other form agreed to by the Parties and set forth in the Supply Agreement. The Supply Agreement will set forth that Evelo will provide at ALJ's request and required quantity, Product in Finished Form for purposes of Commercialization at a cost of [***] of the Manufacturing Costs for the applicable Product.

8.2 **Packaging and Labeling Review**. In accordance with Section 6.8.2 (Branding), ALJ will be responsible for the development of all Packaging and Labeling for the Products for each country of the Territory (which will be based on Evelo's global branding strategy), and the Responsible Party for each country in the Territory will be responsible for filing for approval for the Approved Labeling and all other Packaging and Labeling for each Product in each country in the Territory. If there is any deviation or planned exception from the current Approved Labeling of any Product in Finished Form in any country in the Territory, then the Parties will discuss a revised strategy to ensure continuity of supply through the PCC, and ALJ will provide to the Responsible Party for the applicable country revised Approved Labeling or other Packaging and Labeling (as applicable) for such country that implements such revised strategy for filing by the Responsible Party of appropriate Regulatory Submissions with the Regulatory Authorities in such country. The Parties will discuss and agree in writing on the implementation of any label changes based on then-current Product inventory labels prior to making any submission to any Regulatory Authority regarding such label changes. ALJ will be solely responsible for any costs or expenses associated with any changes to the Packaging and Labeling for the Products in the Territory or remanufacturing of any Product for the Territory, including reimbursement to Evelo of all costs and expenses incurred by or on behalf of Evelo to dispose of any inventory of Product in Finished Form or packing and labeling materials, in each case, in outdated form as a result of such changes. On a Product-by-Product and country-by-country basis, if Evelo is then Manufacturing the applicable Product for the applicable country, at such time prior to the anticipated date of the first shipment of Finished Form of a Product intended for Commercialization in a country in the Territory as is determined by the PCC, ALJ will provide to Evelo the most up-to-date version of all Packaging and Labeling to be included in the Finished Form of such Product in such country in the form of image files.

8.3 **ALJ Manufacturing Option; Technology Transfer**. Beginning [***] after the First Commercial Sale of any Product in the Territory, if the PCC reasonably determines that ALJ has established the capability to perform the ALJ Manufacturing Activities for one or more countries in the Territory in accordance with GMP standards, then, upon agreement of the PCC, ALJ may conduct ALJ Manufacturing Activities in the Field in or for the Territory pursuant to the license in Section 2.1 (License Grant to ALJ). Upon such notice, the Parties will, through the PCC: (a) negotiate in good faith the terms and conditions of a technology transfer plan pursuant to which Evelo would transfer to ALJ that Licensed Know-How necessary to enable ALJ to perform the ALJ Manufacturing Activities for the Products for the Territory (the "**Manufacturing Tech Transfer Plan**"); and (b) negotiate in good faith amendments to the Supply Agreement to contemplate API-only manufacturing by Evelo. Under such amended Supply Agreement, Evelo will provide, at ALJ's request and required quantity, API for purposes of Commercialization at a cost of [***] of the Manufacturing Costs for such API. ALJ will not have the right to, and will not, conduct any ALJ Manufacturing Activities for any Product unless (i) the PCC determines that ALJ has established the capabilities to perform the ALJ Manufacturing Activities for the Territory in accordance with GMP standards for such activities and agrees to permit ALJ to perform the ALJ Manufacturing Activities, (ii) the

Parties have completed all activities under the Manufacturing Tech Transfer Plan, and (iii) ALJ (or its appointed Third Party manufacturer, as applicable) has received all Regulatory Approvals required to perform such ALJ Manufacturing Activities in the Territory. In any event, ALJ's right to perform the ALJ Manufacturing Activities with respect to the Products will begin no sooner than 12 months following receipt by Evelo of such notice from ALJ and will continue during the Term only for so long as ALJ maintains the capabilities to perform the ALJ Manufacturing Activities for one or more countries in the Territory in accordance with GMP standards. Any Manufacturing activities conducted by ALJ outside the Territory shall be solely for purpose of Commercializing Products inside the Territory.

9. PAYMENTS

9.1 **Upfront Payment**. ALJ will pay to Evelo a one-time upfront payment of $7,500,000 ("**Upfront Payment**") no later than five days after the Effective Date.

9.2 **Equity Investment**. On the earlier of (a) Evelo's next stock equity financing (the "**Financing**") or (b) February 5, 2021, ALJ Health Care & Life Sciences Company Limited will purchase $7,500,000 of Evelo's common stock in a stand-alone transaction at the then-current fair market value (the terms and conditions of such purchase, the "**Stock Purchase Agreement**"). The "current fair market value" shall be equal to (i) if sold in connection with the Financing, the price per share sold to other investors in the Financing, and (ii) if sold not in connection with the Financing, the closing price per share of the publically traded shares of common stock on February 4, 2021. In connection with such investment, ALJ will agree to a lock-up agreement on customary terms that will restrict ALJ's ability to sell shares of Evelo's common stock or any derivative securities for a period equal to six months following the closing of such investment.

9.3 **Profit and Loss Share**. Evelo and ALJ will share the Operating Profits or Losses for all Products in the Territory as follows: ALJ will bear (and be entitled to) 50%, and Evelo will bear (and be entitled to) 50%, of such Operating Profits or Losses. Schedule 9.3 (Profit and Loss Share) sets forth the procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters. To the extent either Party, in bearing 50% of Operating Profits or Losses for the Territory, is obligated to reimburse any losses accruing for the Territory in a given Calendar Quarter, that Party will not be obligated to make any direct reimbursement payment to the other Party in consideration of such loss, and instead that Party may offset any such loss against any other payments owed to the other Party under this Agreement at the relevant time, provided that, if no other payments are owed to the other Party under this Agreement at the relevant time, then that Party will pay such reimbursement in accordance with the payment procedures set forth in Schedule 9.3 (Profit and Loss Share).

9.4 **Payment Method**. All payments to be made between the Parties under this Agreement will be made in Dollars and may be paid by wire transfer in immediately available funds to a bank account designated by the Receiving Party. Net Sales will first be calculated in

the currency of sale, as applicable, and then converted into Dollars at the exchange rate set forth in *The Wall Street Journal* or any successor thereto for the last day of the Calendar Quarter prior to the Calendar Quarter in which the applicable payment obligation became due and payable. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Section 9.4 (Payment Method), then the Parties will agree upon a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then ALJ may elect, in its sole discretion, to deliver such payment in Euros.

9.5 **Late Payments**. If a Party does not receive payment of any undisputed sum due to it on or before the due date set forth under this Agreement, then simple interest will thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of [***] points over the then-current prime rate reported in *The Wall Street Journal* or the maximum rate allowable under Applicable Law, whichever is lower.

9.6 **Taxes**.

9.6.1 **General**. ALJ hereby represents that it is a tax resident of Jersey. If, during the Term, ALJ becomes a tax resident in any other jurisdiction, ALJ will use reasonable efforts to mitigate any adverse impact on Evelo; provided that if, despite such efforts, any incremental withholding taxes are imposed on any amount payable by ALJ pursuant to this Agreement as a result of such change in ALJ's tax residency, then such amount payable by ALJ shall be increased to take into account such incremental withholding taxes so that Evelo receives an amount equal to the sum it would have received had no such incremental withholding taxes been withheld. The Parties acknowledge and agree that no withholding taxes are expected to be deducted or withheld from amounts payable by ALJ pursuant to this Agreement, and no such amounts will be reduced on account of any taxes; provided, that if required under Applicable Law, ALJ will be entitled to deduct and withhold from the such amounts any taxes that it is required by Applicable Law to deduct or withhold including from subsequent payments made pursuant to this Agreement. If, in accordance with the foregoing, ALJ withholds any amount, then, subject to Section 16.1 (Assignment), it will pay to Evelo the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send Evelo proof of such payment within 45 days following that payment. The Parties will use reasonable efforts to reduce any withholding required under Applicable Law. Evelo shall provide a complete and accurate Form W-9 to ALJ prior to payment of the due date of the Upfront Payment. ALJ agrees to hold Evelo harmless for any fees, penalties, and interest that are imposed on the Evelo arising out of ALJ's failure to withhold and remit withholding taxes to Governmental Authorities in accordance with this Section 9.6 (Taxes) and Applicable Laws, unless ALJ fails to withhold and remit such withholding taxes as a result of a failure by Evelo to timely provide, upon reasonable request from

ALJ, accurate forms or information necessary for ALJ to determine whether and to what extent it has an obligation to so withhold.

9.6.2 **Foreign Partnership.** The Parties intend to treat the ownership of the Licensed Technology and the non-U.S. distribution and sales activities described in this Agreement as a foreign partnership for U.S. federal income tax purposes ("**Foreign Partnership**"). The Parties intend that all activities conducted by the Foreign Partnership take place solely in the Territories outside of the United States. Unless otherwise required under applicable law, (a) neither Party will file an IRS Form 1065 or issue a Schedule K-1 with respect to the Foreign Partnership and (b) Evelo shall file and report any income allocable to it in respect of the Foreign Partnership on an IRS Form 8865. Further, if either (i) as a result of any change in applicable tax law in the Territory or (ii) for any other reason which is not reasonably foreseeable as at the Effective Date, the arrangement created by this Agreement causes, or is reasonably likely to cause, Evelo to be treated as subject to net income tax in any jurisdiction in the Territory, Evelo will notify ALJ of the same in writing and the Parties will (y) discuss in good faith whether there are mutually acceptable steps which would mitigate any adverse tax consequences from arising to Evelo as a result of being subject to net income tax in any such jurisdiction and (z) if the Parties agree on any such steps, promptly implement those agreed.

9.6.3 **VAT**.

(a) All payments or amounts due under this Agreement, whether monetary or non-monetary are exclusive of VAT. Where the prevailing legislation requires the recipient of a supply under this Agreement to self-account for VAT (for example, but not limited to, the reverse charge mechanism), then each Party (to the extent (i) it is such a recipient and (ii) such VAT is recoverable by such recipient Party) covenants that it will correctly account for VAT in respect of the services received. Each Party, to the extent it makes such a supply, agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT, if applicable.

(b) Each Party will be responsible for any penalties or interest accruing due to incorrect VAT treatment of the supplies of goods or services made by that Party or any failure to correctly account for VAT on any receipt of a supply of goods or services under this Agreement except where those penalties or interest arise as a result of the actions of the other Party, in which case that Party will be liable to reimburse the value of the penalties and interest.

(c) Each Party will be responsible for reporting its own transactions to the local tax authorities, if required, for VAT purposes. There will be no shared, mutual, or otherwise collective VAT filings that may suggest that

the Parties are anything other than separately operational entities for VAT purposes.

9.7 **Financial Audits**.

9.7.1 **Record Retention; Audits**. Each Party will keep (and will cause its Affiliates and Sublicensees to keep) complete and accurate records in accordance with the applicable Accounting Standards in relation to this Agreement, including in relation to all amounts relevant to the calculation of Eligible Development Expenses, Operating Profits or Losses and Net Sales. Each Party will keep such books and records for [***] following the Calendar Year to which they pertain. Each Party (the "**Auditing Party**") may, upon written request and no more than annually (or more frequently as reasonably required for cause), cause an independent accounting firm (the "**Auditor**") that is reasonably acceptable to the other Party (the "**Audited Party**") to inspect the relevant records of the Audited Party and its Affiliates to verify the payments made pursuant to this Agreement and the related reports, statements and books of accounts, as applicable. Before beginning its audit, the Auditor will execute an undertaking by which the Auditor agrees to keep confidential all information reviewed during the audit. The Audited Party and its Affiliates will make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The Auditor will review the records solely to verify the accuracy of Development Costs, Operating Profits or Losses or Net Sales, and the Audited Party's compliance with the financial terms of this Agreement. The Auditing Party agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any law, regulation or judicial order. The Auditor will provide its audit report and basis for any determination to the Audited Party at the time such report is provided to the Auditing Party.

9.7.2 **Audit Disputes**. Either Party may refer any disputes with respect to the findings of the Auditor for resolution pursuant to the dispute resolution procedures set forth in Section 16.3 (Dispute Resolution). If either Party is found to have been underpaid any amounts payable to such Party hereunder or to have overpaid to the other Party any amounts payable hereunder, then such first Party will be entitled to recover any undisputed discrepancy, plus interest as set forth in Section 9.5 (Late Payments), no later than 45 days after delivery to the Parties of the final report of the Auditor. The fees charged by the Auditor will be paid by the Auditing Party; provided that, if the audit discloses a net underpayment of amounts owed or over reporting of expenses by the Audited Party of more than [***] of total amounts owed or expenses reported by the Audited Party for any Calendar Year covered by the audit, then the Audited Party will pay the fees and expenses charged by the Auditor.

10. INTELLECTUAL PROPERTY

10.1 **Ownership and Licensing of Intellectual Property**. Subject only to the rights expressly granted to the other Party under this Agreement, each Party will retain all rights, title, and interests in and to any Intellectual Property rights that are owned, licensed, or sublicensed by such Party prior to or independent of this Agreement. All determinations of ownership of Inventions invented, conceived, discovered, created, or otherwise developed under this Agreement will be made in accordance with U.S. patent law.

10.2 **Patent Prosecution and Maintenance**.

10.2.1 As between the Parties, Evelo will have the sole right and authority to prepare, file, prosecute, and maintain the Licensed Patent Rights (including, any supplementary protection certificates or other legal instruments that would extend the term of any Patent Rights within the Licensed Patent Rights) in the Territory, and ALJ will provide such assistance related thereto as Evelo may reasonably request. Evelo will provide ALJ a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding the Licensed Patent Rights, as well as drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Evelo will consider ALJ's comments regarding such communications and drafts in good faith.

10.2.2 If, during the Term, Evelo intends to allow any Licensed Patent Right to lapse or become abandoned without having first filed a substitute or continuation, Evelo shall notify the PCC of such intention reasonably in advance of the date upon which such Licensed Patent Right shall lapse or become abandoned and the PCC will determine whether ALJ shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance of such Licensed Patent Right at its own expense, with counsel of its choice.

10.3 **Patent Filings in the Territory**. ALJ will not, and will cause its Affiliates, Sublicensees, and Subcontractors to not, file any Patent Rights in the Territory or outside the Territory that (a) disclose or claim a Product or any Licensed Know-How, or (b) otherwise exclusively relate to a Product. ALJ agrees to grant and hereby grants a perpetual, irrevocable, transferable, sublicensable (through multiple tiers), fully-paid up, royalty-free, license to Evelo under all Patent Rights owned or Controlled by ALJ, or any of its Affiliates, Sublicensees or Subcontractors, during the Term and for [***] thereafter, that Cover the Exploitation of the Products worldwide, solely to Exploit the Products for any and all purposes worldwide. Such license will be co-exclusive (between ALJ and Evelo) with respect to Exploitation of the Products in or for the Territory and exclusive with respect to any other Exploitation of the Products for all other purposes.

10.4 **Patent Enforcement**.

10.4.1 **Third Party Infringement**. During the Term, each Party will promptly inform the other Party in writing if such Party becomes aware of any suspected, threatened, or actual infringement by any Third Party of any Licensed Technology (an "**Infringement**"), including any Infringement that arises as a result of the making, using, offering to sell, selling, or importing of a product that is Covered by any Licensed Patent Right in the Territory (a "**Competing Infringement**"). Each Party will provide to the other Party any available evidence of such Infringement with such notification.

10.4.2 **Evelo's Rights**. During the Term, Evelo will have the initial right, but not the obligation, to initiate an infringement or other appropriate suit (an "**Infringement Action**") against any Competing Infringement in the Territory with respect to any Licensed Patent Rights, and the Parties will equally share such costs and any recoveries.

10.4.3 **ALJ's Rights**. If Evelo fails to initiate an Infringement Action under Section 10.4.2 within [***] (or such shorter period necessary to initiate and maintain full rights of enforcement under such action) of a request by ALJ to do so, then the PCC will determine whether ALJ or its designee may initiate an Infringement Action with respect to such infringement.

10.4.4 **Procedures**. If either Party is permitted to (with respect to ALJ) and desires to initiate an Infringement Action under this Section 10.4 (Patent Enforcement) but may not do so due to Applicable Law or regulation (even as the exclusive licensee of such infringed Patent Right), then that Party may join the other Party as a named party in such action or itself initiate such Infringement Action. The Party initiating the Infringement Action under Section 10.4.2 or 10.4.3 above will control the conduct of any such Infringement Action under this Section 10.4 (Patent Enforcement) and will keep the other Party reasonably informed of any such Infringement Action, and each Party will reasonably assist the other Party in any such Infringement Action under this Section 10.4 (Patent Enforcement). In no event may either Party settle any such Infringement Action in a manner that would limit the rights of the other Party or impose any obligation on the other Party, in each case, without the other Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed.

10.4.5 **Recoveries**. Any amount recovered in any Infringement Action under this Section 10.4 (Patent Enforcement), including any amount recovered in any settlement of such Infringement Action, will first be used to reimburse each Party's costs and expenses with respect to such Infringement Action (which reimbursement will be on a *pro rata* basis to the extent such costs and expenses exceed such recovered amount) and will thereafter be treated as Net Sales.

10.5 **Defense of Patent Rights; Defense Actions**. As between the Parties, Evelo will have the sole right, but not the obligation, to defend against a declaratory judgment action, *inter partes* review, opposition proceeding, post-grant review, interference, or other action

challenging any claims within the Licensed Patent Rights in the Territory. As between the Parties, Evelo will have the sole right, but not the obligation to initiate any declaratory judgment action, *inter partes* review, opposition proceeding, post-grant review, interference, or other action challenging any claims within any Patent Right Controlled by any Third Party. Neither Party will compromise or settle any such action in a manner that would limit the rights of the other Party under this Agreement, impose any obligation on the other Party, or admit any fault or liability on the part of the other Party or any of its Affiliates, in each case, without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned, or delayed.

10.6 **Infringement of Third Party Rights**.

10.6.1 **Notice**. If any Product used or sold by ALJ or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then the Party aware of such claim will promptly notify the other Party within five Business Days after receipt of such claim or assertion and will include in such notice a copy of any summons, complaint (or the equivalent thereof), or claim received regarding the foregoing. Thereafter, the Parties will promptly meet to discuss the claim or assertion and recommend an appropriate course of action and may, if appropriate, agree on and enter into a separate "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

11. CONFIDENTIALITY

11.1 **Confidential Information**. It is understood and agreed by the Parties that:

11.1.1 The terms and conditions of this Agreement will be considered Confidential Information of both Parties and kept confidential by each of the Parties in accordance with this Article 11 (Confidentiality).

11.1.2 Unpublished patent applications or Know-How solely owned by a Party are such Party's Confidential Information, and Patent Rights and Know-How jointly owned by the Parties will be deemed both Parties' Confidential Information, in each case, regardless of which Party is the Disclosing Party. All information exchanged between the Parties regarding the prosecution and maintenance, defense, and enforcement of the Licensed Patent Rights under Article 10 (Intellectual Property) will be the Confidential Information of the prosecuting Party. The Products and all Evelo Know-How will be the Confidential Information of Evelo. All data, results, and reports relating to any Product (a) generated by ALJ under this Agreement will be the Confidential Information of ALJ and (b) generated by Evelo under this Agreement will be the Confidential Information of Evelo.

11.2 **Non-Disclosure and Non-Use Obligation**. Except as otherwise expressly set forth herein, each Party (the "**Receiving Party**") will keep the Confidential Information of the other Party (the "**Disclosing Party**") confidential using at least the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a reasonable degree of care) and will not (a) disclose such Confidential Information to any Person without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its employees, Affiliates, Sublicensees, Subcontractors, consultants, or agents who have a need to know such Confidential Information, all of whom will be similarly bound by confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement and for whom the Receiving Party will be responsible, or (b) use such Confidential Information for any purpose other than for the purposes contemplated by this Agreement. The Receiving Party will use diligent efforts to cause the foregoing Persons to comply with the restrictions on use and disclosure set forth in this Section 11.2 (Non-Disclosure and Non-Use Obligation) and will be responsible for ensuring that such Persons maintain the Disclosing Party's Confidential Information in accordance with this Article 11 (Confidentiality). Each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information. The obligations of confidentiality and non-use set forth in this Section 11.2 (Non-Disclosure and Non-Use Obligation) will remain in place during the Term and for a period of [***] thereafter (or for so long as the applicable Confidential Information remains a trade secret, if longer).

11.3 **Exemptions**. Subject to, and except as provided in, Section 11.1 (Confidential Information), information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information: (a) is already in the possession of the Receiving Party at the time of its receipt from the Disclosing Party and not through a prior disclosure by or on behalf of the Disclosing Party, as evidenced by contemporaneous written records; (b) is generally available to the public before its receipt from the Disclosing Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or discloses in breach of this Agreement; (d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or (e) except with respect to information that is deemed the Confidential Information of the Disclosing Party hereunder, is developed independently by employees, Subcontractors, consultants, or agents of the Receiving Party or any of its Affiliates without use of or reliance upon the Disclosing Party's Confidential Information, as evidenced by contemporaneous written records. No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

11.4 **Permitted Disclosures**. In addition to the exceptions contained in Section 11.2 (Non-Disclosure and Non-Use Obligation) and Section 11.3 (Exemptions), the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:

11.4.1 in connection with any Regulatory Submissions or other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Products in the Territory;

11.4.2 disclosure of the existence and applicable terms of this Agreement and the status and results of the Exploitation of one or more Products to actual or *bona fide* potential investors, Acquirers, Sublicensees, Subcontractors, collaboration partners, lenders, or other financial or commercial partners, and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, sublicense, debt transaction, or collaboration; provided that, in each such case, such Persons must be bound by obligations of confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement or otherwise customary for such type and scope of disclosure and that any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

11.4.3 to comply with Applicable Law or the rules of a security exchange (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that, in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, the Receiving Party will notify the Disclosing Party of such required disclosure and provide a draft of the disclosure to Evelo reasonably in advance of such filing or disclosure for the Disclosing Party's review and comment. The Disclosing Party will provide any comments as soon as practicable, and the Receiving Party will consider in good faith any timely comments provided by the Disclosing Party. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 11.4.3 (Permitted Disclosures), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 11 (Confidentiality) with respect to the Party disclosing such Confidential Information, and such Party will take all steps necessary, including seeking of confidential treatment or a protective order for a period of at least [***] (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 11.4.3 (Permitted Disclosures);

11.4.4 to prosecute or defend litigation, so long as there is 30 days' prior written notice given by the Receiving Party before filing, and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement;

11.4.5 to present, disclose, and discuss general information about the existence of this Agreement and the general progress of the Products at investor press conferences or similar events; and

11.4.6 to allow the Receiving Party to exercise its rights and perform its obligations hereunder, provided that such disclosure is covered by terms of confidentiality and non-use at least as restrictive as those set forth herein.

11.5 **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 11.4 (Permitted Disclosures), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

11.6 **Publications**.

11.6.1 **Coordination**. Neither Party will make any public announcement relating to Exploitation of Products in the Territory without the other Party's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned), subject to Section 11.4 (Permitted Disclosures) and Section 11.6.3 (Publication Rights), as applicable. Parties will share the final copies of the public announcement prior to distribution so that Parties may remain informed of all public announcements being made relating to the Exploitation of Products in the Territory. Evelo will have the right to make academic, scientific, or medical publications or public presentations regarding the Products in accordance with Section 11.6.3 (Publication Rights). ALJ acknowledges and agrees that Evelo retains the right to make any public announcement or other disclosure relating to Exploitation of the Products outside the Territory in its sole discretion.

11.6.2 **Announcements**. Except as may be expressly permitted under Section 11.4 (Permitted Disclosures), neither Party will make any public announcement regarding this Agreement or any of the terms hereof without the prior written approval of the other Party. The Parties each intend to individually release the press release regarding the signing of this Agreement promptly after the Effective Date, with the content of such initial press release to be mutually agreed. After the issuance of such press release or other public disclosures by a Party, each

Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

11.6.3 **Publication Rights**.

(a) **ALJ Publications**. ALJ may make academic, scientific, or medical publications or public presentations regarding the Products or that otherwise contains Evelo's Confidential Information only with Evelo's prior review and written consent. ALJ will submit to Evelo for review and approval any proposed academic, scientific, medical, or other publication or public presentation, in each case, regarding the Products or that contains Evelo's Confidential Information. Evelo may approve or prohibit any such proposed publication in its sole discretion, and ALJ will incorporate any comments it receives from Evelo with respect to any such publication or presentation. ALJ will submit to Evelo written copies of such proposed publication or presentation no later than 30 days before submission for publication or presentation. The review period may be extended for an additional 30 days in the event Evelo can demonstrate reasonable need for such extension, including for the preparation and filing of patent applications by Evelo.

(b) **Evelo Publications**. During the Term, Evelo will not include any ALJ Confidential Information in any proposed academic, scientific, medical, or other publication or public presentation without ALJ's prior review and written consent.

(c) **Standards**. ALJ and Evelo will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication. The Parties may agree to an alternate review period for documents other than academic, scientific, or medical publications or presentations from time to time.

12. REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 **Mutual Representations and Warranties of the Parties**. Each Party represents and warrants to the other Party as of the Effective Date that:

12.1.1 It is duly organized, validly existing, and in good standing under the Applicable Law of the jurisdiction of its incorporation and has all requisite corporate power and authority to enter into this Agreement and to perform its obligations, in each case, under this Agreement.

12.1.2 The execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized by all requisite corporate action and does not require any action or approval of equity holders.

12.1.3 This Agreement has been duly executed and delivered on behalf of such Party, and is valid, legally binding, and enforceable against such Party in accordance with its terms.

12.1.4 The performance of this Agreement by such Party does not create a breach or default under any other agreement to which it is a Party.

12.1.5 The execution, delivery, and performance of this Agreement by such Party does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or regulation of any Governmental Authority.

12.1.6 It has obtained all necessary government authorizations, consents, approvals, licenses, exemptions of, or filings or registrations with Governmental Authorities, under any Applicable Law currently in effect, that are necessary for the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

12.2 **Additional Representations and Warranties of Evelo**. Evelo represents and warrants to ALJ as of the Effective Date that:

12.2.1 Schedule 1.86 (Licensed Patent Rights) lists all Patent Rights Controlled by Evelo that are necessary or reasonably useful to Commercialize or perform the ALJ Manufacturing Activities for the Products in the Territory.

12.2.2 None of the Patent Rights listed in Schedule 1.86 (Licensed Patent Rights) has been invalidated or held unenforceable and, to Evelo's Knowledge, there are no facts that will cause any such Patent Rights to be invalid or unenforceable.

12.2.3 Evelo has not granted rights to any Third Party under the Licensed Technology that conflict with the rights granted to ALJ under this Agreement.

12.2.4 There is no pending litigation, or litigation that has been threatened in writing, that alleges, or any written communication alleging, (and, to its Knowledge, there are no circumstances that make it likely) that Evelo's practice of the Licensed Technology or the Development, Manufacturing, or Commercialization of the Products has infringed, misappropriated, or otherwise violated, or would infringe, misappropriate, or otherwise violate, any of the Intellectual Property of any Third Party.

12.2.5 To its Knowledge, the Development activities conducted by or on behalf of ALJ prior to the Effective Date in relation to EDP1815 have not infringed, misappropriated or otherwise violated any of the Intellectual Property of any Third Party

12.2.6 To its Knowledge, the Development, Manufacturing, or Commercialization of EDP1815 in the Territory in the manner envisaged by this Agreement will not infringe, misappropriate or otherwise violate, or would infringe, misappropriate, or otherwise violate, any of the Intellectual Property of any Third Party.

12.2.7 To its Knowledge, no Third Party is infringing, misappropriating, or otherwise violating, or threatening to infringe, misappropriate, or otherwise violate the Licensed Technology in the Field in the Territory.

12.2.8 To its Knowledge, all Development activity conducted by or on behalf of ALJ prior to the Effective Date in relation to EDP1815 have been conducted in compliance with Applicable Laws.

12.2.9 Evelo has the rights to grant the licenses in Sections 2.1, 6.14.3(a) and 6.14.3(b) of this Agreement.

12.2.10 To its Knowledge, there are no facts or circumstances that are reasonably likely to result in the need to cease all Development of EDP1815.

12.2.11 Evelo has not intentionally withheld from ALJ any information in its possession and Control regarding the Product that is material to the Exploitation activities with respect to the Product in the Territory contemplated by this Agreement.

12.3 **Certain Covenants**. Each Party covenants to the other Party that:

12.3.2 It will, and will ensure that its Affiliates, comply with all Applicable Laws and, to the extent applicable, Professional Requirements, with respect to the performance of its obligations under this Agreement, including, as applicable, the Approved Labeling.

12.3.2 In performing its obligations under this Agreement, it will and will cause its Affiliates, Sublicensees, and Subcontractors to comply with all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended from time-to-time; the anti-corruption laws in the Territory; and all laws enacted to implement the Organization for Economic Co-operation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

12.3.3 With respect to any Products, payments, or services provided under this Agreement, it will not and will cause its Affiliates, Sublicensees, and Subcontractors to not, take any action to directly or indirectly to offer, promise or

pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and will not accept such payment.

12.3.4 It will, and will cause its Affiliates, Sublicensees, and Subcontractors to, be in compliance with all applicable Global Trade Control Laws.

12.3.5 If a Party or any of its Affiliates, Sublicensees, or Subcontractors becomes a Restricted Person during the Term, then it will (a) promptly inform the other Party; (b) suspend all activities under this Agreement; and (c) take reasonable steps to obtain a license or other authorization to continue activities under this Agreement.

12.3.6 It will and will cause its Affiliates, Sublicensees, and Subcontractors to conduct Restricted Person Screening of the names and addresses of all individuals, agents, employees, contractors, or any other relevant party, directly or indirectly invited by it or its Affiliates to participate in any activities related to its interaction with the other Party, including those contemplated under this Agreement.

12.4 **Use and Handling of Products**. ALJ will treat all Product with care and take specific precautions to prevent any leakage to or contamination of the Products. ALJ will and will cause its Affiliates, Sublicensees, and Subcontractors to (a) handle, transport, and store all Products expressly in accordance with any reasonable instructions from Evelo, (b) disseminate the Products only for use as a pharmaceutical product and solely in accordance with the terms of this Agreement and for no other use, and (c) not modify, engineer, re-engineer, or otherwise attempt to derive the composition or underlying information, structure, ideas, or trade secrets embodied in any Products. In addition, ALJ acknowledges and stipulates that the Products themselves constitute valuable, proprietary property of Evelo that (a) if misappropriated or (b) was subject to conversion, in each case, by an unauthorized third party and propagated, would result in irreparable harm to Evelo, and ALJ will not, and will not permit any of its Affiliates, Sublicensees, or Subcontractors to, access, use, or otherwise Exploit such Products, other than as expressly licensed in this Agreement. Upon Evelo's request, ALJ will provide Evelo with a reasonably detailed written summary of all safeguards employed by ALJ or its Affiliates, Sublicensees, and Subcontractors and demonstrate how it has implemented such safeguards so as to avoid disclosure or dissemination of Products (or any Licensed Know-How related thereto) to individuals that do not have a need to access the Products for the purposes of performing ALJ's obligations or exercising ALJ's rights under this Agreement.

12.5 **Compliance with Law**. Each Party will not and will cause its Affiliates (and, in the case of ALJ, its Sublicensees and Subcontractors) to not, directly or indirectly, engage in any transactions or dealings in or with any Restricted Countries or Restricted Person in connection with any activities relating to with the Products or the other Party, including those contemplated under this Agreement, to the extent such transactions or dealings would cause the other Party or its Affiliates (and, in the case of ALJ, its Sublicensees and

Subcontractors) to violate applicable Global Trade Control Laws or any other laws applicable to the other Party or its Affiliates (and, in the case of ALJ, its Sublicensees and Subcontractors).

12.6 **DISCLAIMER OF WARRANTIES**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

12.7 **LIMITATION OF LIABILITY**. EXCEPT FOR DAMAGES RESULTING FROM WILLFUL MISCONDUCT, INTENTIONAL WRONGFUL ACT, GROSS NEGLIGENCE, BREACHES OF SECTION 2.4.2 (EXCLUSIVITY AND RESTRICTIONS), ARTICLE 11 (CONFIDENTIALITY) OR AMOUNTS PAYABLE TO A THIRD PARTY UNDER INDEMNIFIABLE CLAIMS UNDER ARTICLE 13 (INDEMNIFICATION; INSURANCE), IN NO EVENT WILL EITHER PARTY HAVE ANY CLAIMS AGAINST OR LIABILITY TO THE OTHER PARTY WITH RESPECT TO ANY INDIRECT, PUNITIVE, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR (WHETHER DIRECT OR INDIRECT) ANY CLAIMS FOR LOST PROFITS OR REVENUES ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT UNDER ANY THEORY OF LIABILITY, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. INDEMNIFICATION; INSURANCE

13.1 **Indemnification by Evelo**. Evelo will indemnify, defend, and hold harmless ALJ and its Affiliates, and each of its and their respective employees, officers, directors, and agents (each, an "**ALJ Indemnified Party**") from and against any and all liabilities, losses, damages, fees (including royalties and license fees), expenses (including reasonable attorneys' fees and expenses), and costs (collectively, "**Liabilities**") that any ALJ Indemnified Party may be required to pay to one or more Third Parties arising from or relating to:

13.1.1 [***];

13.1.2 [***]; or

13.1.3 [***].

13.2 **Indemnification by ALJ**. ALJ will indemnify, defend, and hold harmless Evelo, its Affiliates, and each of its and its Affiliates' employees, officers, directors, and agents (each, an "**Evelo Indemnified Party**") from and against any and all Liabilities that any Evelo Indemnified Party may be required to pay to one or more Third Parties arising from or relating to:

13.2.1 [***];

13.2.2 [***]; and

13.2.3 [***].

13.3 **Certain Indemnified Losses**. Any Liabilities and all Out-of-Pocket Expenses incurred by a Party to conduct its indemnification obligations under Section 13.1 (Indemnification by Evelo) or Section 13.2 (Indemnification by ALJ), (other than those Liabilities and Out-of-Pocket Expenses that result from (a) the unlawful conduct, negligence, reckless conduct, or willful misconduct of a Party or its Affiliates or its or their respective directors, officers, employees, or agents, or (b) breach of Applicable Law, this Agreement or any other Transaction Document by a Party), in connection with any Third Party claim brought against either Party resulting directly or indirectly from (i) the performance of any Development activities by either Party (or its Affiliates, employees, or agents) in accordance with the Development Plan (including Manufacturing in support of such Development activities) or Regulatory Plan (as applicable) will be included as an Eligible Development Expense, (ii) the performance of any Medical Affairs activities by either Party (or its Affiliates, employees, or agents) in accordance with the Medical Affairs Plan will be included as an Eligible Medical Affairs Expense, or (iii) the performance of any Commercialization activities by either Party (or its Affiliates, employees, or agents) in accordance with the Commercialization Plan (including Manufacturing in support of such activities) will be included as an Eligible Commercialization Expense. If either Party learns of any Third Party claim with respect to Liabilities covered by this Section 13.3 (Certain Indemnified Losses), then such Party shall provide the other Party with prompt written notice thereof. The Parties will confer with respect to how to respond to such Third Party claim and how to handle such Third Party claim in an efficient manner.

13.4 **Procedure**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) will be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 13 (Indemnification; Insurance), such Party (the "**Indemnified Party**") will promptly notify the other Party (the "**Indemnifying Party**") in writing and the Indemnifying Party and Indemnified Party will, without limiting the applicable Party's indemnification obligations under Section 13.1 (Indemnification by Evelo) or Section 13.2 (Indemnification by ALJ), meet to discuss how to respond to any claims that are the subject matter of such proceeding. The Indemnified Party will cooperate fully with the Indemnifying Party in defense of such matter. In any such proceeding, the Indemnified Party will have the right to retain its own counsel, but the fees and expenses of such counsel will be at the expense of the Indemnified Party unless (a) the Indemnifying Party and the Indemnified Party will have agreed to the retention of such counsel or (b) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between

them. All such fees and expenses will be reimbursed as they are incurred. The Indemnifying Party will not be liable for any settlement of any proceeding effected without its written consent, but, if settled with such consent or if there is a final judgment for the plaintiff, then the Indemnifying Party agrees to indemnify the Indemnified Party from and against any Liability by reason of such settlement or judgment. The Indemnifying Party will not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding and does not include any admission of liability by the Indemnified Party.

13.5 **Insurance**. Each Party will maintain insurance with respect to its activities hereunder. Such insurance will be in such amounts and subject to such deductibles as are customary based upon standards prevailing in the industry at the time. Notwithstanding the foregoing, beginning at such time as any Product is being sold by ALJ or any of its Affiliates, (a) ALJ will, at its sole cost and expense, procure and maintain commercial general liability insurance and products liability coverage in amounts not less than [***] per incident and [***] annual aggregate, and (b) Evelo will, at its sole cost and expense, procure and maintain commercial general liability insurance and products liability coverage in amounts not less than [***] per incident and [***] annual aggregate. Insurance shall be procured with carriers having an A.M. Best Rating of A-VII or better. If requested in writing by either Party, the minimum insurance coverage referenced in this Section 13.5 (Insurance) shall be referred to the next meeting of the PCC for review and the PCC shall determine whether any amendments need to be made thereto.

14. TERM AND TERMINATION

14.1 **Term**. This Agreement will be effective as of the Effective Date and will continue in full force and effect until terminated pursuant to this Article 14 (Term and Termination) (such period, the "**Term**").

14.2 **Termination Events**

14.2.1 **Termination for Cause**.

(a) **By ALJ**. In the event of a material breach of this Agreement by Evelo or its Affiliates, which material breach remains uncured for 90 days measured from the date of written notice of such material breach by ALJ that identifies the material breach, ALJ may terminate this Agreement in whole or with respect to one or more Products or one or more countries in the Territory to which such material breach relates, by written notice of termination to Evelo.

(b) **By Evelo**. In the event of a material breach of this Agreement by ALJ or its Affiliates or Sublicensees, which material breach remains uncured for

90 days measured from the date of written notice of such material breach by Evelo that identifies the material breach, Evelo may terminate this Agreement in whole or with respect to one or more Products or one or more countries in the Territory to which such material breach relates, by written notice of termination to ALJ.

(c) **Disputes Regarding Material Breach**. In case the Party (the "**Defaulting Party**") alleged by the other Party (the "**Non-Defaulting Party**") to have committed a material breach under Section 14.2.1(a) (By ALJ) or Section 14.2.1(b) (By Evelo) disputes, acting reasonably and in good faith, the occurrence of such a material breach, then the issue of whether or not the Defaulting Party materially breached this Agreement such that, if not cured, the Non-Defaulting Party may properly terminate this Agreement on expiration of the applicable cure period will be resolved in accordance with Section 16.3 (Dispute Resolution). If, as a result of such dispute resolution process, it is determined that the Defaulting Party committed a material breach of this Agreement and the Defaulting Party does not cure such material breach within 90 days after the date of such determination, (the "**Additional Cure Period**"), then such termination will be effective as of the expiration of the Additional Cure Period. If the Parties dispute whether such material breach was so cured, then such dispute will also be resolved in accordance with Section 16.3 (Dispute Resolution). This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the cure periods set forth in Section 14.2.1(a) (By ALJ) or 14.2.1(b) (By Evelo), as applicable, and any Additional Cure Period, in each case, will be tolled during any such dispute resolution proceeding, such proceeding will not suspend any obligations of either Party hereunder, and each Party will use reasonable efforts to mitigate any damage. If, as a result of such dispute resolution proceeding it is determined that the Defaulting Party did not commit such material breach (or such material breach was cured in accordance with this Section 14.2.1 (Termination for Cause)), then no termination will be effective, and this Agreement will continue in full force and effect.

14.2.2 **Termination for Convenience**. ALJ may terminate this Agreement (a) in respect of one or more Products, or (b) in its entirety, in each case, at its sole discretion at any time upon [***] prior written notice to Evelo thereof.

14.2.3 **Termination upon Replacement Event**. If a Replacement Event occurs, ALJ may terminate this Agreement (a) prior to designation of a Second Product, in its entirety at its sole discretion upon written notice to Evelo, and (b) following designation of a Second Product, solely with respect to EDP1815 at its sole discretion upon written notice to Evelo.

14.2.4 **Termination for Cessation of Commercialization in the Major Market**. If:

(a) for a continuous period of at least [***] (the "**Suspension Period**"), ALJ has not (either itself or through its Affiliates or Sublicensees) conducted any material regulatory or Commercialization activities with respect to a Product in the Major Market;

(b) such suspension of activity (i) is not contemplated in the Commercialization Plan or Regulatory Plan or otherwise by written agreement of the Parties, (ii) is not a result of ALJ's reasonable response to guidance from or action by a Regulatory Authority in such countries in the Territory (such as a clinical hold, or a recall or withdrawal), or (iii) would not have occurred but for Evelo's failure to perform any of its obligations under this Agreement or the Supply Agreement; and

(c) ALJ does not remedy such suspension of activity within [***] after the date of written notice of termination from Evelo (the "**Suspension Cure Period**"),

then Evelo may, at its election, terminate this Agreement with respect to that Product to which such cessation of Commercialization relates upon expiry of the applicable Suspension Cure Period and any such Product will be a Terminated Product for purposes of this Agreement. For the avoidance of doubt, Evelo's right to terminate this Agreement with respect to a Product under this Section 14.2.4 shall not apply if ALJ or any of its Affiliates or Sublicensees have conducted any material regulatory or Commercialization activities with respect to that Product in one or more of the Major Market Countries at any time during the Suspension Period or the Suspension Cure Period.

14.2.5 **Termination for Regulatory Failure.** If, with respect to any Product, Regulatory Authorities in five Major Market Countries provide written notice that they will not grant any Regulatory Approval required for Commercialization in such Major Market Countries, ALJ may terminate this Agreement with respect to that Product upon written notice to Evelo.

14.2.6 **Termination for Insolvency.** In the event that either Party:

(a) is liable to be wound up by a court of competent jurisdiction;

(b) enters into a compromise or arrangement with its creditors or moratorium is declared in respect of any of its indebtedness or any creditor action;

(c) takes any action to appoint, to request the appointment of, or suffers the appointment of, a receiver, administrative receiver, administrator, trustee or similar officer over all or a material part of its assets or undertaking;

(d) takes any action to appoint a monitor or obtain a moratorium;

(e) has a winding-up or administration petition presented in relation to it or has documents filed with a court for an administration in relation to it; or

(f) is affected in any way in any jurisdiction by anything equivalent to any of the things referred to in subsections (a) to (e) above,

the other Party may terminate this Agreement upon written notice to the defaulting Party.

14.2.7 **Cross Termination**. If this Agreement is terminated by either Party for any reason, then the Supply Agreement will be automatically terminated with respect to the applicable Terminated Products and Terminated Countries.

15. EFFECTS OF TERMINATION

15.1 **Objectives.** When performing its obligations under this Article 15 (Effects of Termination), each Party shall use all reasonable efforts to (i) minimize disruption to the Exploitation of the Products in the Territory and (ii) maintain continuity of supply to patients in the Territory.

15.2 **Licenses**.

15.2.1 Upon termination of this Agreement for any reason (whether in whole or in part), then:

(a) as of the effective date of termination of this Agreement, all licenses and all other rights granted by Evelo to ALJ under the Licensed Technology for any Terminated Product in any Terminated Country will terminate and all sublicenses granted by ALJ pursuant to Section 2.2 (Sublicensing and Subcontracting by ALJ) will also terminate with respect to the Terminated Products in the Terminated Countries;

(b) upon the termination of this Agreement Evelo will have, and ALJ hereby grants to Evelo, effective upon such termination, a worldwide, exclusive, fully-paid, royalty-free, perpetual, irrevocable, and sublicensable (through multiple tiers) license under ALJ's rights in any Know-How (and any Intellectual Property therein) or Patent Rights that (i) are owned (either solely or jointly) and Controlled by ALJ and (ii) are necessary to Exploit the Terminated Products, for the sole purpose of Exploiting any Terminated Products in Terminated Countries; and

(c) ALJ will assign to Evelo any Third Party agreement entered into during the Term by ALJ pursuant to which ALJ then Controls any Know-How or Patent Rights from a Third Party relating exclusively to Terminated Products in Terminated Countries and that are necessary or reasonably

useful to Exploit the Terminated Products in the Terminated Countries (such rights, "**ALJ Exclusive Identified Rights**", and each such agreement, a "**Third Party Exclusive IP Agreement**"), if permitted under such Third Party Exclusive IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party Exclusive IP Agreement cannot be assigned to Evelo, then upon Evelo's reasonable request, ALJ will maintain such Third Party Exclusive IP Agreement and Evelo will pay to ALJ 100% of all payments due to the applicable Third Party under any such Third Party Exclusive IP Agreement in consideration of the sublicense to Evelo and Evelo's Exploitation of such ALJ Exclusive Identified Rights with respect to Terminated Products in the Terminated Countries. If ALJ is unable to sublicense any ALJ Exclusive Identified Rights to Evelo pursuant to this Section 15.1 (Effect of Termination; Licenses) without the consent of the Third Party, then ALJ undertakes, on request from Evelo, to use reasonable efforts to procure such licenses with respect to the applicable Terminated Products in the applicable Terminated Countries on behalf of Evelo to the extent that it is able to do so, and Evelo will pay such fees and agree to be bound by the terms agreed between ALJ and the Third Party licensor; and

(d) where this Agreement is not terminated in its entirety, if ALJ Controls any Know-How or Patent Rights from a Third Party that (i) relate to Terminated Products in Terminated Countries but do not relate exclusively to Terminated Products in Terminated Countries and (ii) are necessary or reasonably useful to Exploit the Terminated Products in the Terminated Countries (such rights, "**ALJ Non-Exclusive Identified Rights**", and each such agreement, a "**Third Party Non-Exclusive IP Agreement**"), ALJ will maintain such Third Party Non-Exclusive IP Agreement and Evelo will pay to ALJ 100% of all payments due to the applicable Third Party under any such Third Party Non-Exclusive IP Agreement (solely to the extent such payments relate to Exploitation of the Terminated Products in the Terminated Countries) in consideration of the sublicense to Evelo and Evelo's Exploitation of such ALJ Non-Exclusive Identified Rights with respect to Terminated Products in the Terminated Countries. If ALJ is unable to sublicense any ALJ Non-Exclusive Identified Rights to Evelo pursuant to this Section 15.1 (Effect of Termination; Licenses) without the consent of the Third Party, then ALJ undertakes, on request from Evelo, to use reasonable efforts to procure such licenses with respect to the applicable Terminated Products in the applicable Terminated Countries on behalf of Evelo to the extent that it is able to do so, and Evelo will pay such fees and agree to be bound by the terms agreed between ALJ and the Third Party licensor.

15.3 **Regulatory Submissions and Regulatory Approvals**. To the extent requested by Evelo following the date that a Party provides notice of termination of this Agreement, ALJ will and hereby does, and will cause its Affiliates and Sublicensees to, (a) no later than [***] after the effective date of termination of this Agreement with respect to any Terminated Product in any Terminated Country, assign and transfer to Evelo or its designee, all of ALJ's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals for such Terminated Product in such Terminated Countries then owned or Controlled by ALJ or any of its Affiliates, Sublicensees, or Subcontractors, if any, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Evelo to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by ALJ or its Affiliates, Sublicensees, or Subcontractors with respect to such Terminated Product. ALJ will take, or will cause its Affiliates, Sublicensees, and Subcontractors to take, all steps necessary to transfer ownership of all such assigned Regulatory Submissions and Regulatory Approvals to Evelo, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Evelo) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and Regulatory Approval. In addition, upon Evelo's written request, ALJ will provide to Evelo copies of all material related documentation relating to any Terminated Product in any Terminated Country, including material non-clinical, preclinical, and clinical data that are held by or reasonably available to ALJ or its Affiliates, Sublicensees, or Subcontractors. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, if applicable.

15.4 **Assignment and Disclosure**. To the extent requested by Evelo following the date that a Party provides notice of termination of this Agreement, ALJ will promptly upon request (and in any event within [***] after the effective date of termination):

15.4.1 assign and transfer to Evelo or its designee all of ALJ's or its Affiliates', Sublicensees', or Subcontractors' rights, title, and interests in and to all clinical trial agreements, manufacturing and supply agreements, and distribution agreements (to the extent assignable and not cancelled), confidentiality and other agreements, data and other Know-How (including commercial information) in ALJ's or its Affiliates', Sublicensees', or Subcontractors' Control, in each case, relating exclusively to Terminated Products in Terminated Countries and that are necessary or useful for the Exploitation of such Terminated Products in such Terminated Countries;

15.4.2 to the extent ALJ or any of its Affiliates is a party to any clinical trial agreement, manufacturing and supply agreement or distribution agreement which either (i) relates exclusively to Terminated Products in Terminated Countries but which is not assignable or (ii) relates to Terminated Products in any Terminated Countries but does not relate exclusively to Terminated Products in Terminated Countries and, in either case, is necessary or useful for the Exploitation of such Terminated Products in such Terminated Countries, ALJ shall use reasonable efforts to

introduce Evelo to the relevant Third Party counterparty to such agreement and shall, upon Evelo's request and at Evelo's expense, provide Evelo with reasonable assistance with respect to Evelo's negotiation of a replacement agreement with such Third Party;

15.4.3 disclose to Evelo or its designee all documents, records, and materials relating to any Terminated Product in any Terminated Country in the possession or Control of ALJ or its Affiliates, Sublicensees, or Subcontractors, and that embody the foregoing; and

15.4.4 assign and transfer to Evelo or its designee all of ALJ's or its Affiliates', Sublicensees', or Subcontractors' rights, title, and interests in and to any Promotional Materials, Training Materials, Medical Education Materials, packaging and labeling, and all other literature or other information relating exclusively to any Terminated Product in any Terminated Country and copyrights and any registrations for the foregoing.

To the extent that any asset described in Section 15.4.3 or 15.4.4 is not assignable by ALJ or its Affiliates, Sublicensees, or Subcontractors or do not relate exclusively to Terminated Products in Terminated Countries, then such asset will not be assigned, and upon the request of Evelo, ALJ will take, or cause its or its Affiliates, Sublicensees, or Subcontractors to take, such steps as may be necessary to allow Evelo to obtain and to enjoy the benefits of such asset, without additional payment therefor. For clarity, Evelo will have the right to require that ALJ take, or cause its or its Affiliates, Sublicensees, or Subcontractors to take, any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in Section 15.4.3 and Section 15.4.4.

15.5 **Transfer Support**.

15.5.1 **Regulatory Transfer Support**. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 15.3 (Regulatory Submissions and Regulatory Approvals) and Section 15.4 (Assignment and Disclosure), ALJ will appoint, or cause its Affiliate, Sublicensee, or Subcontractor (as applicable) to appoint, Evelo as ALJ's or its Affiliate's representative for all matters to the extent relating to Terminated Products in Terminated Countries involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Evelo's or its Affiliate's name have been assigned to Evelo or its designee. In the event of failure to obtain such assignment, ALJ hereby consents and grants, and will cause its or its Affiliates, Sublicensees, or Subcontractors to consent and grant, to Evelo the right to access and reference (without any further action required on the part of ALJ or any such Affiliate, Sublicensee, or Subcontractor, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the applicable Terminated Products in the Terminated Countries.

15.5.2 **Know-How Transfer Support**. Where applicable, in furtherance of the assignment of Know-How pursuant to Section 15.4 (Assignment and Disclosure), ALJ will, and will cause its or its Affiliates, Sublicensees, or Subcontractors to, for a period of [***] from the effective date of termination of this Agreement with respect to a Terminated Product in a Terminated Country, provide such consultation or other assistance as Evelo may reasonably request to assist Evelo in becoming familiar with such Know-How in order for Evelo to undertake further Exploitation of such Terminated Product, without charge.

15.6 **Inventory**. At Evelo's election and request, ALJ will, or cause its or its Affiliates, Sublicensees, or Subcontractors to, transfer to Evelo or one or more designees some or all inventory of each Terminated Product (including all final product, bulk drug substance, intermediates, works-in-process, packaged retention samples, and the like) then in the possession or Control of ALJ, or its Affiliates, Sublicensees, or Subcontractors to the extent such inventory has been allocated by ALJ or its Affiliates for sale in Terminated Countries; provided that Evelo will pay ALJ a price equal to the price paid by ALJ to Evelo for such transferred Terminated Product (if Manufactured by Evelo) and at cost (if Manufactured by ALJ). Where this Agreement is terminated throughout the Territory with respect to a Terminated Product, ALJ will, and will cause its Affiliates, Sublicensees, and Subcontractors to, destroy pursuant to Evelo's instructions, all inventory of that Terminated Product (including all final product, bulk drug substance, intermediates, works-in-process, packaged retention samples, and the like) then in the possession or Control of ALJ, or its Affiliates, Sublicensees, or Subcontractors, to the extent Evelo does not request to transfer thereof to Evelo or one or more designees.

15.7 **Wind Down and Transition**. ALJ will be responsible for the wind-down of ALJ's and its Affiliates', Sublicensees', and Subcontractors' Exploitation of each Terminated Product in each Terminated Country. ALJ will, and will cause its Affiliates, Sublicensees, and Subcontractors to, reasonably cooperate with Evelo to facilitate orderly transition of the Exploitation of each Terminated Product in each Terminated Country to Evelo or its designee, including performing, or procuring the performance by its Affiliates or Subcontractors of, any activities relating to the Exploitation of Terminated Products in Terminated Countries, reasonably cooperating with Evelo to transfer such activities to Evelo or its designee and continuing to perform such activities on Evelo's behalf for a reasonable time after termination of this Agreement with respect to such Terminated Product until such transfer is completed.

15.8 **Costs**. Save to the extent expressly stated otherwise in this Article 15:

15.8.2 where this Agreement is terminated (in whole or in part) by ALJ pursuant to Section 14.2.1(a) (Termination for Cause; By ALJ) or 14.2.6 (Termination for Insolvency), Evelo shall reimburse ALJ for all costs and expenses reasonably incurred by ALJ in performing its obligations pursuant to Sections 15.3 to 15.7;

15.8.2 where this Agreement is terminated (in whole or in part) by ALJ pursuant to Section 14.2.3 (Termination upon Replacement Event) or 14.2.5 (Termination for

Regulatory Failure), Evelo shall reimburse ALJ for 50% of all costs and expenses reasonably incurred by ALJ in performing its obligations under Section 15.3 (Regulatory Submissions and Regulatory Approvals) through Section 15.7 (Wind Down and Transition); and

15.8.3 where this Agreement is terminated (in whole or in part) for any other reason not referenced in Section 15.8.1 or Section 15.8.2, ALJ shall bear its own costs and expenses incurred in performing its obligations pursuant to Sections 15.3 to 15.7.

15.9 **Return of Confidential Information**. Upon the termination of this Agreement, the Receiving Party will return to the Disclosing Party (or, as directed by the Disclosing Party, destroy) all Confidential Information of the Disclosing Party that is in the Receiving Party's possession or Control (other than any Confidential Information required to continue to exercise a Party's rights that survive termination of this Agreement), provided, however, (i) where this Agreement is only terminated with respect to certain Terminated Products in certain Terminated Countries, such obligation shall only apply to Confidential Information relating exclusively to such Terminated Products in such Terminated Countries and (ii) in all cases, the Receiving Party may retain and store copies thereof solely for the purpose of performing its obligations under this Agreement, subject to the non-disclosure and non-use obligation under Article 11 (Confidentiality). In addition, the Receiving Party will not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business; provided that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or as required by Applicable Law.

15.10 **Rights Accruing Prior to Termination**. Termination of this Agreement will not relieve the Parties of any obligation accruing prior to such termination. Any termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination, including any payment obligation that accrued prior to the effective date of such termination.

15. **Survival**. The following provisions, as well as any other provisions which by their nature are intended to survive termination, will survive termination of this Agreement: Articles 1 (Definitions), 9 (Payments), solely to the extent of any payment obligations accruing prior to the effective date of termination or expiration, 10.1 (Ownership and Licensing of Intellectual Property), 11 (Confidentiality), 13 (Indemnification; Insurance), 14 (Term and Termination), 15 (Effects of Termination) and 16 (Miscellaneous).

16. MISCELLANEOUS

16.1 **Assignment**. Neither this Agreement nor any interest hereunder will be assignable by either Party without the prior written consent of the other Party, except as follows: (a) each Party may, subject to the terms of this Agreement, assign its rights and obligations under this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger,

acquisition, or similar transaction or series of related transactions, provided that such sale is not to an Affiliate or primarily for the benefit of its creditors; and (b) each Party may assign its rights and obligations under this Agreement to any of its Affiliates with the other Party's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned); provided, that if any withholding taxes are imposed with respect to any payment contemplated under this Agreement as a result of an assignment or other transfer by a Party of its rights or obligations hereunder to another entity, or as a result of a subsequent transfer following such assignment or transfer (such Party, the "**Transferee Party**"), and such withholding taxes would not have been imposed with respect to such payment under then-applicable tax laws if such Party had not assigned or transferred its rights or obligations hereunder (or had such subsequent transfer not occurred) (such incremental withholding taxes, "**Incremental Taxes**"), then the amount payable under this Agreement by the Transferee Party shall be increased to take into account such Incremental Taxes so that the recipient of such payment receives an amount equal to the sum it would have received had no such Incremental Taxes been withheld. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 16.1 (Assignment) will be null, void, and of no legal effect.

16.2 **Governing Law**. This Agreement, and all claims arising under or in connection therewith, will be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof.

16.3 **Dispute Resolution**. Any dispute arising out of or in connection with this Agreement (except for disputes arising at the PCC, which will be resolved pursuant to Section 3.3 (Decision-Making) and Section 3.4 (Resolution of Disputes)) will be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within 30 days after first considering such dispute, then such dispute will be referred to the Chief Executive Officer of each Party. Such officers will meet to attempt to resolve such dispute. Such resolution, if any, of a referred issue will be final and binding on the Parties. All negotiations pursuant to this Section 16.3 (Dispute Resolution) are confidential and will be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such officers cannot resolve such dispute within 30 days after either Party requests such a meeting in writing, then either Party will have the right to pursue any and all remedies available at law or equity, consistent with Section 16.4 (Jurisdiction; Venue). Nothing in this Section 16.3 (Dispute Resolution) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, concerning a dispute either prior to or during any dispute resolution proceeding if necessary to protect the interests of such Party or to preserve the status quo pending the resolution of such proceeding.

16.4 **Jurisdiction; Venue**. Each Party irrevocably submits to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, New York County, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action, or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit, or proceeding either in the United States District Court for the Southern District of New York or if such suit, action, or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit, or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) the Supreme Court of the State of New York, New York County or (ii) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum. Each Party irrevocable consents to service of process in the manner provided under Section 16.5 (Notices) or by first class certified mail, return receipt requested, postage prepaid. THE PARTIES EXPRESSLY, IRREVOCABLY, AND UNCONDITIONALLY WAIVE AND FOREGO ANY RIGHT TO TRIAL BY JURY.

16.5 **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Evelo:
Evelo Biosciences, Inc.
620 Memorial Drive, 5th Floor
Cambridge, MA 02139
United States of America
Attention: Chief Executive Officer
Email: [***]

With a copy to:
Evelo Biosciences, Inc.
620 Memorial Drive, 5th Floor
Cambridge, MA 02139
United States of America
Attention: General Counsel
Email: [***]

If to ALJ:

Meddist Company Limited

37 Esplanade, 5F St Helier, Jersey, JE1 2TR
Attention: Director
Email: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the second Business Day after dispatch if sent by an internationally recognized overnight courier; or (b) on the fifth Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

16.6 **Relationship of the Parties**. Each Party is an independent contractor under this Agreement. Subject to Section 9.6.2 (No Partnership), nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other.

16.7 **No Third Party Rights or Obligations**. Subject to the express terms of this Agreement (including the rights and remedies conferred on each ALJ Indemnified Party and each Evelo Indemnified Party under Article 13 (Indemnification; Insurance)), no provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement.

16.8 **Performance by Affiliates**. Each Party recognizes that the other Party may perform some or all of its obligations or exercise some or all of its rights, in each case, under this Agreement through Affiliates to the extent permitted under this Agreement; provided, however, that such other Party will remain responsible for the performance by its Affiliates as if such rights or obligations were performed by such other Party.

16.9 **Further Assurances**. Each of Evelo and ALJ agrees to duly execute and deliver, or cause to be duly executed or delivered, such further instruments and do and cause to be done such further acts, including the filing of additional assignments, agreements, documents, and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

16.10 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in achieving any objective, satisfying any condition, or performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts or events beyond the reasonable control of such Party, including acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, the spread of infectious diseases, and quarantines ("**Force Majeure**"). The Parties agree the effects of the COVID-19 pandemic that is ongoing as

of the Effective Date (including related government orders) may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other Force Majeure event. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under this Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such written notice to the other Party on a weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume, and if such Force Majeure circumstance continues for a period of 90 days, then the unaffected Party will have the right to terminate this Agreement and the effects of termination set forth in Article 15 (Effects of Termination) will apply.

16.11 **Waiver**. The failure of either Party to require performance by the other Party of any of that other Party's obligations under this Agreement will in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party of any condition, or of the breach of any provision, term, representation or warranty contained in this Agreement will be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation, or warranty hereof. No remedy provided in this Agreement is exclusive and the Party suffering from a breach or default of this Agreement may pursue all other remedies under this Agreement or otherwise, both legal and equitable, alternatively, or cumulatively.

16.12 **Severability**. If any provision or portion thereof in this Agreement is for any reason held to be invalid, illegal, or unenforceable, then the same will not affect any other portion of this Agreement and its validity, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity, and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such provision or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefore such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law unless doing so would have the effect of materially altering the right and obligations of the Parties in which event this Agreement may be terminated by written agreement of the Parties.

16.13 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person's or entity's successors and assigns, (f) the words "herein," "hereof," and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to sections or schedules of or to this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding email and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) references to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.2" would be part of "Section 2," and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)").

16.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

16.16 **Entire Agreement; Amendments**. This Agreement and the Supply Agreement set forth the entire agreement between the Parties and supersedes all previous and contemporaneous negotiations, representations, or agreements, written or oral, regarding the subject matter hereof, including the Confidentiality Agreement, which is hereby terminated. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof and the licenses granted hereunder are superseded by the terms of this Agreement. This Agreement may be amended only by an instrument in writing duly executed on behalf of the Parties. In case of inconsistencies between this Agreement and any Schedule hereof, the terms of this Agreement will prevail unless agreed to explicitly that the Schedule

should prevail. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliates' obligations pursuant to the Confidentiality Agreement.

16.16 **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date.

EVELO BIOSCIENCES, INC.

By: /s/ Balkrishan "Simba" Gill
(Signature)

Name: Balkrishan "Simba" Gill, Ph.D.
Title: President and Chief Executive Officer

MEDDIST COMPANY LIMITED

By: /s/ Sidhesh Kaul
(Signature)

Name: Sidhesh Kaul
Title: Director

SCHEDULE 1.86

Licensed patent rights

PCT Applications Relating to EDP1815*

Title	Country/ Region	App Serial #	Filing Date
[***]	[***]	[***]	[***]

*** National applications to be filed in countries in the Territory as determined by the PCC.**

SCHEDULE 1.145

TERRITORY

Africa	**Middle-East - Turkey**
Algeria	Bahrain
Angola	Cyprus
Benin	Jordan
Botswana	Kuwait
Burkina Faso	Iraq
Burundi	Israel
Cabo Verde	Lebanon
Cameroon	Oman
Central African Republic	Palestine
Chad	Qatar
Comoros	Saudi Arabia
Congo, Democratic Republic of the	Turkey
Congo, Republic of the	United Arab Emirates
Cote d'Ivoire	Republic of Yemen
Djibouti	
Egypt	
Equatorial Guinea	
Eritrea	
Eswatini (formerly Swaziland)	
Ethiopia	
Gabon	
Gambia	
Ghana	
Guinea	
Guinea-Bissau	
Kenya	
Lesotho	
Liberia	
Libya	
Madagascar	

Malawi Mali Mauritania Mauritius Morocco Mozambique Namibia Niger Nigeria Rwanda Sao Tome and Principe Senegal Seychelles Sierra Leone Somalia South Africa South Sudan Tanzania Togo Tunisia Uganda Zambia Zimbabwe	

SCHEDULE 2.2

SUBCONTRACTOR REQUIREMENTS

Any Third Party that ALJ or its Affiliates wishes to engage as a Subcontractor under this Agreement must demonstrate to the PCC's satisfaction:

- That it has appropriate facilities to perform the obligations that ALJ wishes to engage it to perform.
- That is has appropriate expertise to perform the obligations that ALJ wishes to engage it to perform.
- That it is not a Restricted Person.

SCHEDULE 8.1

SUPPLY TERMS

This Schedule 8.1 describes the material terms of the Supply Agreement to be entered into by Evelo and ALJ pursuant to the Agreement for the supply by Evelo to ALJ of Product in Finished Form ("**Final Product**") as contemplated in the Agreement and as set forth in more detail below.

The obligations of the Parties with respect to the matters covered by the terms contained in this Schedule are subject to the due execution and delivery by Evelo and ALJ of the written Supply Agreement. The Supply Agreement will become effective when signed by duly authorized representatives of both Parties. Capitalized terms used in this Schedule, and not otherwise defined, shall have the meaning set forth in the Agreement.

To the extent of any conflict between the terms of this Schedule 8.1 and the terms of the Agreement, the terms of the Agreement will take precedence.

Supply of Final Product. During the Term of the Supply Agreement, as defined below, Evelo shall, subject to the terms of the Supply Agreement, supply to ALJ all Final Product for the Territory, in sufficient quantity as is necessary for ALJ's Commercialization activities with respect to the Products in the Territory in accordance with the Agreement, as forecasted pursuant to the forecasting terms in the Supply Agreement. Evelo shall undertake those of the foregoing supply obligations pursuant to written purchase orders issued by ALJ to Evelo under terms to be set forth in the Supply Agreement (each, a "**Purchase Order**"). The supply price for Final Product will be [***] of Evelo's Manufacturing Costs for the applicable Product. ALJ may use Final Product supplied to it under the Supply Agreement solely for purposes of Commercialization in the Field in the Territory in accordance with, and subject to, the terms and conditions of the Agreement. Evelo is responsible for ordering and purchasing all materials required to meet its obligations under the Supply Agreement.

Statements of Work; Quality Agreement. General terms of supply will be described in the Supply Agreement. Specific non-routine work orders will be described in statements of work issued under the Supply Agreement. Quality-regulated requirements and provisions governing Product quality will be described in a quality agreement to be entered into by and between the Parties (the "**Quality Agreement**"). In the event of any conflict between the Supply Agreement and the Quality Agreement relating to technical and quality-related matters, the Quality Agreement will take precedence.

Use of Approved Facilities. All Final Product to be supplied by Evelo to ALJ or the Parties under the Supply Agreement will be manufactured at the facilities used by Evelo or its third-party contract manufacturer(s) for supply of its requirements of Product (the "**Facilities**"), subject to the quality review procedures to be set forth in the Quality Agreement. Evelo shall be responsible for ensuring that it or its third-party contract manufacturer(s) hold all relevant Regulatory Approvals required for the manufacture of Final Product at those facilities. The Quality Agreement shall specify the change control procedures applicable to Facilities.

Compliance with GMP. Evelo shall ensure that Final Product shall be manufactured in accordance with Applicable Law, the applicable specifications to be attached to the relevant Supply Agreement ("**Specifications**") and GMP. Evelo shall maintain such records as are necessary and appropriate to demonstrate compliance with Applicable Law, the Specifications and GMP. To the extent permitted under Evelo's agreements with its contract manufacturers, ALJ will have reasonable rights to audit those records, as well as parts of Facilities used for the manufacture of the Final Product.

Quality Control and Quality Assurance. Evelo will perform the quality oversight of manufacturing, quality assurance and quality control testing at its third-party contract manufacturing partners, as specified in the Quality Agreement. Batch review and disposition to ALJ or the Parties will be the responsibility of Evelo's quality unit. Evelo will perform its batch review and disposition responsibilities in accordance with GMP, the Specifications, Applicable Law, and the requirements according to the Quality Agreement.

Recalls, Withdrawals and Field Corrective Actions. The Quality Agreement shall specify the procedures for Product recalls, withdrawals and field corrective actions consistent with Section 5.5 (Recalls) and other general terms of the Agreement.

Regulatory Matters and Filings. Responsibility for regulatory filings and subsequent regulatory variations and actions will be as set forth in the Agreement. Each Party will assist in such activities, to the extent consistent with obligations in the Agreement and the Supply Agreement. Such assistance will include providing all information necessary for preparation of documentation, as well as reviewing such documentation if requested by the other Party.

Binding Period and Long-term Forecasts. The Supply Agreement shall specify forecasting provisions for Final Product applicable to ALJ that are sufficient to enable Evelo to satisfy its own forecasting obligations and Purchase Order timelines with respect to the Product under its agreements with its third-party contract manufacturer(s). Unless otherwise agreed, [***] forecasts shall be agreed at the PCC and reviewed and updated at a frequency agreed by the PCC.

Delivery and Acceptance of Batch Documentation. Evelo will oversee appropriate manufacture and storage of Final Product in accordance with the applicable Specifications, GMP and agreed-upon conditions/technical requirements specified under the applicable Supply Agreement. Evelo will provide the appropriate documentation and information to ALJ as set forth in the Quality Agreement.

. **Lead Times; Delivery; Inspection**. The Supply Agreement shall set forth terms and conditions for lead times relating to Purchase Orders and for delivery of Final Product from Evelo's third-party manufacturing and logistics partners. The Supply Agreement shall include customary provisions that ensure that ALJ may reject Final Products containing defects (including latent defects).

. **Invoicing**. Evelo shall invoice ALJ for Final Products at the time of delivery of the Final Products to ALJ. All amounts shall be invoiced and paid in Dollars. ALJ shall remit payment of each invoice within [***] of receipt.

. **Storage Fees**. ALJ shall be responsible for storage costs for Products for the Territory and such costs shall be deemed to be Eligible Commercialization Expenses for the purposes of the Agreement.

. **Statement of Work or Specification Changes**. Either Party may request a modification to a statement of work or the Specifications under a Supply Agreement, *provided* that any changes to Specifications will be subject to change procedures to be set forth in the Quality Agreement.

. **Shortfall**. The Supply Agreement shall include provisions which ensure that, in the event of there being insufficient supply of Final Product to satisfy demand for Final Product worldwide, ALJ is allocated available quantities for Commercialization in the Territory on a pro rata basis based on required volumes for Commercialization in the Territory compared with required volumes for Commercialization outside the Territory.

. **Term**. Once in effect, the term of the Supply Agreement as it relates to the supply of Final Product for the Products shall continue during the term of the Agreement, unless earlier terminated by either Party in accordance with the terms and conditions of the Supply Agreement.

. **Limitations on Liability**. Subject to paragraph 17 below and except for damages resulting from willful misconduct, intentional wrongful acts and gross negligence, neither Party shall have any liability under the Supply Agreement for any indirect, punitive, special, incidental, or consequential damages or (whether direct or indirect) any claims for lost profits or revenues arising under or in connection with the Supply Agreement, in each case subject to, and not inconsistent with, the terms of the Agreement.

. **Indemnity**. The Supply Agreement shall contain customary indemnification provisions for a supply agreement in the context of the type of transaction contemplated by the Agreement, including but not limited to, an indemnity given by Evelo for Liabilities incurred by ALJ or its Affiliates arising from product liability claims resulting from Evelo's breach of the Supply Agreement. Such indemnities shall not be subject to the limitations on liability referenced in paragraph 16 above, but shall be subject to, and not inconsistent with, the terms of the Agreement.

. **Assignment**. The Supply Agreement shall contain terms on assignment that are consistent with the equivalent provisions set out in Section 8.1 of the Agreement.

. **Miscellaneous**. The Supply Agreement shall contain other reasonable provisions that are customary for supply agreements in the context of the type of transaction contemplated by the Agreement, in each case subject to, and not inconsistent with, the terms of the Agreement.

SCHEDULE 9.3

PROFIT AND LOSS SHARE

This Schedule 9.3 covers financial planning, accounting policies and procedures to be followed in determining the Operating Profits or Losses and the P&L Share.

1. **Principles of Reporting**.

1.1 **Profit & Loss Statement**. ALJ will provide a report in the following format of the results of its operations for the applicable period with respect to Medical Affairs activities and Commercialization activities, in each case, for the Products in the Territory, which report will include the cost categories set forth below ("**P&L**"):

Cost Category	ALJ
Net Sales by ALJ or its Affiliates	
***plus* any amounts received by ALJ or its Affiliates from Third Party Distributors to the extent they relate to the grant of rights to distribute, market and resell Products (other than the purchase price for such Products)**	
***less* [***] of Manufacturing Costs, if applicable**	
=*Gross Profit*	
***less* Eligible Commercialization Expenses (other than Manufacturing Costs)**	
***less* Eligible Medical Affairs Expenses**	
***less* Other Operating Expenses**	
=Operating Profits or Losses	

1.2 **Standards**. It is the intention of the Parties to interpret each of the definitions used in the P&L in a manner that is consistent with this Agreement, this Schedule 9.3 and the applicable Accounting Standards; it being understood and agreed that "Operating Profits or Losses" will be calculated in accordance with ALJ's then-current Accounting Standard practices, which will include reasonable methodologies, consistently applied. Reasonable methodologies may include a standard rate or some other appropriate basis for allocating costs. For reconciliation, billing, and reporting hereunder, any costs included in the P&L incurred in a currency other than Dollars will be translated into Dollars in accordance with Section 9.4 (Payment Method).

1.3 The Parties understand that all Net Sales of each Product in the Territory will be booked in accordance with ALJ's Accounting Standards and calculated in accordance with Section 1.98 (Net Sales).

2. **Reporting Obligations**

Each Party shall designate a finance officer to be its representative with respect the preparation of the consolidated P&L (the "**Finance Officers**"):

2.1 **Eligible Shared Expenses**. So long as Evelo incurs any Eligible Shared Expenses, Evelo will submit to ALJ's Finance Officer within 20 days of the end of each Calendar Quarter in which Evelo or its Affiliates performs relevant activities, a report detailing Evelo's Eligible Shared Expenses on a Product-by-Product basis. So long as ALJ incurs Eligible Shared Expenses, ALJ will submit to Evelo's Finance Officer (i) within 25 days of the end of each Calendar Quarter, a written report of ALJ's Eligible Shared Expenses, if Evelo provided a report of any Eligible Shared Expenses for such Calendar Quarter, total Eligible Shared Expenses ("**Co-Funded Expense Report**") in the format of the P&L, and (ii) an estimate of such Eligible Shared Expenses within three days after the end of such Calendar Quarter. Each report for Eligible Shared Expenses provided by a Party and any Co-Funded Expense Report will specify in reasonable detail all such Eligible Shared Expenses. Where this Agreement requires a calculation involving Eligible Shared Expenses, the Eligible Shared Expenses that are to be used in such calculations are the net Eligible Shared Expenses after any recovery of related VAT (for the avoidance of doubt, except for VAT, taxes will not be treated as an item of expense to be deducted against Net Sales for purposes of determining the Operating Profits or Losses and the P&L Share). Where VAT is paid by a Party with respect to any transactions under this Agreement, that Party will use reasonable efforts to recover such VAT as permitted by Applicable Law. Any expenses incurred by or on behalf of a Party in connection with the Exploitation of the Products that do not fall within the definition of Eligible Shared Expenses will be borne solely by such Party, unless the PCC otherwise agrees in writing. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent any cost or expense that may be included in Eligible Shared Expenses is incurred for an activity that is directed to (1) a Product, on the one hand, and (2) the other products of a Party, on the other hand, then such costs and expenses of such activity will be reasonably allocated between the portion of the activity attributable to each respective Product under subsections (1) and (2) and will only be included in the Eligible Shared Expenses to the extent of such agreed allocation.

2.2 **Operating Profits or Losses**. ALJ will submit to Evelo's Finance Officer within 30 days of the end of each Calendar Quarter, a consolidated report of Operating Profits or Losses in the format of the P&L (taking into account the Co-Funded Expense Report for such Calendar Quarter) and the applicable sharing and determination of the corresponding cash settlement (such report, the "**Consolidated Report**"), as well as a preliminary estimate of such Operating Profits or Losses within three days after the end of such Calendar Quarter.

3. **Financial Records**. Each Party will keep all financial records and reports required by this Schedule 9.3 in accordance with its Accounting Standards to the extent applicable hereunder.

4. **Operating Profits and Loss Sharing**.

4.1 The Parties agree to share the Operating Profits or Losses for the Territory as set forth in Section 9.3 (Profit and Loss Share).

4.2 If, taking into account the Net Sales received and Eligible Shared Expenses and Manufacturing Costs incurred as outlined in the P&L Share by ALJ in any Calendar Quarter, or other amounts payable by ALJ to Evelo hereunder, an amount is due from Evelo to ALJ to effect the P&L Share for such Calendar Quarter, then at the time the applicable Consolidated Report is delivered to Evelo, ALJ will invoice Evelo for an amount such that Evelo will be bearing its P&L Share. Evelo will make payment in full of any undisputed invoiced amounts to ALJ within [***] after the date of such invoice. If with respect to such Calendar Quarter, a balancing payment is due from ALJ to Evelo to effect the P&L Share for such Calendar Quarter, then, within [***] after the applicable Consolidated Report is delivered to Evelo, ALJ will pay Evelo an amount such that Evelo will receive its P&L Share. In the event of any disagreement with respect to the calculation of payments owed, the owing Party will pay any undisputed

portion of such payment in accordance with the foregoing timetable and will pay the remaining, disputed portion within [***] after the date on which the Parties, using good faith efforts, resolve the dispute, which dispute, at the request of either Party, will be resolved in accordance with Section 16.3 (Dispute Resolution).

4.3 In the event that any payment that is not otherwise subject to a good faith dispute is made after the date specified in Paragraph 4.2 of this Schedule 9.3, the paying Party will pay the additional amounts or the Receiving Party will reimburse such excess payments, with interest from the date originally due as provided in Section 9.5 (Late Payments), and the remaining, disputed portion of any such payment will be paid within [***] after the date on which Evelo and ALJ, using good faith efforts, resolve the dispute.

5. **Start of Operations and Effective Accounting Date Termination**.

The P&L Share will commence on the Effective Date.

6. **Audits**.

The record-keeping and audit provisions set forth in Section 9.7 (Financial Audits) will apply with respect to all amounts payable by either Party to the other Party under the P&L Share, including with respect to the calculation of Operating Profits or Losses and Eligible Shared Expenses.