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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of: August 2022 (Report No. 2)

Commission File Number: 001-38428

PolyPid Ltd.
(Translation of registrant's name into English)

18 Hasivim Street
Petach Tikva 495376, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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On August 3, 2022, PolyPid Ltd. (the “Company”) announced that it has entered into a License, Distribution and Supply Agreement (the “Agreement”) with Mercury Pharma Group Limited, under the trade name Advanz Pharma Holdings, in accordance with the terms described in the Company’s Report on Form 6-K submitted on August 3, 2022. Attached hereto as Exhibit 10.1 and incorporated herein is the Agreement.

This Report on Form 6-K is incorporated by reference into the Company’s registration statements on Form F-3 (File No. 333-257651) and Form S-8 (File No. 333-239517), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit No.

10.1* [License, Distribution and Supply Agreement, dated August 2, 2022, by and between PolyPid Ltd. and Mercury Pharma Group Limited, under the trade name Advanz Pharma Holdings.](#)

* Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) is the type that the Company treats as private or confidential.

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, thereunto duly authorized.

POLYPID LTD.

Date: August 8, 2022

By: /s/ Dikla Czaczkes Akselbrad
Name Dikla Czaczkes Akselbrad
Title: Chief Executive Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) IS THE TYPE THAT POLYPID LTD. TREATS AS PRIVATE OR CONFIDENTIAL. OMISSIONS ARE DENOTED IN BRACKETS THROUGHOUT THIS EXHIBIT.

LICENSE, DISTRIBUTION AND SUPPLY AGREEMENT

This License, Distribution and Supply Agreement (the "Agreement") is entered into as of 2nd of August 2022 (the "Effective Date"), by and between PolyPid Ltd., a company existing under the laws of Israel, having offices at 18 Hasivim St. Petach Tikva 4917002, Israel ("PolyPid"), and Mercury Pharma Group Limited, under the trade name Advanz Pharma Holdings, a corporation organized under the laws of England, having its registered office at Capital House, 85 King William Street, London, EC4N 7BL, United Kingdom ("Partner") and shall become effective on the Effective Date. PolyPid and Partner are sometimes referred to collectively herein as the "Parties" or singly as a "Party."

RECITALS

A. PolyPid wishes to grant to Partner, and Partner wishes to obtain from PolyPid, the exclusive right under PolyPid's Licensed Technology to market, advertise, promote, distribute, offer for sale, sell and import the Product in the Territory on the terms and subject to the conditions set forth herein.

B. Partner wishes PolyPid to exclusively Manufacture or have Manufactured and supply the Product to Partner in the Territory, and PolyPid desires to Manufacture and supply the Product to Partner to Commercialize in the Territory in accordance with the terms of this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and agreements contained herein, the Parties hereto, intending to be legally bound, do hereby agree as follows:

DEFINITIONS

(a) The following terms as used in this Agreement shall have the meaning set forth below:

"*Accounting Records*" shall have the meaning set forth in Section 9.03(b).

"*Acquiring Entity*" shall have the meaning set forth in Section 6.08(d).

"*Adverse Event*" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have to have a causal relationship with this treatment. An adverse event can be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product whether or not considered related to the medicinal product.

“*Affiliate*” means an individual, trust, business trust, joint venture, partnership, corporation, association or any other entity which owns, is owned by or is under common ownership with, a Party. For the purposes of this definition, the term “owns” (including, with correlative meanings, the terms “owned by” and “under common ownership with”) as used with respect to any Party, shall mean the possession (directly or indirectly) of more than fifty percent (50%) of the outstanding voting securities of a corporation or comparable equity interest in any other type of entity. In the case of Partner, except in respect of the definition of “Net Sales”, this definition shall exclude any entities which are under common control with the Partner solely as a result of being controlled by Nordic Capital branded or associated investment or management vehicles. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

“*Agreement*” shall have the meaning set forth in the preamble to this Agreement.

“*Alliance Manager*” shall have the meaning set forth in Section 4.04(a).

“*Alternate Study*” shall have the meaning set forth in Section 6.04(h)(i)(2).

“*Anti-Corruption Laws*” means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the Corruption of Foreign Public Officials Act (CFPOA), the US Foreign Corrupt Practices Act (FCPA), the UK Bribery Act 2010, and similar laws governing corruption and bribery, money laundering and terrorism.

“*Applicable Laws*” or “*Laws*” means all applicable laws, rules, regulations and mandatory guidelines that may apply to the Packaging, Commercialization and Manufacture of the Product in the Territory or the performance of either Party’s obligations under this Agreement including laws, regulations and mandatory guidelines governing the import, export, marketing, distribution and sale of the Product in the Territory, to the extent applicable and relevant, and including all cGMP or Good Clinical Practices standards or mandatory guidelines promulgated by the European Medical Agency or other Regulatory Authorities in the Territory, including ICH and trade association guidelines, where applicable, as well as export control laws.

“*ARR*” has the meaning set forth in Section 6.04(f).

“*Batch*” for each Product, means a quantity of units for each batch of Product.

“*Big Four*” shall have the meaning set forth in Section 8.01(d).

“*Brand Book*” shall have the meaning set forth in Section 3.05(c).

“*Business Day*” means any day other than a Friday, Saturday or a Sunday on which the banks in Israel and London are open for business.

“*Business Plan*” shall have the meaning set forth in Section 6.05(a).

“*Calendar Quarter*” means each of the three (3) month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year, or the applicable portion of such period.

“*Calendar Year*” means each twelve (12) month period commencing on January 1, and ending on December 31, or the applicable portion of such period; provided, that the first Calendar Year commences on the Effective Date and ends on December 31, 2022.

“*Central Steering Committee*” shall have the meaning set forth in Section 4.01(a).

“*Centralized Procedure*” the European Union-wide procedure for receipt of the MA for the Product from the EMA, where there is a single application, a single evaluation and a single authorisation for the Product throughout the European Union.

“*Certificate of Compliance*” means the certificate of compliance as set out in the Quality Agreement.

“*cGCP*” means those current good clinical practice standards and regulations from time to time applicable to the performance of clinical trials that involve the participation of human subjects as set forth by, but not limited to, the International Conference on Harmonization (ICH) guidelines (Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance) and current industry standards, as amended from time to time.

“*cGLP*” means those current good laboratory practice standards and regulations from time to time applicable to the performance of laboratory activities for pharmaceutical products for human use as required by, but not limited to, European Commission Directives 2004/9/EC and 2004/10/EC on Good Laboratory Practice, and current industry standards, as amended from time to time.

“*cGMP*” means current good manufacturing practices issued from time to time by the EU or any other country in the Territory for medicinal products for human use, in particular the European Commission’s “EU Guidelines to Good Manufacturing Practices – Medicinal Products for Human and Veterinary use”.

“*Change of Control*” has the meaning set forth in Section 6.08(d).

“*Change of Control Concern Notice*” shall have the meaning set forth in Section 6.08(h).

“*Change of Control Meeting*” shall have the meaning set forth in Section 6.08(h).

“*Closing Date*” has the meaning set forth in Section 6.08(f).

“*COGs*” shall have the meaning set forth in Schedule 1.

“*CMO*” shall have the meaning set forth in Schedule 1.

“*Commercially Reasonable Efforts*” means, from time to time with respect to the performance at such time of the Development Plan, the submission or maintenance of any Regulatory Approvals, Manufacture, supply, Commercialization or other obligation of a Party under this Agreement as it relates to the Product and that expressly requires efforts characterized as such, the performance by such Party of such obligation by expending reasonable, diligent, good faith efforts to accomplish such obligation as a similarly situated company would use to accomplish a similar obligation under similar circumstances through the exercise of reasonable business judgment, where the assessment of being similarly situated would be undertaken by reference to company size and financial position, competitive factors in the relevant market relating to the proprietary position of the relevant product in terms of market and profit potential, the safety and effectiveness profile of the relevant product, strategic value, and applicable regulatory matters. With respect to the Commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources that a similarly placed company would generally devote to its own internally discovered compounds or products of similar market, at a similar stage in its development or product life as the Product, with similar safety and effectiveness profile, strategic value, and regulatory matters as the Product, taking into account the competitiveness of alternative products marketed by Third Parties in the marketplace, the patent and other proprietary position of the Product, the likelihood of receipt of a MA approval given the Regulatory Authority involved, the actual pricing, reimbursement and formulary status and, with respect to Section 6.01(iii), also taking into account the Product’s actual or potential profitability. For the sake of clarity, Commercially Reasonable Efforts will be considered on a country-by-country basis in the Territory.

“*Competing Product*” has the meaning set forth in Section 6.08(g).

“*Competitive Product*” means [**]

“*Competitor’s Product*” has the meaning set forth in Section 6.09.

“*Complying Product*” means unlabeled vials of Product which comply with the Product Requirements and the Minimum Shelf Life upon delivery to Partner.

“*Confidential Information*” of a Party means any and all Information of such Party or its Affiliates that is disclosed to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by a Party or its Affiliates pursuant to the confidentiality agreement between the Parties dated as of 24 February 2021 (the “*Confidentiality Agreement*”) is deemed the Confidential Information of such Party and deemed to have been disclosed hereunder and accordingly, in the event that this Agreement (including Article XI) authorized the use or disclosure of such Information, such use or disclosure shall not be deemed a violation of the Confidentiality Agreement even if the provisions of the Confidentiality Agreement are more restrictive. For clarity, PolyPid Licensed Know-How is the Confidential Information of PolyPid.

“*Confidentiality Agreement*” shall have the meaning under the term “*Confidential Information*”.

“Commercialize”, “Commercializing” or “Commercialization” means, with respect to the Product and on a country-by-country basis, any and all activities directed to launching, marketing, market researching, detailing, promoting, advertising, educating, importing, distributing, selling, offering for sale, post-market approval pharmacovigilance and safety reporting, customer service, securing from both government agency payors and non-government third-party payors reimbursement of such drug product after all Regulatory Approvals have been obtained in such country (including, without limitation, obtaining and maintaining Pricing and Reimbursement Approvals), regulatory compliance, planning with respect to each of the foregoing, and reporting. For clarity, “Commercialization” shall not include any activities related to (i) clinical research or development of Products, (ii) the Manufacture of Products, or (iii) the application, securement or maintenance of the MAs.

“Control” means the possession of the ability to, as applicable, (i) grant a license as provided for herein without violating the terms of any Third Party agreement or other arrangement, or (ii) disclose, share or otherwise grant access to any Information or Data without violating applicable law or the rights of any Third Party under a confidentiality agreement, and “Controlled” shall be construed accordingly.

“Data” means all data, non-clinical data, preclinical data and clinical data generated by or on behalf of a Party or its Affiliates or their respective sublicensees or subcontractors pursuant to activities conducted under this Agreement, but excluding marketing material developed solely by Partner, its Affiliates or their respective sublicensees or subcontractors.

“Decentralized Procedure” the country-by-country procedure for receipt of MA for the Product from the applicable Regulatory Authority in a country of the Territory (rather than from the EMA), which procedure may be conducted in parallel in more than one European Union Member State.

“Defect Notice” shall have the meaning set forth in Section 8.05(a).

“Defective” means Product that fails to meet the then-effective Product Requirements, and “Defect” shall be construed accordingly.

“Development Plan” means the milestones and target timelines specifying key activities intended to achieve MA submission, as set forth in Schedule 6.

“Effective Date” shall have the meaning set forth in the preamble to this Agreement.

“EMA” means the European Medicines Agency.

“Enforcement Action” has the meaning set forth in Section 10.02(b).

“Enforcing Party” has the meaning set forth in Section 10.02(d).

“Ethical Business Conduct Laws” means all applicable international, national and local laws, statutes, regulations and codes relating to taxation, exchange controls, customs matters, bribery, modern slavery, corruption, competition law, money laundering, trade sanctions, financial sanctions and criminal matters.

“Excluded Information” shall have the meaning set forth in Section 1.02(c).

“Executives” shall have the meaning set forth in Section 4.03(b).

“*Extended MA Date*” has the meaning set forth in Section 1.01(b)(i).

“*Firm Purchase Order*” has the meaning set forth in Section 8.03(a).

“*Force Majeure*” shall have the meaning set forth in Section 16.04.

“*Government Official*” means any one of the following: (i) any officer or employee, appointed or elected, of a Governmental Authority; (ii) any physician or other health care professional employed by a public hospital or clinic; (iii) any individual who, although temporarily or without payment, holds a public position, employment, or function; (iv) any officer or employee of a public international organization, such as the United Nations, the World Health Organization, or the World Bank; (v) an individual acting in an official capacity for or on behalf of a Governmental Authority; (vi) a political party official, officer, or employee, or any candidate for political office; (vii) any officer or employee of an entity owned or controlled by a government, as well as entities that perform a government function (e.g., air or sea transport, utility, energy, water, or power); or (viii) a member of a royal family, including one who may lack formal authority, but could otherwise be influential in advancing either Party’s business interests, through, for example, partially owning or managing a state-owned or state-controlled entity.

“*Governmental Authority*” means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

“*Hidden Defect*” means a defect to a Product which renders it Defective and is already present at the date of its delivery, but, despite diligent, industry standard visual inspection, is not detected at the time of an inspection carried out pursuant to Section 8.05.

“*ICH*” means International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“*IFRS*” means the International Financial Reporting Standards, as amended from time to time.

“*Indemnitee*” shall have the meaning set forth in Section 13.03.

“*Indemnitor*” shall have the meaning set forth in Section 13.03.

“*Independent Auditor*” shall have the meaning set forth in Section 8.01(d).

“*Indication(s)*” means the prevention of (i) post abdominal surgery incisional infection and/or (ii) post cardiac surgery sternal infection; as ultimately approved by the applicable Regulatory Authority following completion of the D-PLEX [**] studies.

“*Information*” means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including Know-How, copyrights, trade secrets, practices, customer lists, business information, developments, specifications, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), stability data and other study data and procedures.

“*Intermediaries*” shall have the meaning set forth in Schedule 7B.

“*Invoice Dispute*” shall have the meaning set forth in Section 8.01(c).

“*Key Countries*” means [**].

“*Know-How*” means all know-how, trade secrets, inventions, data, processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether or not patentable, which are not generally publicly known, including, without limitation, all chemical, biochemical, toxicological, and scientific research information, whether in written, graphic or video form or any other form or format.

“*Launch*” shall have the meaning set forth in Section 6.04(a).

“*Launching Countries*” means [**].

“*Launch Order(s)*” means, on a per country basis, the first Product’s orders, as placed by Partner in accordance with the terms of this Agreement.

“*Licensed Know-How*” means all Know-How owned or Controlled by PolyPid related to the Product for the Indication as of the Effective Date and created during the Term of this Agreement including, but not limited to, data and documentation of clinical trials or useful for clinical trials whether or not created in or outside the Territory as of the Effective Date and during the Term of this Agreement, which is not covered by the Licensed Patent Rights and which is required or used to Package or Commercialize the Product in the Territory.

“*Licensed Patent Rights*” means all Patent Rights in the Territory that claim the Product for the Indication which are owned or under the Control of PolyPid as of the Effective Date and at any time during the Term of this Agreement. The Licensed Patent Rights as of the Effective Date are set forth on Schedule 4.

“*Licensed Technology*” means the Licensed Patent Rights and the Licensed Know-How.

“*Loss*” shall have the meaning set forth in Section 13.01.

“*Manufacture,*” “*Manufacturing*” or “*Manufacturing Process*” mean, with respect to the Product, the synthesis, the receipt, handling, storage, testing and release of the Product’s active pharmaceutical ingredients and other materials, activities directed to manufacturing, processing, filling, finishing, holding (including storage), quality control, quality assurance testing and release, inventory control and management, storing of the Product for use in the Territory.

“*Marketing Authorization*” or “*MA*” means the authorization granted by the applicable Regulatory Authority in the Territory, approving the commercial sale of the Product in the Territory, together with all subsequent submissions, supplements, variations and amendments thereto.

“*Marketing Authorization Application*” or “*MAA*” means a new drug application or any other application to the European Medicines Agency, the Medicines and Healthcare products Regulatory Agency and any other applicable Regulatory Authority in the Territory for approval to market a Product.

“*Marks*” means those trademarks registered in PolyPid’s name (i) set forth in Schedule 5; and (ii) approved by the applicable Regulatory Authorities for use as the Product’s branded name.

“*Medical Affairs Activities*” means the following activities, to the extent related to a Product in the Territory: responding to external inquiries or complaints, the planning for and conduct of investigator sponsored clinical studies, medical education, speaker programs, advisory boards, thought leader activities, educational grants and fellowships, local country government affairs, phase IV studies or programs, generating Commercialization support data, scientific publications and medical communications. For the sake of clarity, “*Medical Affairs Activities*” shall exclude any activity mandated by the Regulatory Authorities, unless Partner expressly consents to undertaking such activity at its cost.

“*Milestone Date*” means each of the dates set forth opposite each of the milestones to achieve regulatory submission, as set out in Schedule 6 under the column headed “*Milestone Dates*”.

“*Milestone Payments*” shall have the meaning set forth in Section 9.01(a).

“*Minimum Sales Period*” shall have the meaning set forth in Section 6.04(a).

“*Minimum Sales Requirements*” has the meaning set forth in Section 6.04(c).

“*Minimum Shelf Life*” has the meaning set forth in Section 8.04.

“*Minimum Volumes*” shall have the meaning set forth in Section 6.04(b).

“*MSR Launch Date*” shall have the meaning set forth in Section 6.04(j).

“*Net Sales*” means [**].

“*Net Sales Milestones*” has the meaning set forth in Section 9.01(a)(vii).

“*No Launch Country*” shall have the meaning set forth in Section 6.04(k).

“*Notice Period*” shall have the meaning set forth in Section 6.04(i)(v).

[**]

[**]

“*Package*” or “*Packaging*” means the final commercial packaging, labelling, QP release and serialization of the Product’s unlabeled vials, as needed for the Commercialization of the Product in the Territory, in accordance with the Packaging Specifications and Quality Agreement.

“*Packaging Company*” means the packager appointed by the Partner to perform the Packaging.

“*Packaging Material*” means any material employed in the packaging of the Products, excluding any outer packaging used for transportation or shipment. Packaging Materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the Product.

“*Packaging Specifications*” means the packaging specifications and the labeling specifications for each Product, which shall include, where allowed by the applicable Regulatory Authority, the Partner’s livery (design, size and colors to be agreed upon by PolyPid, such agreement not to be unreasonably withheld, delayed or conditioned), as more fully set forth in the applicable Marketing Authorization for the Product, and in compliance with Applicable Laws. For the sake of clarity, and in any event, Polypid shall at its sole discretion but in accordance with requirements of applicable Regulatory Authorities, decide on the technical specifications of the Packaging to be used, such as, and without limitation, type of ink, label adhesive and carton packaging specifications.

“*Partner*” shall have the meaning set forth in the preamble to this Agreement.

“*Partner Indemnitee*” shall have the meaning set forth in Section 13.01.

“*Partner’s Technology*” means any Know-How and other information, discoveries, knowledge, technology, skills, expressed ideas, designs, drawings, trademarks, assembly procedures, computer programs and information (including trial designs and protocols) owned or Controlled by Partner, its Affiliates, sublicensees or suppliers (other than PolyPid) on the Effective Date or during the Term that are required or used for Packaging or Commercialization of the Product.

“*Patent Rights*” means all rights under patents and patent applications, and any and all patents issuing therefrom (including utility, model and design patents and certificates of invention), together with any and all substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, re-examinations, renewals and foreign counterparts of the foregoing, and all improvements, supplements, modifications or additions.

“*Person*” means an individual, corporation, partnership, limited liability company, limited partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

“*Pharmacovigilance Agreement*” means an agreement setting forth the applicable pharmacovigilance responsibilities of each Party related to Adverse Event reporting, to be attached hereto as Exhibit B once agreed upon and executed by the Parties in accordance with Section 5.07 below, as amended by the Parties from time to time.

“Phase III Post Cardiac Sternal Surgeries Study” shall have the meaning set forth in Section 6.04(h)(i)(1).

“PolyPid” shall have the meaning set forth in the preamble to this Agreement.

“PolyPid Indemnatee” has the meaning set forth in Section 13.02.

“Pricing and Reimbursement Approvals” means any pricing and reimbursement approvals which either (i) currently exist or otherwise must be obtained before placing the Product on the market in any country in the Territory in which such approval is required, (ii) is reasonably required for the successful and financially sound launch of the Product in a certain country(ies) of the Territory, or (iii) is reasonably required for a certain service provider (e.g. hospitals) to provide health care services to its patients utilizing the Product.

“Product” means [**] for the Indication.

“Product Amount Deficiency” shall have the meaning set forth in Section 6.04(h)(iii).

“Product Net Sales” shall have the meaning set forth in Schedule 1.

“Product Price” shall have the meaning set forth in Schedule 1.

“Purchase Order” shall have the meaning set forth in Section 8.03(a).

“Purchase Price” shall have the meaning set forth in Section 8.01(a).

“Product Requirements” shall have the meaning set forth in Section 12.03(a).

“Product Specifications” means the specifications for the Product, including packaging and labeling specifications, as set forth in the MA for each country in the Territory, as may be amended from time to time in accordance with the terms of this Agreement.

“QP” has the meaning set forth in Section 1.02(c).

“Quality Agreement” means an agreement setting forth the applicable quality control and quality assurance responsibilities of each Party related to the Product, to be attached hereto as Exhibit C once agreed upon and executed by the Parties in accordance with Section 7.02(a) below, as amended by the Parties from time to time.

“Quarterly Net Sales Report” has the meaning set forth in Section 8.01(e).

“Recall” shall have the meaning set forth in Section 5.09(a).

“Regulatory Approval” means any and all approvals, including where applicable, the MA approval, Pricing and Reimbursement Approval, schedule classifications, permits, licenses, filings and certifications of any Regulatory Authority, that are necessary for the Manufacture, Packaging, Commercialization or use of the Product in a given country or regulatory jurisdiction.

“*Regulatory Authority*” means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

“*Regulatory Materials*” means regulatory applications (including MAA), submissions, notifications, communications, correspondence, registrations, dossiers, risk management plans, benefit risk assessment reports, and other filings made to, received from or otherwise conducted with a Regulatory Authority in order to manufacture, market, sell or otherwise Commercialize the Product in a particular country or jurisdiction.

“*Revised Minimum Sales Requirement*” has the meaning set forth in Section 6.04(h)(i)(2).

“*Right of First Offer*” has the meaning set forth in Section 6.07(a).

“*ROFO Notification*” has the meaning set forth in Section 6.07(a).

“*Rolling Forecast*” has the meaning set forth in Section 8.02(a).

“*Safety Stock*” has the meaning set forth in Section 8.02(d)

“*Shipment*” means each individual group of unlabeled vials of Products dispatched by PolyPid to Partner.

“*Shortfall*” has the meaning set forth in Section 6.04(h)(ii)(2).

“*SSIs*” has the meaning set forth in Section 6.04(e).

“*Term*” has the meaning set forth in Section 14.01.

“*Termination Pre-Requisite*” has the meaning set forth in Section 6.08(h).

“*Territory*” means European Economic Area and the United Kingdom.

“*Third Party*” means any Person other than: (a) PolyPid, (b) Partner or (c) an Affiliate of PolyPid or Partner.

“*Third Party Accountant*” has the meaning set forth in Section 9.03(b).

“*Third Party Claim*” has the meaning set forth in Section 13.01.

“*True-Up Amount*” has the meaning set forth in Schedule 1.

“*Upfront Payment*” has the meaning set forth in Section 9.01(a)(i).

**ARTICLE I
DEVELOPMENT**

Section 1.01 Development Plan.

(a) PolyPid shall, at its sole cost, carry out all activities in accordance with the Development Plan to ensure the Regulatory Materials are suitable to submit to the Regulatory Authority to obtain an MA in each country of the Territory and shall use Commercially Reasonable Efforts to meet the Milestone Dates.

(b) PolyPid shall keep the Partner reasonably informed on the progress of the Development Plan and shall promptly report to Partner any and all material issues which occur and/or are reasonably foreseen which are reasonably likely to delay the achievement of the milestones by the Milestone Dates in the Development Plan as soon as reasonably practicable. In such case, PolyPid shall prepare a revised Development Plan and share it with the Partner as soon as practicable. In the event that:

(i) [**]

(ii) [**]

(iii) [**]

(c) PolyPid shall bear sole responsibility for all planning, execution, equipment and costs associated with each and every element of the Development Plan.

(d) PolyPid shall be wholly accountable and liable for the safety, health and environmental aspects of all work performed in relation to the development of the Product and the Development Plan and shall have management systems in place which at all times ensure:

(i) the risks and impact of any activity undertaken are assessed and recorded; and

(ii) that prompt and appropriate actions are taken to effectively mitigate against any hazards identified.

Section 1.02 Development of the Product

[**]

Section 1.03 Compliance with Law.

In conducting the development activities hereunder, PolyPid shall comply in all respects with any and all Applicable Laws, including but not limited to cGMP, cGCP and cGLP.

**ARTICLE II
APPOINTMENT**

Section 2.01 Appointment.

During the Term of this Agreement, and subject to the terms and conditions contained herein, PolyPid hereby appoints Partner as its exclusive authorized distributor of the Product in the Territory, with the right to obtain and maintain all Regulatory Approvals (other than the MA, which PolyPid is solely responsible for obtaining and maintaining at PolyPid's cost) including Pricing and Reimbursement Approval, and to Package and Commercialize the Product in the Territory, and Partner hereby accepts such appointment.

Section 2.02 Sole Supplier.

Partner shall purchase all of its requirements of Product from PolyPid in accordance with the terms of this Agreement.

Section 2.03 Excluded Sales.

Partner will promptly inform PolyPid of any material sale (including any tender related to the Products) in which the Partner is not entitled to participate in the Key Countries and the Launching Countries. PolyPid shall be entitled to bid for, and to directly or indirectly enter into, any such sale or tender, and in such case this shall not constitute a breach by PolyPid of the exclusivity granted to Partner under Sections 2.01 and 3.01(a). The sales made under this Section 2.03 shall be counted towards the Minimum Sales Requirements.

Section 2.04 Restrictions.

(a) Partner shall not, directly or indirectly, market, promote, distribute, sell or advertise the Products: (i) for any indication other than the Indications; or (ii) outside the Territory; or effect any sale in the Territory under circumstances where it would be reasonable to assume that the Product being sold shall be resold outside of the Territory. In addition, Partner shall immediately notify PolyPid if, at any time, it becomes aware that any Third Party has exported any Products or has made such Products available outside the Territory. In such event, Partner shall identify the Third Party customer of Partner that is the direct source of such exported Products and immediately thereafter cease its supply of Products to such Third Party, unless otherwise agreed to by the Parties.

(b) Partner shall not duplicate, reverse engineer, modify or adapt the Product (save for the Packaging). Subject to Section 5.06, Partner shall not modify or adapt any documentation submitted to the Regulatory Authorities in connection with the Product nor shall Partner modify or adapt any documentation provided by PolyPid together with the Product provided this clause shall not restrict amendment to marketing materials based on prior approvals and where further submission to Regulatory Authority is not required.

Section 2.05 []**

**ARTICLE III
LICENSE**

Section 3.01 License Terms.

The terms and conditions of the exclusive license granted by PolyPid to Partner shall be as follows:

(a) *License Grant.* Subject to the terms of this Agreement, PolyPid hereby grants to Partner, during the Term, an exclusive license, with the right to sublicense (subject to the restrictions set forth in Section 3.02), under the Licensed Technology and the Marks to Package, test (if needed), release and Commercialize the Product in the Territory, and, with respect to the Licensed Know-How, only to the extent necessary and sufficient for Partner to exercise its rights and perform its obligations hereunder. Partner shall have no right, title or interest in or to the Licensed Technology or the Marks, except as specifically set forth in this Agreement.

Subject to the terms of this Agreement, PolyPid hereby also grants to Partner, during the Term, a non-exclusive license to re-produce PolyPid's trademarked name and logo as set out in Schedule 5, solely as required to perform Partner's obligations hereunder, including without limitation Packaging and Commercialization of the Product.

(b) *PolyPid Retained Rights.* Save for Partner's Technology, PolyPid and its Affiliates shall retain the exclusive right, title and interest in, under and to, any and all intellectual property rights in the and Data, the Product and any improvements, enhancements, and derivatives thereof.

(c) *Partner's Technology.* Save for Partner's trademarks, drawings and designs, and subject to the terms of this Agreement, Partner hereby grants to PolyPid, during the Term, a license under the Partner's Technology, only to the extent necessary and sufficient for PolyPid to exercise its rights and perform its obligations hereunder.

Section 3.02 Sublicense Rights.

Partner shall have the right to sublicense its rights under Section 3.01 to any Third Party sublicensee with PolyPid's prior written consent, which shall not be unreasonably delayed. Partner may grant sublicenses of the license to its Affiliates, including through multiple tiers, without requiring PolyPid's prior consent. Partner shall ensure that each sublicense granted by Partner pursuant to the terms of this Section 3.02 is consistent with the terms and conditions of this Agreement and Partner shall be solely responsible for all of its sublicensees' activities and any and all failures by its sublicensees to comply with the terms of this Agreement. Without limiting the foregoing, each such sublicense shall include the following additional terms and conditions:

(a) the sublicensee shall be bound by confidentiality obligations no less stringent than those set forth in this Agreement;

(b) the sublicensee shall not have any right to prosecute or maintain or enforce any Licensed Patent Rights; and

(c) the sublicensee shall assign or license to Partner all Know-How and Data generated by or on behalf of such sublicensee related to the Product, and Partner shall assign same onwards to PolyPid, and shall grant Partner all of the rights necessary for Partner to fulfill its obligations to PolyPid.

Section 3.03 Documents and Declarations.

PolyPid shall execute all documents, give all declarations regarding the licenses granted hereunder and reasonably cooperate with Partner to the extent such documents, declarations and/or cooperation is/are required for the recording or registration of the licenses granted hereunder at the patent office in the Territory for the benefit of Partner. Partner shall reimburse PolyPid for its reasonable out-of-pocket Third Party costs associated therewith. Following the termination or expiration of the Agreement, PolyPid shall have the right to revoke such recording or registration and Partner shall provide any reasonable support required to give effect to such revocation.

Section 3.04 No Implied Licenses.

Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel, implication, or otherwise to have granted the other Party any license or other right to any intellectual property of such Party.

Section 3.05 Licensed Marks.

(a) *Commercializing the Mark.* Subject to the terms and conditions of this Agreement, Partner shall, and shall ensure that its Affiliates and sublicensees, use the Marks and PolyPid's trademarked name and logo solely in connection with the Packaging and Commercialization of Products in the Territory.

(b) *PolyPid Retained Interest.* PolyPid shall own and retain all right, title, and interest in and to all Marks and in and to the PolyPid's trademarked name and logo. PolyPid shall register and maintain the Marks in the countries of the Territory at PolyPid's cost and expense, and all goodwill in any such Marks shall accrue to PolyPid. Partner shall, and shall ensure that its Affiliates and sublicensees and subcontractors shall not undertake any act that will or may weaken, damage or be detrimental to the Mark and/or to PolyPid's trademarked name and logo or the reputation or goodwill associated with the Mark, PolyPid's trademarked name and logo or PolyPid. If PolyPid, in its reasonable opinion, finds and evidences that use of any of the Marks and/or PolyPid's trademarked name and logo by Partner, its Affiliates or sublicensees or subcontractors, will or may weaken, damage or be detrimental to the Mark or the reputation or goodwill associated with the Mark, PolyPid's trademarked name and logo, or PolyPid, Partner shall, upon written notice from PolyPid, promptly, and no later than ten (10) days after receipt of such notice, take all measures reasonably necessary to correct the deviation(s) or misrepresentation(s) in, or misuse of, the applicable Mark and/or PolyPid's trademarked name and logo.

(c) *Usage of Marks.* Partner shall, and shall ensure that its Affiliates and sublicensees and subcontractors shall, use the Marks in accordance with PolyPid's Brand Book, and in compliance with all Applicable Laws in the Territory. The Parties acknowledge that the Brand Book has not been finalized by PolyPid and once finalized, provided that the process detailed below in this 3.05(c) has been followed prior to finalization of such Brand Book, shall be attached to the Agreement as Exhibit A (the "Brand Book"). Once finalized, the draft Brand Book shall be presented to Partner for its review. In the event that Partner reasonably objects to any of the terms of the draft Brand Book (other than the Mark's hallmark), Partner shall provide notice to PolyPid within fifteen (15) days after receipt of the draft Brand Book. In the event that Partner provides such objection notice, the Partner's objection shall be discussed at the Central Steering Committee with the aim of resolving the Partner's issues. For avoidance of doubt, PolyPid shall have final decision-making authority regarding the terms of the Brand Book. Subject to Section 6.02(c), Partner shall follow the Brand Book following its finalization in accordance with this Section 3.05(c).

Furthermore, Partner shall not use the Marks and/or PolyPid's trademarked name and logo in any manner that might reasonably be expected to tarnish, disparage, or reflect adversely on the trademarks or the owner of such trademarks. Partner shall, and shall ensure that its Affiliates and sublicensees and subcontractors shall use, in connection with the Marks and/or PolyPid's trademarked name and logo, all legends, notices and markings required by law. Partner, its Affiliates, sublicensees and subcontractors may not materially alter the appearance of the Marks and/or PolyPid's trademarked name and logo in any advertising, marketing, distribution, or sales materials, or any other publicly distributed materials without the prior written consent of PolyPid, which consent PolyPid may withhold at its sole discretion.

(d) *Protection of the Marks.* The Parties agree that neither Party nor their Affiliates shall publish, employ nor cooperate in the publication of, any misleading or deceptive advertising material with regard to the Parties, the Marks or PolyPid's trademarked name and logo.

Section 3.06 Competitive Product.

Partner shall not, and shall cause its Affiliates to not, whether directly or indirectly, in-license, develop, register, supply, market, sell or distribute a Competitive Product in any country in the Territory during the Term and for [**]. A breach of this Section 3.06 shall allow PolyPid to terminate this Agreement in accordance with Section 14.02(c).

ARTICLE IV GOVERNANCE

Section 4.01 Central Steering Committee.

(a) *Central Steering Committee.* The Parties shall form a Central Steering Committee (the "Central Steering Committee") to coordinate, oversee and monitor the Product's development, the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization, and to facilitate the exchange of information between the Parties regarding the development, the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization of the Product.

(b) *Establishment of the Central Steering Committee.* Promptly following the Effective Date, the Parties shall establish the Central Steering Committee, to be composed of an equal number of representatives from PolyPid and Partner [**], unless another number is agreed between the Parties. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Product and sufficient seniority within the applicable Party consistent with the scope of the Central Steering Committee's responsibilities. A Party's representatives will be appointed and may be replaced by such Party on written notice to the other Party, provided, however, that each Party will use reasonable efforts to ensure continuity of its representatives on the Central Steering Committee.

(c) *Meetings.* The Central Steering Committee shall meet (in person or by teleconference or video-teleconference) periodically (but in any event no less than once per Calendar Quarter) during the Term. The Central Steering Committee will have a quorum if at least one (1) representative of each Party is present or participating. The Parties will endeavor to schedule meetings of the Central Steering Committee at least two (2) months in advance. Each Party may invite guests to certain items on the agenda of the meetings, with reasonable prior notice, in order to discuss special technical or commercial topics and these guests will be subject to the confidentiality obligations aligned with those set forth in this Agreement. No guest shall have the right to vote at such meeting. In advance of any Central Steering Committee meetings, the Parties will exchange copies of their respective data, Information, regulatory documents and other documents relating to the issues to be addressed at such meeting. The Central Steering Committee shall be co-chaired by one representative of Partner and one representative of PolyPid. The co-chairs shall have the responsibilities set forth in Section 4.01(d), but shall have no additional powers or rights beyond those held by the other Central Steering Committee representatives. For the avoidance of doubt, Polypid shall not be required to share any Excluded Information with the Central Steering Committee, without derogating from Polypid's obligation to share Excluded Information with Partner in accordance with and subject to Section 1.02(c).

(d) *Agendas and Meeting Minutes.* The co-chairs shall be responsible for agreeing upon and distributing an agenda for each meeting of the Central Steering Committee at least five (5) Business Days in advance of any such meeting. Each Party shall have the right to request the co-chairs to include any matter or issue related to the development, the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization of the Product on the agenda for a Central Steering Committee meeting, which requests shall be accommodated by the co-chairs. The co-chairs shall alternate responsibility for generating and issuing minutes of each Central Steering Committee meeting, which shall include a summary of any actions agreed at the meetings. The minutes will be issued in draft form and provided to the Alliance Managers and the Central Steering Committee representatives of each Party for review. Any corrections or comments must be provided to the co-chair with responsibility for preparing the minutes within ten (10) Business Days after the draft minutes are issued, and such co-chair shall then issue the approved (or, if no comments are provided within such ten (10) Business Day period, deemed approved) minutes in final form to the Alliance Managers and the Central Steering Committee representatives of each Party.

Section 4.02 Functions and Powers of the Central Steering Committee

The Central Steering Committee shall have strategic oversight over and shall monitor the development, the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization of the Product. The Central Steering Committee shall have solely the powers expressly assigned to it in this Section 4 and elsewhere in this Agreement, and shall not have any power to amend, modify, or waive compliance with this Agreement, notwithstanding anything that may be construed to the contrary herein. In particular, the Central Steering Committee shall be responsible for:

(a) overseeing the development of the Product for the Territory and monitoring, reviewing and recording PolyPid's progress under the Development Plan;

(b) overseeing Partner's Medical Affair Activities and PolyPid's support for those activities;

(c) overseeing the Marketing Authorization Application, and monitoring the submission of filings for Regulatory Approvals for the Product in the Territory;

(d) overseeing and discussing forecasts, the Manufacture, Packaging and supply of the Product;

(e) overseeing and discussing the Business Plan for the Territory, and monitoring, reviewing and recording the Partner's Commercialization progress;

(f) serving as an information sharing forum and facilitating the exchange of information on the development, the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization of the Product in the Territory; and

(g) such other responsibilities as may be assigned to the Central Steering Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

Section 4.03 Decision-Making

(a) The Central Steering Committee will make decisions (i) by consensus of the members present at a meeting at which a quorum exists, with each Party's representatives collectively having a single vote, or (ii) by a written resolution signed by all Central Steering Committee members, or (iii) by email confirmation from all Central Steering Committee members.

(b) [**]

(c) [**]

Section 4.04 Alliance Managers

(a) *Appointment.* Each Party shall appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement (each an "Alliance Manager"). The Alliance Managers shall have the right to attend all Central Steering Committee meetings as non-voting participants and may bring to the attention of the Central Steering Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as set forth in Section 4.04(b) 1.1(a) and elsewhere in this Agreement or as the Parties may mutually agree. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.

(b) *Responsibilities of the Alliance Managers.* The Alliance Managers will facilitate communication between the Parties to assure a successful relationship between the Parties. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder, except to the extent such matters are coordinated by the Central Steering Committee.

Section 4.05 Business Visits.

Without derogating from the foregoing, or from any of Partner's liabilities or obligations hereunder, PolyPid will have the right to, once per year and upon thirty (30) days' notice, accompany Partner's sales representatives on site-visits in the Key Countries where (i) only the Product is being discussed; and (ii) customer does not object to PolyPid's presence. Partner shall also inform and invite PolyPid to certain scientific advisory board meetings where the Product will be discussed.

**ARTICLE V
REGULATORY MATTERS AND COMPLIANCE**

Section 5.01 Marketing Approval Holder; Maintenance of Regulatory Approvals.

(a) MAA. During the Term, PolyPid and/or any of its Affiliates shall be responsible for and shall obtain, maintain and renew, at its sole cost, all MAA(s) and Marketing Authorization(s), issued by the Regulatory Authorities and which are necessary for the Packaging, use and Commercialization of the Product in the Territory. PolyPid and/or its Affiliates shall be the MA holder for the Product. All MAA filings and materials and associated documentation with respect to the Product shall be owned and held by PolyPid, and PolyPid hereby grants Partner the right to use or refer to PolyPid's proprietary information over the Product (excluding, subject to clause 1.02(c), the Excluded Information), including, but not limited to, intellectual property related to the Product, filings, materials and documentation, all as required to perform its Packaging, testing, release, Commercialization and other obligations hereunder.

(b) Regulatory Approvals.

(i) Partner shall secure and maintain, at its sole cost, all Regulatory Approvals (other than MAAs and Marketing Authorizations and those Regulatory Approvals required for the Manufacture of the Product, the whole of which PolyPid is, at its sole cost, responsible for), required for the Packaging and Commercialization of the Product in each country of the Territory. PolyPid shall provide Partner with the necessary authorization and support to submit the application for the Product's Pricing and Reimbursement Approval in the Territory, to the extent relevant.

(ii) Each Party agrees that neither it nor its Affiliates will do anything to adversely affect a Regulatory Approval in the Territory or country of Manufacture during the Term of this Agreement.

(iii) As it relates to the Product, PolyPid shall, at its sole cost, perform all post-marketing validation testing, to the extent required by the applicable Regulatory Authority.

(c) *Allocation of Tasks and Responsibilities re Regulatory Approvals.* In addition to the foregoing, Schedule 8 sets forth each of the Parties' responsibilities as it relates to the Regulatory Approvals in more detail.

Section 5.02 Regulatory Information Sharing.

(a) PolyPid shall notify Partner of any material questions or decisions relating to the Product received from the Regulatory Authority in the Territory and shall provide Partner with copies of its proposed answer. Partner shall be given a reasonable opportunity (taking into account the Milestone Dates and other timelines (including regulatory timelines)) to review and comment on PolyPid's proposed answers, however PolyPid shall make the final determination as to such answers. In addition, PolyPid shall notify Partner of any material Regulatory Materials received from any Regulatory Authority in the Territory and shall provide Partner with copies thereof within five (5) days after receipt. Partner shall be given a reasonable opportunity to review and comment on any material Regulatory Materials for the Product to be submitted by PolyPid or an Affiliate or sublicensee to any Regulatory Authority in the Territory (taking into account the Milestone Dates and other timelines (including regulatory timelines)) however PolyPid shall make the final determination as to the submission of such Regulatory Materials.

(b) For the Key Countries and for those other countries in the Territory where Partner intends to apply for Pricing and Reimbursement Approval, Partner shall provide PolyPid with a copy of the Pricing and Reimbursement Approval application and shall explain the content to PolyPid. Should PolyPid reasonably object to Partner's strategy, the Parties shall discuss in good faith and shall refer the matter to the Central Steering Committee for resolution. Partner shall notify PolyPid of any material Regulatory Materials relating to the Pricing and Reimbursement Approvals for the Product received from the Regulatory Authority in the Territory and shall provide PolyPid with copies thereof within five (5) days after receipt. PolyPid shall be given an opportunity to review and comment on Partner's proposed answers, however Partner shall make the final determination as to such answer.

(c) In addition, during the Term and with respect to all Products supplied and purchased under this Agreement, each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from a concerned Regulatory Authority which may affect the safety or efficacy claims of the Products or the continued marketing of the Products. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

Section 5.03 Regulatory Audits and Inspection.

Prior to Partner's qualification by the Regulatory Authorities as the Product's packager, upon reasonable written notice, PolyPid may conduct an audit, with a maximum of [**] auditors, on Partner's safety and regulatory systems, procedures, and practices, quality system, facility' utilities, systems and equipment, including on site evaluations and/or a cGMP inspection in each case as relates to Packaging of the Product. Following Partner's qualification by the Regulatory Authorities as the Product's packager, upon six (6) weeks' written notice, PolyPid may conduct, once every [**] years or at any time upon reasonable cause, with a maximum of [**] auditors, an audit of safety and regulatory systems, procedures, and practices, quality system, facility utilities, systems and equipment of Partner, its Affiliates and the Packaging Company, including on site evaluations and/or cGMP inspections in each case as relates to Packaging of the Product. Partner shall promptly notify PolyPid of any inspections relating to the Products by any Regulatory Authority in the Territory, of which it becomes aware. Unless prohibited by Applicable Law or if the audit is to be conducted at the Packaging Company's facilities, then unless prohibited by such Packaging Company, Partner shall permit PolyPid's representative to observe such inspection as one of the [**] auditors present. Partner shall also provide PolyPid with copies of all correspondences submitted to or received from the Regulatory Authority relating to such inspection. In the event that the audit is conducted by a Regulatory Authority, Partner shall promptly notify PolyPid of any critical or major observation noted by any such Regulatory Authority concerning the facility, equipment systems and other GMP related topics, all as they relate to the Product.

Section 5.04 Meetings with Regulatory Authorities.

Each Party shall provide the other Party with at least fifteen (15) days' prior written notice (or, to the extent such meeting or discussion is scheduled in less than fifteen (15) days, notice as quickly as practicable) of any meeting or discussion with any Regulatory Authority in the Territory related to Products. In respect of interactions related to the request, issuance or maintenance of Pricing and Reimbursement Approvals, Partner shall use reasonable efforts to secure a time and date for such meeting or conference that is reasonably acceptable to PolyPid. If PolyPid elects not to attend a meeting or discussion relating to the Pricing and Reimbursement Approvals, Partner shall update PolyPid (and with respect to the Key Countries, provide a written summary thereof in English) following such meeting or discussion. Save for interactions related to the request, issuance or maintenance of Pricing and Reimbursement Approvals, PolyPid shall lead all interactions with Regulatory Authorities in the Territory with respect to Marketing Authorization. For the avoidance of doubt, the obligations on Partner in this Section 5.04 shall only apply insofar as Partner is entitled to request and entitled to attend the relevant meetings with Regulatory Authorities.

Section 5.05 Labeling and Artwork

Partner shall at least one hundred and fifty (150) days prior to submission of the MAA to the Regulatory Authorities, provide PolyPid with packaging mock-ups and specimen to be submitted to the Regulatory Authorities for approval in compliance with the Packaging Specifications. Should the MAA be submitted via a Centralized Procedure, PolyPid shall effect such filing. Should the MAA be submitted via the Decentralized Procedure, and PolyPid requests that Partner do so, Partner shall file the Regulatory Materials specifically related to the Packaging during the national phase, on PolyPid's behalf and at PolyPid's cost (which cost shall be agreed in advance between the Parties), in each country in the Territory for the Packaging Specifications approval; and Partner shall provide PolyPid with assistance with translations as required. PolyPid shall provide Partner with all the necessary powers required for Partner to fulfill this filing obligation. Partner shall be responsible for assuring that packaging and labeling set forth in the Packaging Specifications comply with all Applicable Laws where such Product is to be distributed for sale in the Territory.

Section 5.06 Marketing and Promotional Material

Partner shall, if required by the applicable Regulatory Authorities, submit for such Regulatory Authorities' approval all promotional material and marketing activities to be undertaken with respect to the Product in the Territory.

Section 5.07 Other Required or Requested Changes to Product or Regulatory Approvals

(a) If a Regulatory Authority in a country in the Territory requires any change to be made to the Packaging, the Parties shall promptly enter into discussions and mutually agree on all material terms and conditions of such revisions, and Partner shall implement such revisions in respect of its activities hereunder. Partner will provide PolyPid any documentation or other information with respect to the Packaging change as PolyPid may reasonably request in order to obtain or maintain the MA or comply with cGMP or other Applicable Laws. The cost of implementing such change pursuant to the Regulatory Authority requirement shall be borne by (i) Partner, if the change is due to Partner's act or omission (or any one acting on its behalf); or (ii) PolyPid, in all other cases.

(b) Partner may request changes to the secondary Packaging Specifications, which PolyPid shall consider in good faith for approval (such approval not to be unreasonably withheld, delayed or conditioned). If PolyPid approves the requested change, Partner will request the variation from the applicable Regulatory Authorities to effect such changes (unless the MA is submitted in a Centralized Procedure in which case PolyPid shall use Commercially Reasonable Efforts to make such request), provided however, that Partner will bear all costs for the implementation of such change.

(c) Subject to Section 5.07(a), if a Regulatory Authority in a country in the Territory requires any change to be made with respect to the Manufacture of the Product and/or the Product Specifications, PolyPid shall use Commercially Reasonable Efforts to implement (at its cost) such change pursuant to the Regulatory Authority's requirement.

(d) If Adverse Events or other issues arise with respect to the safety or efficacy of the Product that jeopardizes the Product's performance or are deemed by the Parties to potentially limit the Product's approved Indications, the Parties shall consult with each other with respect to such events or other issues. If the Parties determine that the situation requires clinical testing, modifications to any Regulatory Approval in the Territory or other communication with any Regulatory Authority or entity, PolyPid shall undertake those activities, at its sole cost (unless and to the extent the issues have been caused by the Partner's breach of this Agreement, in which case the portion of cost resulting from Partner's breach of the Agreement shall be borne by Partner).

(e) Save for the Packaging Specifications, PolyPid may request Regulatory Approval for other changes or modifications to the Product Specifications from time to time, including to conform with Product Specifications outside the Territory, modify analytical or stability methods or procedures or due to other developments provided such changes do not adversely affect Partner's ability to have Product available for sale under this Agreement. PolyPid shall notify Partner of the general nature of the envisioned changes at least three (3) months prior to submitting its request for such changes with the Regulatory Authorities in the Territory. PolyPid shall assume all costs related to the request and implementation of such changes. Notwithstanding the foregoing, any changes or modification to the Product Specifications shall be cGMP compliant. Furthermore, should such changes or modifications results in changes to any marketing materials used by Partner to Commercialize the Product in the Territory, the Parties shall discuss in good faith the allocation between them of the costs of updating and/or replacing the affected marketing materials.

Section 5.08 Adverse Event Reporting.

(a) Parties shall commence negotiations on the Pharmacovigilance Agreement promptly following the Effective Date, and no later than six (6) months prior to the first sale of the Product in the Territory, Partner and PolyPid shall execute the Pharmacovigilance Agreement, setting forth the worldwide safety and pharmacovigilance procedures for the Parties with respect to Products, such as safety data sharing and exchange, Adverse Events reporting (including pregnancy reports and special situation) and prescription events monitoring. The Pharmacovigilance Agreement sets forth and describes the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, or sublicensees to comply with its legal obligations. The Parties shall promptly update the Pharmacovigilance Agreement if required by changes in Applicable Laws. Each Party shall comply with its respective obligations under the Pharmacovigilance Agreement and shall cause its Affiliates and sublicensees to comply with such obligations. If there is any conflict or inconsistency between this Agreement and the Pharmacovigilance Agreement, then the Pharmacovigilance Agreement will control to the extent the conflict or inconsistency relates to a matter involving pharmacovigilance, including the safety data exchange of the Product. The Pharmacovigilance Agreement is hereby incorporated by reference.

(b) In accordance with the terms of the Pharmacovigilance Agreement, Partner shall maintain a pharmacovigilance system for Products in the Territory, at its sole cost and expense, and shall promptly report to PolyPid, in writing, any quality complaints, Adverse Events, safety case scenarios and safety events related to Products and shall, for special case scenarios, obtain PolyPid's prior written approval with respect to any information and/or reports to be provided to the applicable Regulatory Authorities in the Territory. Partner shall provide to PolyPid data from the Partner's Adverse Event database for the Territory and any other data required supporting the global pharmacovigilance requirements. PolyPid shall maintain a global Adverse Event database at its sole cost and expense, and, except as prohibited by Applicable Law, shall provide Partner with information contained in such global Adverse Event database in accordance with the terms of the Pharmacovigilance Agreement.

(c) Each Party shall comply with all Applicable Laws governing Adverse Events in its respective territory, and shall notify the other Party on a timely basis of any Adverse Events occurring in its respective territory as set forth in the Pharmacovigilance Agreement. Partner is responsible for complying with Applicable Laws governing Adverse Events in the Territory at its sole expense. Each Party shall submit copies of reports of Adverse Events to the other Party as described in the Pharmacovigilance Agreement.

(d) Notification of Customer and Technical Complaints. Each Party agrees that throughout the Term of this Agreement, and with respect to all Product supplied and purchased under this Agreement, after the termination of this Agreement, it will (a) notify the other Party as soon as possible (but not more than the period to be defined in the Pharmacovigilance Agreement) of all available information concerning any complaint, product defect reports, and similar notices received by either Party with respect to the Product in the Territory, whether or not determined to be attributable to the Product, the whole in accordance with the terms of the Pharmacovigilance Agreement, and (b) with respect to an Adverse Events, comply with the provisions of the Quality Agreement and Pharmacovigilance Agreement. Partner, in consultation with PolyPid, shall define and implement regulatory compliance procedures, including, without limitation, action plans and an SOP for product defect reporting and will handle all product complaint investigations in the Territory, including intake of information, requesting a complaint sample, evaluation of the complaint sample, and conduct the quality investigation per the Partner's procedure. In connection with any such product complaint PolyPid shall cooperate as reasonably requested by Partner including performing any testing and investigations required in accordance with the terms of the Quality Agreement.

Section 5.09 Product Recalls or Withdrawal.

(a) In accordance with the terms of the Quality Agreement, if at any time any Regulatory Authority of any country requests a Party to recall the Product or if a voluntary recall of the Product is contemplated by either Party (collectively, a "Recall"), then the Party to whom such request is made or the Party contemplating such Recall, as the case may be, shall immediately notify the other Party. Partner shall not carry out a voluntary Recall in the Territory without the prior written approval of PolyPid. Any Recall in the Territory shall be carried out by Partner in an expeditious as manner as reasonably possible to preserve the goodwill and reputation of the Product and the goodwill and reputation of the Parties. Partner shall in all events be responsible for conducting any Recall or market withdrawals with respect to the Product in the Territory. Partner shall maintain records of all sales and distribution of Product and customers sufficient to adequately administer a Recall or market withdrawal for the period required by Applicable Law. PolyPid shall be responsible for and shall maintain all records related to any corrections undertaken on the Product in the Territory. PolyPid agrees to notify Partner immediately if a Regulatory Authority outside of the Territory has requested a Recall or if PolyPid is contemplating a voluntary Recall outside of the Territory.

Recall Costs. The cost and expense of a Recall shall be allocated as follows:

(i) if such Recall is due to a Packaging defect or Partner's misconduct (such as improper handling or storage following delivery of the Product pursuant to Section 8.04) or if the Product became Defective following dispatch from PolyPid (excluding for the avoidance of doubt any Hidden Defects), all Recall costs and expenses shall be borne and paid solely by Partner;

(ii) if such Recall is due to any other reason, all such costs and expenses shall be borne and paid solely by PolyPid.

Section 5.10 Sample Retention by Partner.

Partner shall retain at its expense a sample of each Batch of Product for a period equal to such period as required by Applicable Laws and Regulatory Authorities in the Territory.

Section 5.11 Assistance.

Each Party shall provide reasonable assistance to the other at the other's request, in connection with their obligations pursuant to this Article V.

**ARTICLE VI
COMMERCIALIZATION**

Section 6.01 Commercialization of the Product in the Territory.

[**]

Section 6.02 Advertising and Promotional Materials and Promotional Policies.

(a) *Tools, Materials.* Partner, at its expense, will develop all advertising and promotional tools and materials relating to the Commercialization of the Product in the Territory. Key advertising and promotional tools and materials shall be subject to Polypid's review and approval, which shall not be unreasonably withheld, delayed or conditioned. All the advertising and promotional tools and marketing materials shall be made available to PolyPid once finalized.

(b) Partner agrees that any promotional material, promotional literature shall follow the Brand Book (which may incorporate adjustment for any local requirements in the Territory) and shall not be misbranded, changed, altered or adulterated by it or any of its agents in any way prior to their distribution or use by Partner or its sales representatives.

(c) Copies of all promotional materials used by Partner with respect to Products in the Territory will be archived in accordance with Applicable Laws and the terms of this Agreement.

Section 6.03 Medical Affairs

(a) Partner shall undertake the Medical Affairs Activities required for the Commercialization of the Product in the Territory. However, Partner shall not undertake any additional studies that are required by the Regulatory Authorities to Commercialize the Product in the Territory. Partner agrees that all Medical Affairs Activities initiated and/or conducted by Partner shall be coordinated with PolyPid.

(b) Without derogating from the foregoing, the following shall apply with respect to Medical Affairs Activities:

(i) Communication regarding Medical Affairs Activities should be aligned with the global scientific platform to be provided to the Partner by Polypid.

(ii) PolyPid shall be solely responsible for any publications regarding the Product in any global or international journals. Prior to publishing, PolyPid shall provide Partner with copies of its proposed publication. Furthermore, Partner shall be entitled to publish publications regarding the Product in any global or international journals with PolyPid's prior written consent.

Section 6.04 Minimum Sales Requirements.

[**]

Section 6.05 Business Plan.

(a) Eighteen (18) months prior to the first commercial sale of the Product, Partner shall provide PolyPid with a proposed and rolling business plan with respect to Partner's marketing activities, brand strategy, budgets and expected sales of the Product in the Territory for the [**] period following the Effective Date, including information on (i) the Product's positioning and planned price in the Territory; (ii) competitors; (iii) non-binding sales projections and anticipated revenues; (iv) overall strategy; (v) marketing, advertising and sales force activities and budgets; and (vi) the assumptions upon which such business plan is based. Such business plan shall be based on and aligned with the high-level business plan attached hereto as Exhibit E (the "Business Plan"). Partner shall share the updated proposed, and rolling business plan every Calendar Year.

(b) For the sake of clarity, Partner shall provide suitable sales and distribution capacity in the Territory necessary to fully carry out its obligations under this Agreement, with sales training to occur within one (1) month of the Product Launch and periodically thereafter as reasonably necessary to ensure a well-trained sales staff on all aspects of each Product. PolyPid shall have the right to initiate and be present for Product sales training with Partner once per year. Partner shall ensure that its staff are properly trained with respect to: (a) the labeling for the Product approved by the Regulatory Authorities in the Territory; (b) any applicable regulatory guidance for industry-supported scientific and educational activities; (c) any applicable professional code on interactions with healthcare professionals or patients; (d) any applicable standards for commercial support of continuing medical education; (e) any applicable industry guidelines, codes on gifts to physicians or other health care professionals (anti-kickback laws and regulations); and (f) any Applicable Laws governing their activities regarding the Product.

(c) In order to ensure compliance by a Party (or any one on its behalf) with Applicable Laws, including without limitation, compliance with regulatory requirements regarding marketing and promotion of pharmaceutical products, the other Party may request reasonable information and/or written reports confirming such compliance by such Party.

Section 6.06 Additional Studies.

Without the prior written approval of PolyPid, neither Partner nor any of its Affiliates shall, directly or indirectly, initiate, conduct, engage in or fund any studies including, without limitation, pre-clinical, clinical studies, or post marketing or any laboratory or research and development work with respect to the Product. Any studies approved by PolyPid, that Partner agrees to participate in, shall be conducted in accordance with a separate agreement to be entered into between the Parties.

Section 6.07 []**

Section 6.08 Change of Control

[**]

Section 6.09 []**

**ARTICLE VII
MANUFACTURE, SUPPLY AND PACKAGING**

Section 7.01 Agreement to Supply Product.

(a) PolyPid shall Manufacture the Product in compliance with the Product Specifications, the Quality Agreement, cGMP and other Applicable Law, and shall Manufacture Products in sufficient quantities to fulfill the Firm Purchase Orders provided in compliance with the terms of this Agreement.

(b) Subject to the terms hereof, Partner agrees to purchase exclusively from PolyPid, and PolyPid agrees to supply for, and sell exclusively to Partner during the Term of this Agreement, Product in the Territory. PolyPid may subcontract any part of the Manufacturing Process for the Product to a Third Party provided: (a) the Product and the facilities continue to meet the requirements as defined in this Agreement; (b) PolyPid has obtained all required Governmental Approvals to subcontract any part of the Manufacturing Process for the Product to be sold in the Territory; and (c) the Third Party has obtained all required Governmental Approvals for the Manufacturing Process for the Product to be sold in the Territory.

(c) All Product supplied by PolyPid to Partner shall be supplied in vials, unlabeled and bulk-packaged by PolyPid for shipment. Upon receipt of Product, Partner shall Package each individual vial in accordance with the Packaging Specifications, the Quality Agreement, cGMP and other Applicable Laws and using the Packaging Materials approved by PolyPid.

(d) *Allocation of Tasks and Responsibilities re Supply Chain.* The Parties agree that the allocation of the tasks and responsibilities between them with respect to the supply chain of the Products shall be as set forth in Schedule 9 attached hereto.

Section 7.02 Quality Assurance.

(a) Parties shall commence negotiations on the Quality Agreement promptly following the Effective Date, and shall enter into a Quality Agreement as soon as reasonably practicable following the Effective Date.

(b) Release procedures with respect to the Product shall be defined in the Quality Agreement.

(c) The Quality Agreement shall set forth the terms and conditions upon which each Party will conduct its quality activities in connection with this Agreement. Each Party shall duly and punctually perform all of its obligations under the Quality Agreement. If there is any conflict or inconsistency between this Agreement and the Quality Agreement, then the Quality Agreement will control to the extent the conflict or inconsistency relates to a matter involving quality of the Product. The Quality Agreement is hereby incorporated by reference.

Section 7.03 Packaging.

(a) Partner shall ensure that the Packaging Company Packages the unlabeled vials of the Product in accordance with the Packaging Specifications, the Quality Agreement, cGMP and other Applicable Laws.

(b) [**]

(c) [**]

**ARTICLE VIII
PURCHASE PRICE, FORECASTS, ORDERS AND CAPACITY**

Section 8.01 Purchase Price.

(a) PolyPid shall sell, and Partner shall purchase, each unlabeled vial of Product at the price per unit set forth in Schedule 1 (the "Purchase Price").

(b) PolyPid will invoice Partner the Product Price within [**]. PolyPid will invoice Partner the Product Net Sales, as set out in Schedule 1, [**]. Partner shall provide PolyPid with the Purchase Order number to be quoted in said Product Net Sales invoice within [**]. The Product Net Sales invoice shall detail the applicable Net Sales in accordance with Section 8.01(c) below. All Product Price invoices will be sent electronically, in PDF form, to [**] along with the valid Purchase Order number mentioned therein. The Product Net Sales invoice shall be paid [**] calendar days of receipt of the invoice. The Product Price invoices shall contain the number of units of the Product provided during the relevant period. The Product Net Sales invoices shall also be sent electronically, in PDF form, to [**] and shall reference the applicable Quarterly Net Sales Report. Payment of all Product Price invoices will be due within [**]. All payment shall be made by wire transfer of immediately available funds.

(c) In the event that Partner disputes any part of an invoice provided by PolyPid, Partner shall pay the undisputed portion of the invoice in accordance with the applicable payment terms specified in the Agreement and shall provide written notice regarding such dispute to PolyPid within [**] days after receipt of the applicable invoice (an “Invoice Dispute”). In the event that no Invoice Dispute has been received within such [**] days period with respect to a certain invoice, then the entirety of such invoice shall be deemed undisputed. In the event that in an applicable Calendar Year that the aggregate amounts covered in the invoice(s) submitted in such Calendar Year which are subject to an Invoice Dispute constitute more than [**]% of the aggregate amounts covered under all invoices submitted in such Calendar Year, the Parties shall discuss in good faith the invoice management process and a reduction in the aforementioned [**] days period.

(d) If the Parties fail to resolve the Invoice Dispute, they shall refer the dispute to the executives of the Parties for their resolution. If the executives of the Parties fail to resolve the Invoice Dispute within [**] days after the matter was referred to them, the Parties shall mutually select an independent auditor mutually acceptable to both Parties from an independent accounting firm (out of the “Big Four”) and which is unaffiliated with either of the Parties (the “Independent Auditor”). The Independent Auditor shall be required to provide its decision regarding the Invoice Dispute within [**] days after the matter has been referred to him or her. In the event that Independent Auditor shall have resolved the Invoice Dispute in PolyPid’s favor, then Partner shall pay that part of the invoice which Partner has disputed together with interest calculated in accordance with Section 9.02(b) below and shall bear the costs of the Independent Auditor’s review. In the event that the Independent Auditor resolves in Partner’s favor then PolyPid shall issue a revised invoice conforming with the resolution of the Independent Auditor and PolyPid shall bear the costs of the Independent Auditor. In the event that the Independent Auditor has resolved the Invoice Dispute in a manner that both accepts certain claims of Partner and rejects other claims of Partner, then PolyPid shall issue a revised invoice, Partner shall pay the amounts covered under such revised invoice together with interest calculated in accordance with Section 9.02(b) and the Parties shall equally share the cost of such Independent Auditor.

(e) [**]

Section 8.02 Forecasts and Orders.

(a) The Forecast. [**]

(b) Manufacturing Capacity. PolyPid commits [**] to take whatever steps may reasonably be required to the extent required to be able to Manufacture and to meet the Partner’s Minimum Volumes of the Product applicable to a certain Minimum Sales Period. PolyPid shall keep Partner regularly informed of its Manufacturing capacity for the Product, and shall promptly notify Partner if at any time PolyPid anticipates that it will not be able to Manufacture and supply to Partner the amount of Product set forth in the Rolling Forecast [**], and shall provide Partner its best estimate of the timing and quantities of the Product that it will be able to supply.

(c) [**]

(d) [**]

(e) Partner shall handle all Products on a first expired first out (FEFO) basis.

Section 8.03 Purchase Order.

(a) Partner's purchase orders for the Products (each a "Purchase Order") shall set forth (i) the quantity or amount ordered, as set forth above; and (ii) the requested delivery date, which date shall be no less than [**] days from the date of such Purchase Order. PolyPid shall accept each Purchase Order within [**] calendar days of its receipt, except that PolyPid may reject any Purchase Order for failure to comply with [**] the terms of this Agreement, subject to Section 8.02(c) above. If PolyPid rejects a Purchase Order not in accordance with the foregoing or does not confirm its acceptance or rejection of a Purchase Order within such [**] day period provided same complies with the binding portion of the Rolling Forecast and the terms of this Agreement and subject to Section 8.02(c) above, such Purchase Order shall be deemed to have been accepted by PolyPid. If PolyPid is unable to deliver the entire amount of any Purchase Order by the requested delivery date, PolyPid shall promptly notify Partner of such inability and when it expects to delivery such Purchase Order quantities. Each Purchase Order accepted by Polypid or deemed to have been accepted by Polypid under this Section 8.03 shall be deemed a "Firm Purchase Order".

(b) In the event there is a conflict between the terms of the Purchase Order and this Agreement, the terms of this Agreement shall govern.

Section 8.04 Delivery.

PolyPid shall deliver the Products [**] in accordance with the relevant Purchase Order and consistent with the terms of this Agreement. PolyPid shall provide Partner with [**] Business Days' notice prior to delivery. [**]. Each Product Shipment shall be accompanied by a Certificate of Compliance and a Certificate of Analysis confirming that such Products were Manufactured and tested in accordance with this Agreement, the Product Specifications, the Quality Agreement and all Applicable Laws, including, but not limited to cGMP. Title and risk of loss will pass to Partner when the Product is available to Partner's designated carrier in accordance with the above Incoterm.

Section 8.05 Rejection of Product for Failure to Conform to Specifications.

(a) Partner shall visually inspect the Products upon receipt thereof and Partner shall have [**] days following delivery of any Shipment to notify PolyPid in writing that a Product is Defective or there is a shortage against the quantity listed in the Purchase Order, for reasons not attributable to Partner or anyone on its behalf (such notice being a "Defect Notice"). The Defect Notice shall specify in reasonable detail the nature and basis for the claim that the Product is Defective or short. PolyPid shall review any Defect Notice and provide Partner with the results of such review within [**] days after its receipt of the Defect Notice. Notwithstanding the foregoing, should the Product have a Hidden Defect (which is not attributable to Partner or anyone on its behalf), Partner will provide a Defect Notice to PolyPid of the Hidden Defect within [**] Business Days following its discovery. Should Partner fail to provide a Defect Notice within the prescribed timelines, the Product shall be deemed to have been accepted.

(b) If PolyPid’s review confirms that the Product is Defective for reasons not attributable to Partner (or any one acting on Partner’s behalf), then Partner may reject such batch of Defective Product and shall, at PolyPid’s expense, dispose of or deliver such Defective Product to such destination as PolyPid shall direct in writing (provided that such directions are in compliance with applicable environmental laws and regulations). PolyPid shall, deliver replacement Product to Partner for the Defective Shipment, at PolyPid’s expense, no later than [**] months from Partner’s request provided that PolyPid shall use Commercially Reasonable Efforts to provide such replacement product as soon as possible prior to the end of such [**] months period.

(c) If the Parties fail to agree as to whether a Product is Defective for reasons not attributable to Partner (or any one acting on Partner’s behalf), then the Parties agree to have the Shipment in dispute tested and further analyzed by an independent testing laboratory mutually selected by the Parties, whose results shall be binding on the Parties. The cost of the assessment shall be borne by (i) Partner, if the findings indicate the Product is either not Defective or the Defect is attributable to Partner; (ii) PolyPid, if the findings indicate the Product is Defective and such Defect is attributable to PolyPid; or (iii) both, in proportion relative to each Party’s error or oversight if the findings indicate that each Party was at fault.

(d) In the event Product has been previously returned to PolyPid and the independent testing laboratory determines that the Product is not Defective, Partner shall be responsible for all costs associated with the return. If such laboratory testing determines that the Product in dispute is Defective due to the error or oversight of both Parties, then the Parties shall discuss in good faith the costs associated with the disposal of the Defective Products and the delivery of replacement Products (having regard to each Party’s relative error or oversight).

(e) Except as expressly provided in Section 8.05, and other than in respect of the return of stock during the Notice Period following termination, no Product supplied by or on behalf of PolyPid to Advanz may be returned by Advanz after it has been delivered to Advanz.

Section 8.06 Failure to Supply. []**

**ARTICLE IX
COMPENSATION**

Section 9.01 Milestone Payments.

(a) In consideration for the rights and licenses granted under this Agreement and PolyPid’s performance of its obligations under this Agreement, Partner shall pay to PolyPid the following one-time non-refundable, non-creditable milestone payments (the “Milestone Payments”):

(i) € 2,500,000 on the date of last signature of this Agreement (the “Upfront Payment”).

[**]

Section 9.02 Payment Terms.

(a) Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in Euro. All payments owed under this Agreement shall be made by wire transfer to a bank account designated by PolyPid, unless otherwise specified in writing by PolyPid. For avoidance of doubt, Partner shall place Purchase Orders in Euro using the Product Price calculated under Section 8.01.

(b) Late Payments. Any undisputed payment that is past due under this Agreement shall bear interest in the amount of [**] above the Bank of England rate.

(c) Taxes:

Value added taxes will be added to all amounts due, where applicable.

All payments shall be made without deduction or withholding. The Parties understand that PolyPid is resident for tax purposes in Israel. In the event that PolyPid shall cease to be a resident of Israel for tax purposes after the Effective Date, the Parties shall discuss in good faith if adjustments to this Section are required in light of the change in residency. Partner shall be responsible for the payment of any and all currently applicable or hereinafter imposed taxes, duties, levies and other charges that arise out of this Agreement and/or the purchase or importation of the Products.

For the avoidance of doubt, the Partner is not responsible for bearing any tax related cost for which PolyPid is liable in PolyPid's country of Residency unless expressly agreed to in writing.

To the extent withholding taxes are imposed on any payment due to PolyPid, the amount paid by Partner to PolyPid shall be increased by an amount sufficient to result in a net payment to PolyPid, after withholding taxes, equal to the total price which would have been paid to PolyPid had the withholding tax not been imposed.

Section 9.03 Reporting.

(a) *Reports.* No later than the seventh (7th) Business Day following the end of each calendar month, Partner shall provide PolyPid with the previous month's flash sales report. Within [**] Business Days following the end of each calendar month, Partner shall furnish to PolyPid (A) a monthly written report showing on a Product-by-Product and country-by-country basis the total units of Product sold and Net Sales in Euros during the preceding month, and (B) month end inventory amounts (including lot numbers for each Product).

(b) *Records and Audits.* During the Term and for a period of [**] years thereafter or as otherwise required in order for PolyPid to comply with Applicable Law, Partner shall keep complete and accurate records in sufficient detail to permit PolyPid to confirm the completeness and accuracy of the information presented in each Net Sales statement and all payments due hereunder (the "Accounting Records"). Subject to Section 6.08(d), Partner shall permit an independent, certified public accountant (the "Third Party Accountant") reasonably selected by PolyPid and reasonably acceptable to Partner, to audit and/or inspect the Accounting Records to verify their accuracy, completeness and full compliance with the terms of this Agreement. Such inspection shall be conducted during Partner's normal business hours, and (i) no more than [**] per Calendar Year and upon at least thirty (30) days prior written notice by PolyPid to Partner. If the Third Party Accountant concludes that such payments were underpaid for the preceding twelve (12) months period, Partner shall pay PolyPid the amount of any such underpayments for the preceding twelve (12) months period, plus interest at the rate set out in Section 9.02(b), within thirty (30) days of the date PolyPid delivers to Partner such report so concluding that such payments were underpaid for the preceding twelve (12) months period. If the Third Party Accountant concludes that such payments were overpaid for the preceding twelve (12) months period, PolyPid shall pay to Partner the amount of any such overpayments for the preceding twelve (12) months period, plus interest at the rate set out in Section 9.02(b), within thirty (30) days of the date PolyPid delivers to Partner such report so concluding that such payments were overpaid for the preceding twelve (12) months period. PolyPid shall bear the full cost of such audit unless such audit discloses an underpayment by more than [**] ([**]%) of the amount due for the preceding twelve (12) months period. In such case, Partner shall bear the reasonable fees and cost of such audit.

(c) In addition to the audit/inspection right referred to above, in the event that PolyPid acting reasonably and in good faith can demonstrate a compelling business reason for performing an audit/inspection of the Accounting Records, PolyPid shall provide written notice to Partner detailing such compelling reason, and thereafter, shall be granted an additional right to audit and/or inspect the Accounting Records, and the provisions of the subsection (b) above shall apply mutatis mutandis with respect to the period to which the audit/inspection shall be performed.

ARTICLE X PATENTS AND TRADEMARKS

Section 10.01 Maintenance of Patents or Marks.

During the Term, PolyPid shall, at PolyPid's expense, prepare, file, prosecute, maintain and protect the Licensed Patent Rights in the Key Countries and Launching Countries, and the Marks in all European Union countries and in the United Kingdom. Should PolyPid elect not to prosecute, maintain or protect the Licensed Patent Rights in a country in the Territory that is not a Key Country or a Launching Country, Partner shall have the right to do so, at its own expense but in the name of PolyPid. Any such action shall not grant Partner any rights in or to the Licensed Patent Rights or the Marks beyond the rights granted in Section 3.01 herein. [**]

Section 10.02 Prosecution of Infringement.

(a) During the Term, each Party shall give prompt notice to the other of any Third Party act that may infringe the Licensed Patent Rights or the Marks in the Territory.

(b) PolyPid shall have the first option, but not the obligation to take action to obtain a discontinuance of infringement or bring suit against such Third Party infringer (the "Enforcement Action"). Partner shall provide such assistance and cooperation to PolyPid as may be reasonably necessary to support the Enforcement Action against the Third Party infringer.

(c) If Polypid elects not to bring an Enforcement Action against the Third Party infringer, Partner shall have the right to do so. If Partner elects to take action to obtain a discontinuance of infringement or bring suit against such Third Party infringer, Polypid shall not assign its right to sue any potential infringer to any Third Party.

(d) Any recoveries obtained by the Party leading the Enforcement Action (the “Enforcing Party”) shall be allocated as follows:

(i) the recoveries shall first be used to reimburse the Enforcing Party for all reasonable costs and expenses incurred by the Enforcing Party in connection with the Enforcement Action.

(ii) the remainder of the recoveries shall then be retained (a) by PolyPid if PolyPid is the Enforcing Party, or (b) by Partner if Partner is the Enforcing Party.

ARTICLE XI CONFIDENTIALITY

Section 11.01 Confidentiality.

(a) Each Party agrees that, during the Term and for a period of [**] years thereafter, or for [**] years from the Effective Date (whichever period is longer), it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party’s Confidential Information that the receiving Party can demonstrate by competent written proof:

(i) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliate in breach of this Agreement;

(iv) was disclosed to the receiving Party or its Affiliate without any confidentiality obligations by a Third Party who, to the Party’s knowledge, had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(v) was independently discovered or developed by or on behalf of the receiving Party or its Affiliate by persons without access to the other Party’s Confidential Information, as evidenced by a contemporaneous writing.

(b) For purposes of this Section 11.01(a)(i)–(v), Confidential Information disclosed under this Agreement shall not be deemed to be within such exceptions unless such information is readily accessible to the public in a written publication, and such exceptions shall not include information the substance of which must be pieced together from a number of different publications or other sources.

Section 11.02 Authorized Disclosure.

(a) Notwithstanding the obligations set forth in Section 11.01, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(i) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent Rights as contemplated herein; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of Product in the Territory; and (iii) for the prosecuting or defending litigation as contemplated herein;

(ii) such disclosure is reasonably necessary to its or its Affiliate's employees, agents, consultants, contractors, licensees or sublicensees on a "need-to-know basis" for the sole purpose of performing its obligations or exercising its rights hereunder; provided that in each case, the disclosees are bound by written obligations of confidentiality consistent with those contained in this Agreement;

(iii) such disclosure is reasonably necessary on a "need-to-know basis" to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner, as part of such Third Party's due diligence process and for the sole purpose of evaluating or carrying out an actual or potential investment, acquisition or other business relationship, provided that (i) such Third Party is not a competitor of the other Party; and (ii) prior to disclosure, such Third Party must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article XI; or

(iv) it is, in the reasonable opinion of the receiving Party's counsel, required to comply with Applicable Laws, including regulations or rules promulgated by applicable securities commissions (or other securities regulatory authorities), security exchanges, court order, administrative subpoena or order.

(b) Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.02(a)(i) or (iv), such Party shall promptly notify the other Party of such required disclosure, to the extent that it is legally authorized or permitted to so, and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

Section 11.03 Publicity; Terms of Agreement.

(a) The Parties agree that the terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 11.03.

(b) The Parties have agreed upon in principle the initial press release to announce the execution of this Agreement in substantially the form attached hereto as Exhibit D, which shall be finalized upon mutual agreement by the Parties before release. After such initial press release, if either Party desires to make a public disclosure concerning the terms of this Agreement or the engagement hereunder, such Party shall give reasonable prior advance notice of the proposed text of such public disclosure to the other Party for its prior review and written approval (except as otherwise provided herein), which approval shall not be unreasonably withheld, conditioned, or delayed. A Party commenting on such a proposed disclosure shall provide its comments, if any, within fifteen (15) Business Days after receiving the proposed disclosure for review (or such shorter period of time as necessitated by regulatory requirements). In relation to the other Party's review of a public disclosure, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary.

(c) Either or both Parties or their Affiliates may be obligated to file under applicable laws a copy of this Agreement with Governmental Authorities, including the U.S. Securities and Exchange Commission. Each Party and its Affiliates may make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party or its Affiliate intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's timely comments thereon to the extent consistent with the legal requirements.

(d) Partner acknowledges that PolyPid is a public company whose shares are publicly traded on the NASDAQ (ticker symbol PYPD). Accordingly PolyPid's Confidential Information may be considered as "inside information" pursuant to US securities laws and regulations and Partner undertakes not to use any Confidential Information in violation of the applicable securities laws.

Section 11.04 Equitable Relief.

Each Party acknowledges that its breach of this Article XI will cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article XI by the other Party.

ARTICLE XII REPRESENTATIONS AND WARRANTIES; COVENANTS

Section 12.01 Mutual Representations and Warranties.

(a) Each Party hereby represents, warrants and covenants to the other Party that, as of the Effective Date:

(i) *Corporate Power*. It is duly organized and validly existing under the laws of the jurisdiction of its incorporation or formation and has full power and authority to enter into this Agreement and the transactions contemplated herein and to perform its obligations hereunder.

(ii) *Due Authorization; Binding Obligations.* The execution, delivery and performance of this Agreement by such Party does not conflict with any applicable laws, such Party's documents of incorporation or by-laws, or any agreement by which it is bound, and has been duly authorized by all requisite corporate action and does not require any shareholder action or approval.

(iii) *Anti-Corruption and Ethical Conduct.*

- (1) Each Party hereby represents, warrants and covenants that it complies with the Ethical Business Conduct Laws and neither such Party nor any of its employees, directors, or Affiliates is under investigation or trial for violation of any Anti-Corruption Laws and that, neither it nor to the knowledge of such Party, any of its employees, directors or Affiliates has taken any action which is a violation of Anti-Corruption Laws.
- (2) Each Party hereby covenants to comply with the Ethical Business Conduct Laws at all times during the Term.
- (3) Polypid shall comply with Advanz's current Anti-Bribery and Anti-Modern Slavery Declaration (attached as Schedule 7A), and Partner shall comply with Polypid's current Anti-corruption Policy (attached as Schedule 7B).
- (4) Each Party hereby covenants to give regular training on these issues to its employees throughout the Term.

(b) Debarment. Each Party hereby covenants to the other Party it is not and has not been debarred or suspended, and that when performing its activities pursuant to this Agreement, it will not employ any personnel or use a subcontractor or consultant that has been debarred or is subject to a similar sanction by any Governmental Authority or that is the subject of any investigation or proceeding with respect thereto.

Section 12.02 Additional Representations, Warranties and Covenants of Partner.

(a) *Compliance.* Partner represents, warrants and covenants to PolyPid that it will comply with the Product Specifications, Marketing Authorization, Quality Agreement and applicable laws with respect to the Packaging of the Product, procurement of Pricing and Reimbursement Approvals and all Commercialization activities carried out under this Agreement.

(b) *Requisite Approvals.* Partner represents, warrants and covenants to PolyPid that, save for the Marketing Authorizations, it holds and shall cause its sub-licensees and distributors to hold in good standing all Regulatory Approvals and all licenses, permits and approvals required by the Regulatory Authorities to Package and Commercialize the Product in the Territory, including without limitation Pricing and Reimbursement Approvals.

Section 12.03 Additional Representations, Warranties and Covenants of PolyPid.

(a) *Product Representations and Warranties.* PolyPid represents, warrants and covenants to Partner that Products supplied to Partner pursuant to this Agreement shall: (i) conform in all material respects with this Agreement, the Product Specifications, Quality Agreement and all Applicable Laws, including, without limitation, cGMP, at the date of delivery; (ii) be delivered free from any defects, liens and encumbrances and Partner shall receive good and marketable title to the Product; and (iii) at the date of Manufacture that PolyPid have the right to Manufacture and label the Product (items (i) through (iii), collectively, the “Product Requirements”).

(b) *No Conflicting Grant of Licensed Patent Rights.* PolyPid represents and warrants that on the Effective Date, (a) to its knowledge, it Controls or it is the sole owner of all right, title and interest in and to the Licensed Know-How, Licensed Patent Rights and the Marks, and (b) it has not granted any license under the Licensed Know-How, Licensed Patent Rights or the Marks for any Product for the Indication in the Territory to any Third Party.

(c) *Licensed Patent Rights and Marks.* PolyPid represents and warrants that, as of the Effective Date:

(i) the Licensed Patent Rights in existence as of the Effective Date exist and are not invalid, in whole or in part;

(ii) to PolyPid’s knowledge, it has the full right, power and authority to grant the license under Section 3.01(a);

(iii) to PolyPid’s knowledge, there are no threatened or pending claims, judgments or settlements against or owed by PolyPid relating to the Licensed Technology Rights and/or the Marks; and

(iv) to PolyPid’s knowledge, no adverse claim has been made or threatened against it that is likely to prevent or materially interfere with Partner’s performance under this Agreement or materially adversely affect the rights and interests of Partner hereunder.

(d) *Sufficiency.* Except as set forth in Section 12.02, PolyPid represents and warrants that, to PolyPid’s knowledge at the Effective Date, the Licensed Technology constitutes all of the Know-How necessary for Partner to Commercialize the Product for the Indication in the Territory.

Section 12.04 Limitation to the Territory.

Partner covenants and agrees that it will not, nor shall it permit its Affiliates or its or their respective sublicensees, without the prior written authorization of PolyPid, to the extent allowed by Applicable Laws, to:

(a) promote or actively solicit sale of the Product or advertise the Product, in any country:

- (i) where it does not have the necessary Regulatory Approval; or
- (ii) that is not part of the Territory;

(b) with regard to the Product, contact any of PolyPid's suppliers or vendors, without PolyPid's prior approval, to discuss the Product or the Product's components;

(c) liaise with the Regulatory Authorities located outside the Territory regarding the Product, except as required by Applicable Laws or as may be necessary or appropriate to carry out its obligations as set forth in this Agreement; and

(d) knowingly sell or distribute for resale the Product purchased hereunder to a Third Party who intends to sell such Product in a country that is not part of the Territory.

Section 12.05 Compliance With Laws.

(a) Each Party shall, and shall ensure that its Affiliates and their respective subcontractors and sublicensees will, comply in all respects with any and all Applicable Laws, including but not limited to, Anti-Corruption Laws and anti-bribery practices in the development, Manufacturing and Commercialization of Products and performance of its obligations under this Agreement.

(b) The Parties agree that if at any time the representation and warranties under Section 12.01(a)(iii) are no longer true, accurate and complete, the Parties will immediately notify each other in writing and provide a supplementary report detailing such change. The informing Party will take reasonable actions to remedy such breach and to prevent further such breaches from occurring.

(c) In the event of breach of Section 12.01(a)(iii), the non-breaching Party will have the right to suspend or terminate this Agreement upon written notice to the other Party.

Section 12.06 No Other Representations or Warranties.

EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY OR ITS AFFILIATES, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. FOR CLARITY AND WITHOUT LIMITING THE FOREGOING, POLYPID MAKES NO REPRESENTATION OR WARRANTY CONCERNING THE PRODUCTS OR LICENSED TECHNOLOGY EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT.

**ARTICLE XIII
INDEMNIFICATION**

Section 13.01 Partner Indemnified by PolyPid.

PolyPid shall indemnify and hold Partner, its Affiliates, and their respective employees, directors, officers, and their respective permitted successors and assigns (collectively, the "Partner Indemnitee") harmless, from and against any Third Party investigation, claims demand, action or suit (the "Third Party Claim") and any related liabilities, obligations, damages, losses, claims, encumbrances, costs or expenses (including reasonable attorneys' fees) (any or all of the foregoing herein referred to as "Loss"), which Partner Indemnitee may incur or suffer as a result of such Third Party Claim, arising out of or based upon:

- (a) any gross negligence or willful misconduct on the part of PolyPid or any PolyPid Indemnitee;
- (b) the Manufacturing of the Product pursuant to the terms of the Agreement;
- (c) pursuant to Section 5.08, the Recall of a Product;
- (d) [**]

(e) infringement or alleged infringement of any Third Party intellectual property rights in relation to the Product, Marks, Polypid's trademarked name or logo or Licensed Technology; and/or

- (f) [**]

provided that, the indemnity set forth in this Section 13.01 shall not apply to the extent the Loss is attributable to any act or omission of Partner or in the event that Partner has an indemnification obligation pursuant to Section 13.02.

Section 13.02 PolyPid Indemnified by Partner.

Partner shall indemnify and hold PolyPid, its Affiliates, and their respective employees, directors, officers, and their respective permitted successors and assigns (collectively, the "PolyPid Indemnitee") harmless from and against any Third Party Claim and any related Loss, which PolyPid Indemnitee may incur or suffer as a result of such Third Party Claim, arising out of or based upon:

- (a) any gross negligence or willful misconduct on the part of Partner or any Partner Indemnitee; and/or
- (b) following the delivery of the Product as per Section 8.04, the transport, storage and handling of the Product contrary to the terms of the Agreement, by or on behalf of the Partner;
- (c) the Packaging of the Product by or on behalf of the Partner,

(d) [**]

(e) the Commercialization of the Product by or on behalf of the Partner;

(f) pursuant to Section 5.08, the Recall of a Product; and/or

(g) [**]

provided that the indemnity set forth in this Section 13.02 shall not apply to the extent that Partner has an indemnification obligation pursuant to Section 13.01.

Section 13.03 Claims and Proceeding.

In the event that any person (an “Indemnitee”) entitled to indemnification under Section 13.01 or Section 13.02 is seeking such indemnification, such Indemnitee shall (a) inform, in writing, the indemnifying Party (the “Indemnitor”) as soon as reasonably practicable after such Indemnitee receives notice of such Third Party Claim, provided that the failure to notify the Indemnitor shall not relieve the Indemnitor from any liability except to the extent that such failure to notify actually adversely impacts the Indemnitor’s ability to defend such Third Party Claim; (b) permit the Indemnitor to assume direction and control of the defense of the Third Party Claim (provided, that (i) the Indemnitor promptly takes control of the defense of the Third Party Claim following receipt of a notice, and (ii) neither the Indemnitee nor the Indemnitor may settle the Third Party Claim without the prior consent of the other Party, not to be unreasonably withheld, conditioned or delayed), (c) cooperate as reasonably requested (at the expense of the Indemnitor) in the defense of the Third Party Claim, and (d) undertake all reasonable steps to mitigate any loss, damage or expense with respect to the Third Party Claim(s). Without limiting the foregoing, any Indemnitee will be entitled to participate in the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, that such employment will be at the Indemnitee’s own expense unless (i) the employment thereof has been specifically authorized by the Indemnitor in writing, or (ii) the Indemnitor has failed to assume the defense (or having elected to assume control of the defense, has failed to diligently defend such Third Party Claim) and employ counsel in accordance with this Section 13.03, in which case the Indemnitee will be allowed to control the defense. Such notice shall state that the Indemnitor is required to indemnify the Indemnitee for a Loss and shall specify the amount of Loss and relevant details thereof.

Section 13.04 Limitation of Liability.

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT WILL EITHER PARTY’S TOTAL LIABILITY UNDER THIS AGREEMENT EXCEED [**]. THE FOREGOING SHALL NOT APPLY IN RESPECT OF A PARTY’S FRAUD, OR WILFUL MISCONDUCT, DEATH OR BODILY INJURY, INDEMNIFICATION OBLIGATIONS REGARDING BREACH OF A THIRD PARTY’S INTELLECTUAL PROPERTY OR BREACH OF CONFIDENTIALITY OBLIGATIONS. THIS SECTION 13.05 SHALL NOT LIMIT PARTNER’S AND ITS AFFILIATES’ PAYMENT OBLIGATIONS UNDER THIS AGREEMENT AND SHALL NOT APPLY TO THE EXTENT PROHIBITED BY APPLICABLE LAW.

Section 13.05 Insurance.

(a) Each Party shall, at its sole cost and expense, secure and maintain in full force and effect during the Term, and for a period of [**] years thereafter, the following insurance(s): [**]

(b) Each Party will on request provide the other Party with evidence to confirm the insurance coverage it has in place. Failure to maintain insurance coverage in accordance with the minimum limits stated in this Section 13.05 constitutes a material breach of this Agreement.

**ARTICLE XIV
TERM; DEFAULT AND TERMINATION**

Section 14.01 Term.

This Agreement shall commence as of the Effective Date and shall, subject to the early termination provisions as specified herein and subject to applicable law, expire on the later of: (i) 31 December 2035, or, (ii) ten (10) years after the first commercial sale of the Product in the Territory (the "Term").

Section 14.02 Termination by Either Party.

In addition to the early termination rights of each Party as expressly indicated in this Agreement, including, but not limited to in Sections 1.01(b) (iii), 3.06, 6.04(i)(ii), 6.04(k)(iii) , 6.08(a), 8.06(b)(ii), 12.05(c) and 16.04, either Party may terminate this Agreement:

(a) Upon written notice following the cessation of operations of the other Party,

(b) Upon written notice if the other Party (i) files a petition in bankruptcy; (ii) becomes insolvent, (iii) makes a general assignment for the benefit of creditors; (iv) admits in writing its inability to pay its debts as they mature; or (v) has a receiver appointed for its assets and such appointment is not discharged within thirty (30) days, or

(c) If the other Party commits a material breach or default under this Agreement, the non-breaching Party may give the breaching Party written notice of such breach or default, and shall request that such breach or default be cured as soon as reasonably practicable. In the event that the breaching Party fails to cure such breach or default within sixty (60) calendar days after the date of the non-breaching Party's written notice thereof (in the event of either Party's default of undisputed payments due under this Agreement, then within thirty (30) calendar days after the date of the non-breaching Party's notice thereof), the non-breaching Party may terminate this Agreement with immediate effect by giving written notice of termination to the breaching Party.

Section 14.03 Remedies.

Unless otherwise expressly provided for in this Agreement, all of the non-breaching Party's remedies shall be cumulative, and the exercise of one remedy hereunder by the non-defaulting Party shall not be deemed to be an election of remedies. These remedies shall include the non-breaching Party's right to claim damages for such breach without terminating this Agreement.

Section 14.04 Effect of Termination.

Upon the expiration or termination of this Agreement by either Party, the following shall occur:

(a) Partner's license under Section 3.01 of this Agreement shall automatically terminate and all of PolyPid's rights to the Licensed Technology, the Data and Marks shall continue to be the sole property of PolyPid;

(b) each Party shall pay all undisputed amounts then due and owing as of the effective termination date provided that with respect to an Invoice Dispute the Parties shall continue to follow the resolution mechanism specified in Section 8.01(c) above after termination or expiration of this Agreement;

(c) each Party will return to the disclosing Party, or destroy at the disclosing Party's election, all materials, reports, and other documents (including copies thereof) in its possession or control containing Confidential Information of the other Party, and each Party will cease to make use of the other Party's Confidential Information, except that (i) neither Party will have an obligation to return or destroy or to cease to make use of any information that is required for regulatory or compliance purposes; and (ii) neither Party will be obligated to return or destroy automatically generated copies stored on system back-up media, but provided that with respect to any such copies stored on system back-up media the confidentiality obligation specified in Section 11.01 shall continue to apply;

(d) [**]

(e) except as otherwise provided in this Agreement, expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under Sections 3.06, 5.07(c), 5.09, 5.10, 9.03(b), and Definitions Section (to the extent applicable), Article XI, Article XIII, this Article XIV, Article XV, Article XVI shall survive expiration or termination of this Agreement. Furthermore, the Pharmacovigilance Agreement and the Quality Agreement and any provisions of this Agreement relating thereto shall survive expiration or termination of this Agreement.

(f) Save for Partner's trademarks, drawings and designs, upon termination of this Agreement by PolyPid pursuant to Section 14.02(c) or by Partner pursuant to Section 6.04(i)(iii), Partner grants to PolyPid a non-exclusive, royalty-free and perpetual license under the Partner's Technology to the extent (i) it holds such rights following termination of this Agreement; and (ii) such Partner Technology has been used for the Packaging and Commercialization of the Product, in each instance for the continued Packaging and Commercialization of the Product. In addition, to the extent not included in Partner's Technology, Partner shall transfer to PolyPid, at PolyPid's cost, all permits and licenses held by the Partner at the date of termination or expiration which are required to Package and Commercialize the Product in the Territory.

**ARTICLE XV
GOVERNING LAW AND DISPUTE RESOLUTION**

Section 15.01 Dispute Resolution

Subject to Section 4.03, 8.01(d), 8.05(c), in the event of any dispute between the Parties, the senior executives of PolyPid and Partner shall meet as promptly as practicable after receipt of a notice of such dispute to resolve in good faith such dispute. If the Parties are unable to satisfactorily resolve the dispute within thirty (30) calendar days following referral to the senior executives, then, such dispute shall be finally settled Section 15.02.

Section 15.02 Governing Law and Jurisdiction

This Agreement shall be governed by, and construed and enforced in accordance with, the laws of England & Wales, except that no conflict of laws provision shall be applied to make the laws of any other jurisdiction applicable to this Agreement. All disputes hereunder shall be adjudicated by the applicable courts located in London, England, and each Party irrevocably submits to the jurisdiction of such court. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

**ARTICLE XVI
MISCELLANEOUS**

Section 16.01 Entire Agreement; Amendment.

This Agreement (the Schedules and Exhibits attached hereto), the Quality Agreement and the Pharmacovigilance Agreement sets forth all of the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations conditions or understandings, either oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

Section 16.02 Assignment.

Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed); provided, however, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent (a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to another Party, whether by merger, sale of stock, sale of assets or otherwise, or (b) to any Affiliate. Notwithstanding the foregoing, any such assignment to an Affiliate shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be null and void.

Section 16.03 Performance by Affiliates.

Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate

Section 16.04 Force Majeure.

(a) Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for any failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, but not limited to, fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, globally declared pandemics, epidemic, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party, or for any other reason which is completely beyond the control of the Party, but shall not include the inability of either Party to obtain financing or any other financial inability on the Party of either Party (collectively a "Force Majeure"). In the case of a Force Majeure, the affected Party shall (a) immediately notify the non-affected Party in writing setting forth in reasonable detail, the Force Majeure in question, and the likely or anticipated effect such event is likely to have on the performance of affected Party's obligations under this Agreement and the likely duration of the delay or non-performance. During such delay, the affected Party shall continue to use its Commercially Reasonable Efforts to mitigate, avoid or end such delay or failure in performance caused by the Force Majeure as soon as practicable. The non-affected Party shall have the right to terminate this Agreement, giving thirty (30) days written notice to the affected Party, in case such situation of Force Majeure continues for more than nine (9) months or if the correction of the results will take more than twelve (12) months.

(b) For the sake of clarity, the Parties (a) acknowledge the existence and worldwide commercial impact of the COVID-19 epidemic and (b) confirm that they have taken the current state of COVID-19 as it exists as of the Effective Date and its impact into account in making business plans and made arrangements to ensure that, unless there is a material deterioration in the current state of COVID-19 as it exists as of the Effective Date, it will not impair performance.

Section 16.05 Further Actions.

Upon the terms and subject to the conditions hereof, each of the Parties hereto shall use its Commercially Reasonable Efforts to (a) take, or cause to be taken, all appropriate action and do, or cause to be done, all things necessary, proper or advisable under applicable law or otherwise to consummate and make effective the transactions contemplated by this Agreement.

Section 16.06 Notices.

Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below::

If to PolyPid: PolyPid Ltd.

18 Hasivim St., P.O.Box 7126, Petach Tikva:
Attn: Tal Vilnai, General Counsel & Corporate Secretary
e-mail: Tal.V@polypid.com

with a copy to:
PolyPid Ltd.
Address: 18 Hasivim St., P.O.Box 7126, Petach Tikva
Attn: Jean-Marc Hagai, Chief Commercial Officer
e-mail: jeanmarc.h@polypid.com

If to Partner: Mercury Pharma Group Limited

Capital House
85 King William Street
London, EC4N 7BL
United Kingdom
Attn: Chief Corporate Development Officer
with a copy sent by email to: legalteam@advanzpharma.com

or to such other address for such Party as it shall have specified by like notice to the other Party, provided, that notices of a change of address shall be effective only upon receipt thereof. If delivered personally, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. Notwithstanding the foregoing, for any notice delivered outside normal business hours (which shall for these purposes mean in the country of the recipient of the notice), delivery shall be deemed to occur on the Business Day following such delivery. The Parties shall also send a scanned copy of any such notice to the email addresses set forth above.

Section 16.07 Independent Contractors.

It is expressly agreed that PolyPid and Partner shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership or agency of any kind. Neither PolyPid nor Partner shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

Section 16.08 Data Protection

This Agreement is intended to set forth the terms of the license of the Products in the Territory and does not cover the processing of personal data. If either Party processes the personal data shared by the other Party, the Parties shall conclude a separate data processing agreement before beginning the processing activities. The data processing agreement will include terms and conditions in accordance with applicable data protection laws, including the EU General Data Protection Regulation.

Section 16.09 Rules of Construction; Headings.

The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is disjunctive but not necessarily exclusive. The term "including" as used herein means including, without limiting the generality of any description preceding such term.

Section 16.10 English Language.

This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. English shall be used as the common language for routine communication, transmission of all information, legislation and/or any Regulatory Authority questions between the parties.

Section 16.11 Waiver.

Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

Section 16.12 Severability.

In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. Any provision of this Agreement held invalid or unenforceable in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

Section 16.13 Counterparts.

This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The signatures of all the Parties do not need to be on the same counterpart for it to be effective. Delivery of an executed counterpart's signature page of this Agreement, by electronic mail in portable document format (.pdf) or by any other electronic means (e.g., DocuSign or similar electronic signature technology) intended to preserve the original graphic and pictorial appearance of a document, has the same effect as delivery of an executed original of this Agreement.

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

POLYPID LTD.

By: /s/ Dikla Czaczkes Akselbrad

Name: Dikla Czaczkes Akselbrad

Title: Chief Executive Officer

MERCURY PHARMA GROUP LIMITED

By: /s/ Andreas Stickler

Name: Andreas Stickler

Title: Director

SCHEDULE 1
PRICE OF PRODUCT

SCHEDULE 2
MINIMUM BUDGET

SCHEDULE 3

**SALES FORECAST – FOR PURPOSES OF CALCULATING THE MINIMUM VOLUME AND THE RESULTING CALCULATION OF
MINIMAL SALES REQUIREMENT**

SCHEDULE 4
LICENSED PATENT RIGHTS

SCHEDULE 5

MARKS

SCHEDULE 6
DEVELOPMENT PLAN

SCHEDULE 7A

ADVANZ'S ANTI-BRIBERY AND ANTI-MODERN SLAVERY DECLARATION

BRIBERY

Advanz Holdings has adopted a zero-tolerance approach to bribery and expects its trading partners to do likewise. You must ensure that none of your directors, officers, employees, agents or representatives are involved in any bribery. Accordingly, you are requested to review this declaration and by executing this Agreement, you confirm that your organisation agrees and is compliant.

On 1 July 2011, the Bribery Act came into force in the UK. It applies to Advanz Holdings (a company with affiliates in the UK) in all its dealings, wherever those occur around the world.

This guide sets out the key issues you need to know about the Bribery Act as a trading partner of Advanz Holdings. More information is available at the website listed at the foot of this declaration, or from your key contact at Advanz Holdings.

1. Is bribery a serious offence under the Act?

The Bribery Act makes being involved in bribery a serious, criminal offence. Prison sentences and significant fines can be issued to any individual who is involved and/or to the senior management of a company which fails to prevent breaches.

2. How could you commit an offence?

The general offences under the Bribery Act are:

- (1) Offering or paying a bribe;
- (2) Requesting or accepting a bribe;
- (3) Bribing a foreign public official;
- (4) A new “corporate offence” for a business which *fails to prevent bribery from being carried out on its behalf and for its benefit by associated third parties*, such as employees, agents or partners.

The definition of a bribe is very wide under the Bribery Act, as the legislation gives the UK authorities plenty of discretion. Any benefit or advantage is capable of being classed as a bribe (including gifts, excessive or gratuitous corporate hospitality or facilitation payments) if *the purpose of the bribe was to induce improper performance by the recipient* (or in the case of foreign public officials, the purpose of the bribe was to *influence* the official and *obtain an advantage* in business – for example, to speed up or increase the likelihood of success of a tender).

3. The new “corporate offence”

Most press commentary has focused on the new “corporate offence”, as it goes much further than any previous legislation. It arises when a business *fails to prevent bribery from being carried out on its behalf and for its benefit by associated third parties*, such as employees, agents or partners. For example, if a company employee offers a bribe to a third party to obtain or retain business for that company, or if an agent offers a facilitation payment to a Government Official in a tender process, *each of* the individual and the agent and the company can be liable.

4. Does the Bribery Act only apply to bribery carried out in the UK?

No, one of the key features of the Bribery Act is that it applies to bribery which takes place *anywhere in the world*, provided that there is some link to the UK (which there is for Holdings and its partners, because Holdings is a company with affiliates in the UK).

5. Key practical points to note

- There are no exceptions to the offences based on the size, nature or purpose of the bribe.
- There is *no* exception for facilitation or “grease payments”, (unlike under the US Foreign Corrupt Practices Act (“**FCPA**”)) *even if* this is local practice in a particular country. Accordingly, no such payments may be made, however small.
- There is no exception for “reasonable and bona fide business expenditures” (as under the FCPA).
- Corporate entertaining and hospitality, *can* amount to a bribe *if they are excessive or gratuitous*.
- The offence can be committed by an agent, consultant or partner of Advanz Holdings who performs services on Advanz Holdings’ behalf. This is why your involvement and support is critical.

6. Possible “red flags” to watch out for

The UK authorities are given wide discretion by the Bribery Act and everyone is watching closely to see where they draw the line in practice in the numerous grey areas that exist in the legislation. Whilst the following are not necessarily examples of bribery or improper conduct, they are “red flags” which should make you think very carefully before proceeding.

- Any request for a fee to help “oil the wheels” of a commercial deal or tender, or to release goods from customs or speed up a regulatory application
- A counterparty that requests payment to a third party or involving several individuals and companies where there is no obvious relationship between them.
- Transactions where money or property is passed through a consultant or representative with the aim of obtaining or influencing certain government actions or approvals.
- A suggestion that some form of “thank you” would be appropriate in return for past or future business.
- The provision of unusually lavish corporate hospitality or a request that you provide such hospitality.
- A refusal by a counterparty or agent to accept an anti-bribery clause in an agreement.

MODERN SLAVERY ACT

Advanz Holdings is required by the Modern Slavery Act to make an annual public statement of the steps it has taken to ensure that Modern Slavery is not taking place in any of its supply chains and in any part of its business. The statement may include information about its due diligence process in its business and supply chains.

Modern Slavery is a crime resulting in an abhorrent abuse of human rights. It is constituted in the UK Modern Slavery Act 2015 by the offences of 'slavery, servitude and forced or compulsory labour' and 'human trafficking'.

Slavery, in accordance with the 1926 Slavery Convention, is the status or condition of a person over whom all or any of the powers attaching to the right of ownership are exercised. Since legal 'ownership' of a person is not possible, the key element of slavery is the behaviour on the part of the offender as if he/she did own the person, which deprives the victim of their freedom.

Servitude is the obligation to provide services that is imposed by the use of coercion and includes the obligation for a 'serf' to live on another person's property and the impossibility of changing his or her condition.

Forced or compulsory labour is defined in international law by the ILO's Forced Labour Convention 29 and Protocol. It involves coercion, either direct threats of violence or more subtle forms of compulsion. The key elements are that work or service is exacted from any person under the menace of any penalty and for which the person has not offered him/her self voluntarily.

Human trafficking occurs when a person arranges or facilitates the travel of another person with a view to that person being exploited. The offence can be committed even where the victim consents to the travel. This reflects the fact that a victim may be deceived by the promise of a better life or job or may be a child who is influenced to travel by an adult. In addition, the exploitation of the potential victim does not need to have taken place for the offence to be committed. Exploitation can be sexual exploitation or non-sexual exploitation, such as the removal of organs, providing services when subjected to force, threats or deception or providing services when the victim is used because they are a child, mentally or physically ill or disabled or have a family relationship with the exploiter and would have refused had none of those circumstances been applicable.

Identifying potential victims of Modern Slavery can be a challenge because the crime can manifest itself in many different ways. However, businesses have a responsibility to ensure that workers are not being exploited, that they are safe and that relevant employment (including wage and work hour), health and safety and human rights laws and international standards are adhered to, including freedom of movement and communications.

What should you do if you suspect bribery or Modern Slavery?

All partners should *comply not only with the letter but also with the spirit* of this new law, as well as Advanz Holdings' policies and procedures. It is fundamental to all our long-term success to apply high ethical and legal standards in all our business activities.

DECLARATION BY BUSINESS PARTNER

We confirm that we understand the above Anti-Bribery and Anti-Modern Slavery declaration and confirm that:

1. we will comply with this declaration in all our trading activities involving the Advanz Holdings group companies;
2. we will ensure that no bribery or Modern Slavery activities are committed by our company, directors, officers, employees, agents or representatives;
3. if we become aware of any concerns or issues, we will inform Advanz Holdings immediately.

SCHEDULE 7B

POLYPID'S ANTI CORRUPTION POLICY

I. Purpose

PolyPid Ltd. (together with its subsidiaries, the "**Company**") has implemented this policy for the purpose of ensuring compliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**"), the U.S. Travel Act, the U.S. Domestic Bribery Statute, Sections 291A, 293 and 294 of the Israeli Penal Law, 5737-1977, the UK Bribery Act 2010, and all other anti-corruption laws and regulations applicable to the Company's business anywhere in the world. This policy applies to all world-wide directors, officers, employees, and individuals serving as independent contractors of the Company or its subsidiaries. In addition, we expect our agents, consultants, representatives, lobbyists, suppliers/vendors, resellers, distributors, customs or other brokers, contractors, advisors, and other business partners to comply with the principles contained in this policy. Please report all questions or concerns to the Company's Compliance Officer whose contact information appears below.

II. Policy Statements

You are strictly prohibited from promising, offering, providing, or authorizing cash payments (such as bribes or kickbacks) or anything else of value directly or indirectly to any person to achieve an improper purpose related to the Company's business.

You are strictly prohibited from requesting, agreeing to receive, or accepting money or anything else of value from any person to achieve an improper purpose related to the Company's business.

You must comply with all of the Company's internal controls, especially those designed to (i) ensure accurate and complete books and records or (ii) otherwise prevent corruption, self-dealing, embezzlement, fraud, money laundering, or other improper activities.

There are no exceptions to this policy, even if our competitors engage in improper behavior or corruption is an accepted practice in a country where we operate. You are required to adhere to both the spirit and the letter of this policy with respect to our business anywhere in the world.

III. Anti-Bribery Prohibitions

The FCPA and other anti-bribery/anti-corruption laws prohibit you and the Company from corruptly promising, offering, providing, or authorizing the provision of money or anything of value directly or indirectly to a Government Official and certain other persons to achieve an improper purpose. "Improper purposes" include:

- (i) influencing any act or decision of the recipient in his/her official capacity;

- (ii) inducing the recipient to do or omit to do any act in violation of his/her lawful duty;
- (iii) inducing the recipient to influence any act or decision of a government or instrumentality of a government, or
- (iv) securing any improper advantage,

in order to obtain, retain, or direct regulatory approvals, contracts, business or other benefits.

The FCPA prohibits improper payments provided to officials of governments, state- affiliated entities, and political parties outside the United States. However, the provision of improper benefits to government or private-sector recipients within the United States will violate

U.S. domestic bribery statutes.

In addition to the United States, almost all other countries, including but not limited to Israel, the United Kingdom and other European nations, have promulgated their own anti-bribery legislation. Most of those countries prohibit making improper payments to government and private-sector recipients within their borders. However, several countries, including Israel and the United Kingdom, have also adopted legislation similar to the FCPA that prohibit improper payments outside those countries. One of the leading anti-corruption laws other than the FCPA is the UK Bribery Act 2010. **Attachment 1** contains an overview of that law and its potential significance for the Company.

Given the broad prohibitions under the FCPA and other anti-corruption laws applicable to the Company, this policy prohibits bribes, kickbacks, and the provision of other improper benefits and advantages to any person, entity, or organization, including, but not limited to, employees, officials, representatives, or agencies of any

- (i) government;
- (ii) state-owned or affiliated entity, including, but not limited to, a state hospital, research institution, utility, public university, or sovereign wealth fund;
- (iii) public international organization such as the United Nations, the World Health Organization, or the World Bank;
- (iv) political party, including the party itself as well as candidates for public office;
- (v) non-governmental organization, including a sports federation such as FIFA or the International Olympic Committee; or
- (vi) private-sector company.

The scope of “Government Officials” is very broad and can cover (i) doctors or other healthcare professionals employed by state-affiliated hospitals as well as (ii) individuals responsible for classifying our products as eligible for government-subsidized medical reimbursements.

One may be asked by certain parties to provide a bribe or other improper benefit in exchange for

- (i) the award of a contract, sponsorship opportunity, research grant, or other business;
- (ii) the issuance or renewal of a concession, license, or business, construction, or other permit or registration;
- (iii) a favorable government classification of our products;
- (iv) an impermissible reduction in duties or other taxes;
- (v) the successful filing of a patent or trademark application;
- (vi) avoiding mandatory inspections;
- (vii) obtaining a favorable inspection result or court decision, even if the facts or circumstances do not support such a result; or
- (viii) the grant of some other improper advantage.

This policy prohibits you from providing bribes or other improper benefits to any person to achieve any of the above purposes.

A violation of this policy can occur even if the bribe fails to achieve the purpose for which it was intended. This means that a person can violate this policy if that person provides an improper payment or benefit to a recipient and the recipient does not grant any business or other advantage in return. In addition, the mere offer or promise of a bribe or other improper benefit is sufficient to cause a violation. All of the anti-bribery prohibitions contained in this policy apply irrespective of whether you use Company funds or your personal funds to finance improper payments or other benefits.

This policy also prohibits you from soliciting or accepting bribes, kickbacks, or other improper payments/benefits from the Company’s vendors or other persons in relation to our business. For instance, a violation of this policy will occur if you cause the Company to overpay a vendor and that vendor then shares all or a portion of that overpayment with you.

This policy requires you to adhere to high ethical standards and to comply with all applicable laws in the course of performing services for the Company. FCPA and other anti- corruption violations typically involve circumstances that also result in violations of other laws, including those that address money laundering, embezzlement, fraud, export controls, and sanctions/embargoes. Guilty persons can face multiple charges based on the same set of facts.

IV. Accounting Requirements

Our Company adheres to certain accounting requirements. Specifically, the Company must maintain books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the Company's transactions, expenses, and asset dispositions. Our Company is also committed to maintaining a system of internal accounting controls to provide reasonable assurances that transactions are properly authorized by management, executed, and recorded. This means that you must comply with our internal controls and avoid unauthorized activities or expenses.

Violations of the above accounting standards can occur if you conceal bribes or falsify other transactions or expenses, even if they are not related to a bribe, in the Company's ledgers or other records. Also, there is no materiality standard. This means that even small misreported amounts may result in violations.

The U.S. and other governments actively enforce the accounting requirements discussed above. In some cases, they have caused companies to pay hundreds of millions of dollars in fines and penalties for violating those requirements. **Attachment 2** contains examples of potential accounting violations. Please study this list carefully and ensure that you, your colleagues, and the Company's vendors/contractors remain in compliance with these requirements. You must also cooperate with the Company's periodic audits and other efforts to ensure that our internal controls are being observed.

V. Conflicts of Interests/Relatives of Officials

Conflicts of interest can raise FCPA and other anti-corruption concerns. You must disclose any actual or potential conflicts of interest to the Company's Compliance Officer. For example, you must notify the Compliance Officer if you are aware of any (i) Company employee or contractor who is a Government Official or customer (including doctors or other healthcare professionals) responsible for regulating or providing business to the Company or (ii) Company vendor that is wholly or partially owned by you, a member of your family, a personal friend, or other Company employee/contractor.

In addition, significant corruption concerns can be triggered if the Company retains a *relative* of a Government Official or customer as an employee or contractor in exchange for a regulatory approval or business opportunity. These issues are typically uncovered in cases where the employee/contractor (i) is a son or daughter of a Government Official or customer employee and/or (ii) lacks the skills or experience necessary to perform the functions required by the Company or fails to provide any real services to the Company.

You are obligated to notify the Company's Compliance Officer if you become aware of any current or potential employee or contractor who is an immediate relative (parent, sibling, child, or spouse) of a Government Official or customer employee. Please note that persons who are related to Government Officials or customer employees will not be automatically disqualified from working for the Company; however, it is important that the Compliance Officer review their circumstances in advance to ensure that (i) they are properly qualified to serve the Company and (ii) are not related to a person who will improperly award government approvals or any business to the Company or otherwise exert undue influence over matters relevant to the Company's business.

VI. Facilitating, Expediting or Speed Payments

This policy prohibits all corrupt payments or benefits, including so-called grease, speed or facilitating payments provided to Government Officials in their personal capacity to expedite or secure routine government actions (collectively, “Facilitating Payments”). This prohibition applies notwithstanding the fact that the FCPA contains a narrow exemption that permits such Facilitating Payments. Please note that in some cases, government agencies may impose *official* fees that may be paid directly in the name of a governmental entity or enterprise itself, as set out in published fee schedules or other official documents. These *official* government fees can be paid to expedite passports, licenses, or other services, provided that they are deposited in the treasury of a government, an official government receipt is collected, and the expense is accurately recorded in the Company’s books. However, Facilitating Payments provided for the benefit of Government Officials in their *personal* capacity (*i.e.*, are not deposited in an official treasury account belonging to a government) will violate this policy.

VII. Intermediaries/Business Partners/Associated Persons

This policy prohibits you from providing bribes or other improper benefits directly as well as indirectly through third parties or associated persons whether in or outside the United States. This risk can arise in cases where the Company works with agents, consultants, representatives, lobbyists, suppliers/vendors, resellers, distributors, customs or other brokers, contractors, advisors, other business partners, or anyone else that performs services for or on behalf of the Company (collectively “*Intermediaries*”).

In certain cases, you and the Company can be held liable under the FCPA and other laws *even if* you do not expressly authorize an Intermediary to engage in corruption, but they do so anyway. This can occur if you (i) have actual knowledge or a firm belief that a person will engage in corruption or (ii) consciously disregard, deliberately ignore, or are willfully blind to the Intermediary’s corrupt or improper practices. As a result, the Company must understand the ownership, identity of key personnel, reputation and role of its Intermediaries.

Given these risks, this policy forbids you from using or paying any Intermediary responsible for government or customer interactions unless (i) appropriate anti-corruption due diligence is performed and confirms that the Intermediary does not have a history or reputation for corruption or similar wrong doing, and (ii) the Intermediary has executed a written agreement containing anti-corruption compliance clauses. You must confer with the Company’s Compliance Officer on appropriate due diligence measures and anti-corruption clauses.

Throughout any relationship with an Intermediary for which you are responsible, you must monitor their performance to ensure that they do not engage in activities that raise FCPA/corruption concerns. The Compliance Officer can guide you on the types of red flags that you should monitor before and *after* engaging an Intermediary.

This policy requires you to notify the Compliance Officer if you learn of any Company Intermediary or other contractor that engages in corrupt or other improper practices. Also, all payments to Intermediaries or other vendors must be accurately reported in our books and records in accordance with the accounting requirements discussed above.

VIII. Gifts & Hospitalitys

The FCPA and other laws prohibit the provision or acceptance of money or things of value for corrupt or improper purposes. A violation of this prohibition is likely in instances where personal benefits are given or accepted in the course of negotiation or tender bid. However, reasonably priced gifts, meals, entertainment, travel, and other benefits provided for non-corrupt business promotion or goodwill purposes may be permissible under the FCPA and other anti-corruption laws in certain cases. For instance, a plastic pen, a t-shirt, a coffee mug, a paper weight, or a cap of moderate value and embossed with the Company's logo will generally not violate the FCPA. However, a fur coat, a car, or a vacation will raise FCPA and other anti-corruption concerns, especially if such benefits are provided to a Government Official or other person who is responsible for making decisions in relation to the Company's business.

In addition to complying with the FCPA, you must also ensure that the provision of a gift or other benefit does not violate local laws or policies that apply in the country where the recipient of the benefit is located. Some countries impose express limits on the value of gifts/benefits that a recipient can accept; other countries ban such gifts/benefits altogether even if given with no corrupt or improper intention.

Also, this policy prohibits you from providing gift cards or gift certificates that can easily be converted into cash.

IX. Special Concerns in the Healthcare Sector

The healthcare sector has received significant attention with respect to anti-corruption concerns. Several leading companies in this industry have been the subject of investigations and other enforcement actions for violating anti-corruption laws. In light of this risk, it is important that you note the following:

- Improper payments made in exchange for clinical trial permits or other related government approvals are strictly prohibited by this policy.
- Researchers, doctors, other healthcare professionals, or certain other individuals may be considered Government Officials for purposes of the FCPA and other anti-corruption laws by virtue of their employment by government-affiliated hospitals, universities, laboratories, research institutions, or other organizations.
- Employees or officials of public international organizations such as the World Health Organization will be considered Government Officials for purposes the FCPA and other anti-corruption laws.
- In certain cases, private persons acting in an official capacity (such as a prime contractor) on behalf of a government hospital or other health agency or a public international organization could be viewed as Government Officials.
- Special care must be exercised when the Company retains doctors, other healthcare professionals, key opinion leaders, or other Government Officials as conference representatives, advisory board members, consultants, or contractors, especially if their employers are current or prospective customers or regulators of the Company's business. Please confer with the Compliance Officer if you encounter this type of situation.
- Anti-corruption concerns can arise in the context of research grants provided by the Company to persons or organizations at the request of or otherwise affiliated with Government Officials. No grant may be used to confer a personal benefit on a healthcare professional, other Government Official, or other person in exchange for regulatory approvals, business, or other improper advantages. Grant requests must be reviewed by the Compliance Officer to ensure that appropriate anti-corruption standards are followed.

X. Other Activities

Corruption concerns can arise in a number of other cases including, but not limited to (i) joint ventures or teaming arrangements with public or private-sector partners; (ii) mergers and acquisitions, especially if the target business has significant government interactions or an international profile; or (iii) the provision of political or charitable contributions. Please confer with the Compliance Officer before engaging in these types of activities to ensure that appropriate anti-corruption compliance measures are observed.

XI. Non-U.S. Persons

The FCPA applies to companies that are issuers, including foreign companies traded on U.S. exchanges as American Depositary Receipts, and those that are traded over-the-counter and are required to file reports with the U.S. Securities and Exchange Commission. Accordingly, as a non-U.S. issuer, the Company is directly subject to the FCPA. Further, the U.S. government has stated that it will enforce the FCPA against non-U.S. individuals and entities in certain cases. There have been instances where non-U.S. individuals have been extradited to the United States to face charges under the FCPA and other U.S. laws. In addition, non-U.S. individuals are subject to anti-corruption laws in their own as well as in other countries. This policy applies to *all* worldwide directors, officers, employees, and individuals serving as independent contractors of the Company irrespective of whether such individuals are U.S. or non-U.S. nationals or residents.

XII. Violations and Consequences

A violation of this policy will result in appropriate disciplinary action, including demotion, reassignment, additional training, probation, suspension, or even termination.

The FCPA is a criminal statute. Both the Company and you may be subject to substantial fines and penalties for violating these and other anti-corruption laws. In serious cases, you may face imprisonment for up to five years for each FCPA anti-bribery violation and up to 20 years for each FCPA accounting violation. In addition, the Company may face suspension or debarment from government contracts, the loss of U.S. export privileges, and certain other consequences. These results can be devastating to our business.

Anti-corruption enforcement has significantly increased in the United States. In addition, a number of other countries have strengthened their laws on this matter.

XIII. Training and Materials

We encourage all of our business partners to provide training to their personnel as well.

XIV. Reporting/Questions

You have an affirmative obligation to report all violations of this policy to the Compliance Officer as follows:

**Dikla Czaczkes Akselbrad
18 Hasivim Street, P.O Box
7126 Petach Tikva, Israel 4959376
+972 74-719-5753
dikla.c@polypid.com**

Reports may also be submitted anonymously by using the Company's e-mail to **compliance@polypid.com**. However, we encourage you to consider revealing your identity so that we can properly follow up and investigate alleged violations. The Company will ensure that appropriate confidentiality measures are taken and will not retaliate against any individual for reporting violations in good faith.

You must also notify the Compliance Officer of any corrupt, improper, illegal, or other unusual requests for payments or other benefits made by customers, Intermediaries, vendors, business partners, Government Officials, or Company employees. By reporting such matters, you will enable us to explore options to achieve our business goals without having to interact with such persons or provide improper benefits.

ATTACHMENT 1

THE UK BRIBERY ACT 2010

Among various matters, the UK Bribery Act 2010 (the “UKBA”) prohibits individuals and entities from offering, promising, or giving (directly or indirectly through a third party) a financial or other advantage to a recipient with (i) the intention that the advantage induce the recipient to perform improperly a relevant function or activity or to reward a person for the improper performance of such function or activity, or (ii) the knowledge or belief that the acceptance of the advantage would itself constitute an improper performance of a relevant function or activity. A violation of the UKBA will occur irrespective of whether the recipient of an improper payment or advantage is a Government Official or an employee of a private-sector entity.

The UKBA contains four principal offenses as follows: (i) offering, promising, or giving of a bribe to another person (Section 1); (ii) requesting, agreeing to receive, or accepting a bribe (Section 2); (iii) bribery of a foreign (non-UK) public official (Section 6); and (iv) failure by certain commercial organizations to prevent Section 1 or 6 bribery offenses by their associated persons (including employees, contractors, Intermediaries, or anyone else performing services for or on behalf of a company) of any nationality anywhere in the world (Section 7). The UKBA provides a statutory defense to a Section 7 violation for companies that can demonstrate that they had in place adequate systems and controls designed to prevent offenses under UKBA. This policy is part of the Company’s overall effort to establish such systems and controls.

Courts in the United Kingdom exercise broad jurisdiction over UK as well as non-UK persons who commit UKBA offenses. Although the Company does not currently maintain a UK subsidiary, there could be circumstances where the Company’s non-UK entities and employees could be subject to UKBA jurisdiction.

Under the UKBA, individuals guilty of bribery may be subject to imprisonment for up to 10 years and/or subject to a fine of an unlimited amount. Commercial organizations guilty of bribery or failure to prevent bribery may also be subject to a fine of an unlimited amount as well as debarment from government contracts. In addition, UKBA offenses could result in violations of other laws such as the UK Proceeds of Crime Act 2002, which contains the UK’s principal money laundering offenses.

ATTACHMENT 2

FCPA ACCOUNTING REQUIREMENTS

Set forth below are examples of potential FCPA accounting violations. Please note that this is not an exhaustive list.

- The Company fails to record a transaction in its books in a manner that permits the preparation of financial statements in conformity with GAAP or other acceptable criteria.
- Records state that a payment was made to person A, when in reality it was made to person B.
- The records accurately describe the recipient and the purpose of the payment, but misrepresent the amounts involved.
- Bribes or kickbacks are hidden or disguised in company financial records as “consulting fees,” “commissions,” “service fees,” or other misleading terms.
- Any entry is falsified in company financial records even if it has no connection to a bribe.
- Employees incur expenses without the appropriate authorization.
- Employees submit fake expense receipts for reimbursement.
- Employees receive kickbacks from vendors.
- Employees maintain a slush fund or other off-the-books account.
- Employees misuse petty cash funds to make improper payments to third parties or to cover non-business, personal expenses.
- The Company fails to perform effective due diligence on its agents, representatives, contractors, joint venture partners, or target companies in merger/acquisition transactions.
- The Company enters into business relationships with (i) non-existent agents, contractors, or other partners or (ii) existing parties that do not provide any real services or products.
- The Company fails to monitor its on-going relationships with vendors and other business partners to ensure that they do not engage in corrupt or other improper activities.
- Employees engage in self-dealing, embezzlement or other similar schemes involving Company resources.
- The Company fails to impose effective internal controls on subsidiaries or joint ventures in which the Company has more than 50% of the voting interests.
- The Company fails to make a *good faith* effort to cause a joint venture, in which the Company has 50% or less of the voting interests, to adopt effective internal controls.
- Employees have access to unusually high amounts of cash from Company sources.
- The Company fails to conduct effective periodic audits.
- Company employees provide false, misleading, or incomplete information to Company auditors or otherwise prevent effective audits from occurring.
- Employees otherwise circumvent the Company’s internal controls.

SCHEDULE 8

ALLOCATION OF REGULATORY TASKS RESPONSIBILITIES

SCHEDULE 9

ALLOCATION OF SUPPLY CHAIN TASK RESPONSIBILITIES

EXHIBIT A
BRAND BOOK

EXHIBIT B
PHARMACOVIGILANCE AGREEMENT

EXHIBIT C
QUALITY AGREEMENT

EXHIBIT D
INITIAL PRESS RELEASE

EXHIBIT E
BUSINESS PLAN