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: July 2026 (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

CONTENTS

On July 17, 2026 (the "Effective Date"), PolyPid Ltd. (the "Company") entered into a License and Supply Agreement (the "Agreement") with Azurity Pharmaceuticals Ireland Ltd. ("Azurity"), pursuant to which Company granted the exclusive right to Azurity to commercialize the Company's product D-PLEX$_{100}$ (the "Product") in the United States of America and Canada (the "Territory"). The term of the Agreement expires 20 years after the Effective Date. The Agreement is also terminable by either party under certain limited circumstances.

Under the terms of the Agreement, the Company is entitled to receive an upfront payment of $15 million due upon the execution of the Agreement and an additional near-term milestone payment of $15 million payable upon U.S. Food and Drug Administration acceptance of the Product New Drug Application, which is expected in August 2026. The Company is eligible to receive up to approximately $300 million in additional regulatory, development and sales-based milestone payments. Upon commercialization, the Company will manufacture and supply the Product to Azurity for a transfer price and will be entitled to tiered royalties ranging from mid-teen to mid-twenties percentages.

In addition to the upfront and milestone payments, as part of the collaboration, the parties may agree to jointly pursue potential label expansion of the Product in the Territory into additional surgical site infections indications beyond abdominal, with Azurity providing funding for these additional clinical development programs. The Company will retain global commercial rights to the Product outside of the Territory, manufacturing rights worldwide, and full ownership of its PLEX platform, Kynatrix™ technology and associated pipeline assets.

Attached hereto as Exhibit 99.1 and incorporated herein is the Company's press release issued on July 21, 2026, titled "PolyPid Announces Exclusive Partnership with Azurity Pharmaceuticals for the Commercialization of D-PLEX$_{100}$ in the U.S. and Canada."

Forward-Looking Statements

This Report of Foreign Private Issuer on Form 6-K (this "Form 6-K") contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. For example, the Company is using forward-looking statements when it discusses the expected acceptance of the Product New Drug Application and timing thereof, the Company's eligibility to receive up to approximately $300 million in additional regulatory, development and sales-based milestone payments and that the parties may agree to jointly pursue potential label expansion of the Product in the Territory into additional surgical site infections indications beyond abdominal. All statements other than statements of historical facts included in this Form 6-K are forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on the Company's current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of the Company's control. The Company's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company's reports filed from time to time with the Securities and Exchange Commission, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on February 25, 2026. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

The paragraphs above (and not Exhibit 99.1) are incorporated by reference into the Company's registration statements on Form F-3 (File No. 333-257651, File No. 333-276826, File No. 333-280658, File No. 333-281863, File No. 333-284376 and File No. 333-289034) and Form S-8 (File No. 333-239517, File No. 333-271060, File No. 333-277703, File No. 333-280662 and File No. 333-289570), 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 and Supply Agreement, dated July 17, 2026, by and between PolyPid Ltd. and Azurity Pharmaceuticals Ireland Ltd.
99.1	Press release issued by PolyPid Ltd. on July 21, 2026, titled "PolyPid Announces Exclusive Partnership with Azurity Pharmaceuticals for the Commercialization of D-PLEX100 in the U.S. and Canada."

* 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: July 21, 2026

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

Exhibit 10.1

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 AND SUPPLY AGREEMENT

This License and Supply Agreement (the "Agreement") is entered into as of July 17, 2026 (the "Effective Date"), by and between PolyPid Ltd., a company existing under the laws of the State of Israel, having offices at 18 Hasivim St. Petach Tikva 4917002, Israel ("PolyPid"), and Azurity Pharmaceuticals Ireland Ltd., a company organized under the laws of Ireland, having its registered office at The Observatory, 7-11 Sir John Rogerson's Quay, Dublin 2, D02 VC42 ("Azurity") and shall become effective on the Effective Date. PolyPid and Azurity are sometimes referred to collectively herein as the "Parties" or singly as a "Party."

RECITALS

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

B. Azurity wishes PolyPid to Manufacture or have Manufactured and exclusively supply the Products to Azurity for sale in the Territory, and PolyPid desires to Manufacture and supply the Products to Azurity to Exploit 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

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

"Abdominal SSI Indication" shall have the meaning set forth in the definition of "Indication".

"Accounting Records" shall have the meaning set forth in Section 7.04.

"Acquiring Entity" means (a) a Third Party that merges or consolidates with or acquires a Party, or to which a Party transfers all or substantially all of its assets to which this Agreement pertains, and (b) any Affiliate of such Third Party described in clause (a) that is not an Affiliate of such Party at the time of such merger, consolidation, acquisition or transfer, as applicable.

"Activity Milestone Event" shall have the meaning set forth in Section 7.01(a)(viii).

"Activity Milestone Payment" shall have the meaning set forth in Section 7.01(a)(viii).

"Additional Development" shall have the meaning set forth in Section 1.07(d).

"Additional Development Budget" shall have the meaning set forth in Section 1.07(d).

"Additional Development Costs" shall have the meaning set forth in Section 1.07(d).

"Additional Development Data" shall have the meaning set forth in Section 1.07(e).

"Additional Development Plan" shall have the meaning set forth in Section 1.07(d).

"Additional Indication" means any indication for prevention or prophylaxis of SSI other than an Abdominal SSI Indication.

[**]

[**] "Adverse Event" as may be further defined in the Quality Agreement, 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 so long as such ownership exists. 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 actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Party, whether by the ownership of more than fifty percent (50%) of the outstanding voting securities of a corporation, comparable equity interest in any other type of entity, or by contract or otherwise. 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 2.04(a).

"Anti-Corruption Laws" means Applicable Laws 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 US Foreign Corrupt Practices Act (FCPA), the Canadian Corruption of Foreign Public Officials Act (CFPOA), the UK Bribery Act 2010, and similar laws governing corruption and bribery, money laundering and terrorism.

*"*Applicable 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, cGCP or cGLP standards or mandatory guidelines promulgated by the FDA, HC or other Regulatory Authorities in the Territory, including ICH and trade association guidelines, where applicable, as well as applicable patent laws and export control laws.

"Applicable Percentage" shall have the meaning set forth in Section 7.02(a).

"Audit Report" shall have the meaning set forth in Section 7.04.

"Audited Party" has the meaning set forth in Section 7.03(c)(1).

"Audited Period" shall have the meaning set forth in Section 7.04.

"Auditing Party" has the meaning set forth in Section 7.03(c)(1).

"Authorized Generic" means a version of the Product that (i) is marketed, sold or distributed under the same NDA (or supplement thereto) as the Product, or under an ANDA that references the Product's NDA, by or on behalf of Azurity, its Affiliates or Sublicensees, but sold under a different trade name, label or at a different price point than the Product and (ii) during the Term is, or is to be supplied by PolyPid pursuant to the terms of this Agreement.

"Azurity" shall have the meaning set forth in the preamble to this Agreement.

"Azurity CMO" shall have the meaning set forth in Section 12.06(b).

"Azurity Indemnitee" shall have the meaning set forth in Section 11.01.

"Azurity Invention" means any Invention, which is not a PolyPid Invention or Joint Invention, and which are made (a) solely or jointly by one or more employees, consultants or contractors of Azurity or any of its Affiliates, or (b) jointly by one or more employees, consultants or contractors of Azurity or any of its Affiliates on the one hand, and one or more Third Parties on the other.

"Azurity's Technology" means any Information, other than the Licensed Information (or any part thereof), that becomes Controlled by Azurity or its Affiliates during the Term that is generated by Azurity or its Affiliates, Sublicensees or subcontractors in the Permitted Development or Packaging of the Product.

"Baseball Arbitration Matter" shall have the meaning set forth in Section 13.01.

"Baseball Arbitration Notice" shall have the meaning set forth in Schedule 11.

"Baseball Arbitration Procedure" shall have the meaning set forth in Section 13.01.

"Baseball Arbitrator" shall have the meaning set forth in Schedule 11.

"Batch" for each Product, means [**].

"Blocking Technology" shall have the meaning set forth in Section 8.04(e)(i).

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

"Business Plan" shall have the meaning set forth in Section 4.03(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; provided, that the first Calendar Year commences on the Effective Date and ends on December 31, 2026, and the last Calendar Year commences on January 1 of the applicable year and ends on the effective date of termination or expiration of this Agreement.

"Canada" has the meaning set forth in the definition of "Territory".

"Canada MAA" has the meaning set forth in the definition of "Marketing Authorization Application".

"Central Steering Committee" or "CSC" shall have the meaning set forth in Section 2.01(a).

"Certificate of Analysis" means the certificate of analysis for a Batch of Product, as may be further defined in the Quality Agreement.

"Certificate of Compliance" means the certificate of compliance for a Batch of Product, as may be further defined 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 as provided for (and as amended from time to time) in the (i) principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210 and 211 (ii) the HC GMP Guidance GUI-0001, (iii) the current good manufacturing practices in force in the country(ies) where the Manufacturers are located; (iv) principles detailed in the ICH Q7 guidelines, and (v) the equivalent Applicable Law in any relevant country; in each case, as may be amended and applicable from time to time, subject to any arrangements, additions, or clarifications agreed in writing from time to time between the Parties.

"Chronic Failure to Supply" shall have the meaning set forth in Schedule 2.

"CMS" means the U.S. Centers for Medicare & Medicaid Services or any successor agency thereto in the United States having substantially the same function.

"Commercialize", "Commercializing" or "Commercialization" means, with respect to any Product and on a country-by-country basis, any and all activities directed to launching (including without limitation, pre-launch activities), marketing, market access, 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 and clinical compliance, regulatory, planning with respect to each of the foregoing, and reporting. For clarity, "Commercialization" shall not include any activities related to the Manufacture of Products, any Permitted Development and/or Development of Products. Where the context so requires (i.e., the term "Commercialization" is used in connection with activities concerning products other than a Product), reference to "Product" in this definition shall be read as referring to any product.

"Commercially Reasonable Efforts" means, from time to time with respect to the performance at such time of any Commercialization or other obligation of a Party under this Agreement, the performance by such Party of such obligation by expending reasonable, 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, anticipated or approved labeling, strategic value, applicable regulatory matters and all other relevant factors, including legal, scientific, technical, and commercial factors. Commercially Reasonable Efforts shall be determined on a country-by-country and indication-by-indication basis in the Territory.

"Competitive Product" means [**].

"Competitively Sensitive Information" shall have the meaning set forth in Section 9.02(a)(v).

"Competitor" shall have the meaning set forth in Section 9.02(a)(v).

"Confidential Information" of a Party means any and all Information of such Party or its Affiliates that is disclosed directly or indirectly to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form. In addition, this Agreement supersedes the confidentiality agreement between the Parties dated as of January 7, 2025 (the "Confidentiality Agreement") regarding the subject matter of this Agreement, and all Information disclosed by a Party or its Affiliates pursuant to the Confidentiality Agreement shall be deemed to have been disclosed hereunder on a go-forward basis and shall be subject to the terms of ARTICLE IX as of the Effective Date. For clarity, Licensed Information is the Confidential Information of PolyPid, and Azurity Technology is the Confidential Information of Azurity.

"Confidentiality Agreement" shall have the meaning under the term "Confidential Information".

"Control" in the context of intellectual property rights, material, data and/or other information or subject matter, means the possession of the ability (whether by ownership or license, other than pursuant to a license granted to such Person by a Party to this Agreement) 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 such subject matter without violating Applicable Law or the terms of any Third Party agreement, and "Controlled" shall be construed accordingly.

"Cure Period" shall have the meaning set forth in Section 4.02(d)(i).

"Data" means [**].

"Defect Notice" shall have the meaning set forth in Section 6.05(a).

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

"Develop," "Developing" and "Development" means, with respect to any Product, any and all research, discovery, characterization, non-clinical, pre-clinical, clinical, regulatory, or other activities of any nature directed to or in connection with the development, testing, evaluation, modification, or Regulatory Approval of Product or Product Formulation, regardless of stage, including without limitation any basic or applied research, lead optimization, investigational new drug application activities, preclinical studies, clinical trials, regulatory filings or correspondence with any Regulatory Authority in any jurisdiction, and any manufacturing activities conducted in support of any of the foregoing. Where the context so requires (i.e., the term "Develop" is used in connection with activities concerning products or product formulations other than a Product or the Product Formulation, as application), references to "Product" and "Product Formulation" in this definition shall be read as referring to any product or product formulation, as applicable.

"Disclosing Party" shall have the meaning set forth in Section 9.01(a).

"Disputed Termination" shall have the meaning set forth in Section 3.02(d)(iii).

"Distributor" shall have the meaning set forth in the definition of "Sublicensee".

"Divestiture" means, with respect to a Competitive Product: (a) the divestiture of such Competitive Product through (i) an outright sale or assignment of all material rights in such Competitive Product to a Third Party, (ii) an exclusive out-license to a Third Party of all Development, Commercialization and manufacturing rights with respect to such Competitive Product, with no further material role, influence or authority of the applicable Party, directly or indirectly, with respect to such Competitive Product or (iii) a combination of the transactions contemplated by the foregoing clauses (i) and (ii); or (b) the complete cessation of all Development, Commercialization and manufacturing activities with respect to such Competitive Product. For clarity, subject to the preceding sentence, the right of the applicable Party to receive royalties, milestones or other payments in connection with an acquirer's, assignee's or licensee's Development or Commercialization of a Competitive Product pursuant to sub-section (a) above shall not, in and of itself, be deemed to disqualify the applicable sale, assignment or license from constituting such a Divestiture. When used as a verb, "Divest" and "Divested" means to cause or have caused a Divestiture.

"Doxy-Specific Data or Information" means [**].

"Doxy-Specific Invention" means [**].

"Drug Master File" or "DMF" means a document submitted to the FDA or any other Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

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

"Enforcement Action" has the meaning set forth in Section 8.03(a).

"Escrow Agent" shall have the meaning set forth in Section 3.02(d)(i).

"Escrow Agreement" shall have the meaning set forth in Section 3.02(d)(i).

"Escrowed Documents" shall have the meaning set forth in Section 3.02(d)(i).

"Ethical Business Conduct Laws" means all Applicable Laws relating to taxation, exchange controls, customs matters, bribery, modern slavery, corruption, competition law, money laundering, trade sanctions, financial sanctions and criminal matters.

"Evaluation Period" shall have the meaning set forth in Section 1.07(b).

[**]

"Excess Additional Development Costs" shall have the meaning set forth in Section 1.07(d).

"Excess Additional Development Costs Evaluation" shall have the meaning set forth in Section 1.07(d).

"Excluded Information" shall have the meaning set forth in Section 2.01(c).

"Exclusivity Period" shall have the meaning set forth in Section 1.10(a).

"Executives" shall have the meaning set forth in Section 2.03(b).

"Existing Third Party Agreements" means any agreement between PolyPid or its Affiliates and a Third Party pursuant to which PolyPid or its Affiliates obtains, licenses, sublicenses, accesses or otherwise acquires any rights necessary or useful for the practice of the Licensed Technology, Product or Product Formulation or the exercise of the rights granted to Azurity under this Agreement, together with any amendment thereto.

"Expansion Notice" shall have the meaning set forth in Section 1.07(b).

"Exploitation" shall have the meaning set forth in Section 1.01(a).

"External Additional Development Costs" means the costs and expenses paid by Azurity or any of its Affiliates to Third Parties for goods or services, or reimbursed by Azurity or any of its Affiliates to PolyPid for expenses paid by PolyPid to Third Parties for goods or services, all in connection with Additional Development.

"Failure to Supply" shall have the meaning set forth in Schedule 2.

"Failure to Supply Terms" shall have the meaning set forth in Section 5.01(c).

"FDA" means the U.S. Food and Drug Administration or any successor agency thereto in the United States having substantially the same function.

"Filing Acceptance" means, with respect to an NDA, the date on which the FDA determines that the NDA is sufficiently complete to permit a substantive review.

"Finished Packaged Product" means the Product in its final presentation for commercial distribution in the Territory.

"Firm Purchase Order" shall have the meaning set forth in Section 6.03.

"First Commercial Sale" shall mean the first *bona fide*, arm's length sale of the Product for the Indication in the Territory by Azurity, its Affiliates or Sublicensees following receipt of the first Marketing Authorization of the Product in the Territory. Sales for early access programs (meaning pre-approval or immediately post-approval programs specifically authorized by a Regulatory Authority, including expanded access programs under 21 C.F.R. Part 312, Subpart I), named patient programs, registration samples or compassionate use programs shall not constitute a First Commercial Sale. In addition, sales of a Product by and between Azurity and its Affiliates and Sublicensees shall not constitute a First Commercial Sale.

"Force Majeure" shall have the meaning set forth in Section 14.04.

"FTE" means [**].

"FTE Costs" means [**].

"FTE Rate" means [**].

"GAAP" means U.S. generally accepted accounting principles consistently applied.

"Generic Product" means[**].

"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).

"HC" means Health Canada or any successor agency thereto in Canada having substantially the same function.

"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.

"IIA" shall mean the Israel Innovation Authority.

"IIA Basic Liability" shall mean an aggregate amount equal to PolyPid's theoretical liability to the IIA in connection with the IIA Grants plus accrued interest thereon.

"IIA Redemption Payment Authorization" shall have the meaning set forth in Section 1.12(b).

"IIA Sharing Application" shall have the meaning set forth in Section 1.12(e).

"IIA Sharing Option" shall have the meaning set forth in Section 1.12(e).

"IIA Transfer Approval" shall have the meaning set forth in Section 1.12(a).

"IIA Transfer Application" shall have the meaning set forth in Section 1.12(b).

"IIA Transfer Approval Option" shall have the meaning set forth in Section 1.12(b).

"IIA Transfer Approval Option Exercise Notice" shall have the meaning set forth in Section 1.12(b).

"IIA Grants" shall mean [**].

"IIA Law" means the Encouragement of Research, Development and Technological Innovation in Industry Law, 5744-1984 as amended from time to time, together with any regulations, rules, procedures, guidelines or directives promulgated thereunder.

"IIA Restrictions" shall have the meaning set forth in Section 1.11(a).

"Indemnitee" shall have the meaning set forth in Section 11.03.

"Indemnitor" shall have the meaning set forth in Section 11.03.

[**] "Indication" means (a) the prevention or prophylaxis of surgical site infections ("SSI"), including in any abdominal surgery (including any colorectal surgery) ("Abdominal SSI Indication") and (b) any additional indications that are mutually agreed upon by the Parties in writing during the Term or (c) an Additional Indication added pursuant to the process set forth in Section 1.07.

"Indirect Tax" shall have the meaning set forth in Section 7.03(c)(3).

"Information" means any data (including Data), results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, know-how, trade secrets, practices, techniques, methods, processes, compositions, devices, formulas, inventions, 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, in each case whether or not patentable or copyrightable.

"Infringement Action" shall have the meaning set forth in Section 8.04(a).

"Infringement Determination Notice" shall have the meaning set forth in Section 8.04(d)(i).

"Invention" means any invention, whether or not patentable, relating to a Product or a Product Formulation, including the composition, formulation, manufacture or use thereof and/or to any companion diagnostic related thereto, that is made in the course and as a result of the conduct of activities conducted pursuant to this Agreement.

"Invoice Dispute" shall have the meaning set forth in Section 6.01(c).

[**] "Israeli Affiliate" shall have the meaning set forth in Section 1.12(e).

"Joint Invention" means any Invention, which is not an Azurity Invention or PolyPid Invention, made jointly by one or more employees, consultants or contractors of Azurity or any of its Affiliates and one or more employees, consultants or contractors of PolyPid or any of its Affiliates.

"Joint Patent" means any Patent Right claiming a Joint Invention.

"Launch" shall mean the First Commercial Sale of the Product in the Territory.

"Launch Order" means, the first Product commercial order for a given Territory, as placed by Azurity in accordance with the terms of this Agreement.

"Licensed Information" means all Information (including Data) owned or Controlled by PolyPid or its Affiliate as of the Effective Date or during the Term of this Agreement, which is related to the Product and is necessary or reasonably useful to use, offer to sell, sell, import, Package, conduct Permitted Development or Commercialize the Product for the Indication (including any Additional Indication) in the Territory or perform Azurity's obligations under this Agreement, including, but not limited to, data and documentation of clinical trials or useful for clinical trials (to the extent that Azurity has a right to conduct clinical trials under this Agreement), whether or not created in or outside the Territory as of the Effective Date or during the Term of this Agreement. For clarity, Licensed Information shall include the Excluded Information (without derogating from Section 2.01(c) below).

"Licensed Patent Rights" means all Patent Rights in the Territory that cover or claim the Product or the use (including Packaging, Permitted Development or Commercialization) of Product for any Indication (including any Additional Indication), which are owned or under the Control of PolyPid or its Affiliate as of the Effective Date or during the Term of this Agreement. The Licensed Patent Rights existing as of the Effective Date are set forth on Schedule 4.

"Licensed Technology" means the Licensed Patent Rights and the Licensed Information.

"Loss" shall have the meaning set forth in Section 11.01.

"MA Acceptance Letter" shall have the meaning set forth in Section 3.02(d)(i).

"MA Assignment Letter" shall have the meaning set forth in Section 3.02(d)(i).

"Major European Country" shall have the meaning set forth in Section 1.07(e).

"Manufacture," "Manufacturing" or "Manufacturing Process" mean, with respect to a compound or product, the synthesis, the receipt, handling, storage, testing and release of such compound or 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 compound or product. For the avoidance of doubt, Manufacturing does not include any Packaging activities.

"Manufacturer" means (a) PolyPid's contract manufacturers for the Manufacturing of the Product, and (b) Azurity's contracted Packaging manufacturer for the Product. Each Manufacturer and its applicable facilities are listed in Schedule 8.

"Manufacturing Standards" means, with respect to Product, (a) cGMP, (b) the requirements of the FDA and HC (or any other Regulatory Authority) applicable to the Manufacture of the Product for the Territory, and (c) any other requirements or standards with respect to the Manufacture of the Product which Azurity and PolyPid have agreed in writing in advance.

"Manufacturing Technology Transfer" means, pursuant to an agreed upon plan, the transfer to a Third Party contract manufacturer (or Azurity, in the case of Section 12.06) of the Manufacturing Process in the manner conducted by or on behalf of PolyPid to Manufacture and supply the Product to Azurity and its Sublicensees under this Agreement and the validation and qualification (and Regulatory Approval) of such Third Party to manufacture and supply Product to Azurity for use under this Agreement throughout the Territory.

"Marketing Authorization" or "MA" means (a) with respect to the United States, the approval by the FDA of the Product NDA, and (b) with respect to Canada, the approval by HC of the Canada MAA of the Product, in each case together with all subsequent submissions, supplements, variations and amendments thereto.

"Marketing Authorization Application" or "MAA" means (a) with respect to the United States, the NDA filed with the FDA, for approval to market the Product as may be amended and/or supplemented from time to time (currently identified as NDA #220740 as of the Effective Date) (the "Product NDA"), and (b) with respect to Canada, a new drug submission filed with HC for approval to market the Product in Canada (the "Canada MAA").

"Marks" means (a) the product-specific trademarks Controlled by PolyPid and set forth in Schedule 5; and (b) any other product-specific trademarks that PolyPid and Azurity mutually agree upon for use with the Product in a particular country within the Territory during the Term.

"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, government affairs, phase IV studies or programs, generating Commercialization support data, scientific publications and medical communications.

"MFN Adjustment Ratio" shall have the meaning set forth in Section 7.02(e)(ii).

"MFN Ceiling Price" shall have the meaning set forth in Section 7.02(e)(iii).

"MFN-Impacted Net Revenue" shall have the meaning set forth in Section 7.02(e)(i).

"MFN Pricing" shall have the meaning set forth in Section 7.02(e)(iv).

"Middle East" means Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, and Syria, Turkey, UAE, and Yemen.

"Milestone Payments" shall have the meaning set forth in Section 7.01(a).

"Minimum Purchase Requirements" shall have the meaning set forth in Section 4.02(c).

"Minimum Shelf Life" shall have the meaning set forth in Section 6.04(a).

"NDA" means a New Drug Application (as more fully defined in 21 CFR 314.5, et seq.) filed with the FDA, or any successor application thereto in the U.S.

"Negative Profit Quarter" shall have the meaning set forth in Section 7.02(c).

"Net Profit" means [**].

"Net Revenue" means [**].

Net Revenue shall be calculated on an accrual basis, in a manner consistent with the applicable Selling Party's IFRS or GAAP, consistently applied. If any accrued amounts used in the calculation of Net Revenue are estimates, such estimates shall be trued-up in accordance with the applicable Selling Party's GAAP or IFRS, consistently applied, and any resulting adjustments for the Calendar Quarters in a given Calendar Year shall, at the request of PolyPid, be reflected in the Quarterly Revenue and Profit Report for the fourth Calendar Quarter of a given Calendar Year.

The transfer of the Product by a Selling Party to another Selling Party shall not be considered a sale for the purposes of calculating Net Revenue. Only sales of the Product by a Selling Party to a Third Party shall be included in the calculation of Net Revenue.

In the event a Selling Party transfers Product to a Third Party in a transaction that is not a bona fide arm's length transaction, the Net Revenue attributable to such Product shall be deemed to be the amount that would have been invoiced (less applicable deductions) by the Selling Party in an arm's length transaction under similar market conditions with similar customers in the applicable country within the Territory. In the event that Azurity, its Affiliates or Sublicensees includes one or more Products as part of a bundle of products, Azurity agrees not to, and agrees to cause its Affiliates and Sublicensees not to, offer or sell any such Product as a loss leader in determining the price of the bundled products. The following is a non-exhaustive list of entities which could constitute Third Parties for the purposes of this definition: any wholesaler, any hospital, pharmacy or other healthcare organization (e.g. clinics, health, medical insurance organizations, healthcare group purchasing organizations.).

[**]

"NTAP" means the New Technology Add-on Payment program administered by the CMS.

"Offset Period" shall have the meaning set forth in Section 7.02(c).

"Package" or "Packaging" means the final commercial secondary packaging, labelling, QP release and all levels of 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 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, with primary Packaging Materials being in direct contact, and secondary Packaging Materials not being in direct contact.

"Packaging Specifications" means the packaging specifications and the labeling specifications for each Product, as more fully set forth in the applicable Marketing Authorization for the Product, and in compliance with Applicable Laws.

"Party" or "Parties" shall have the meaning set forth in the preamble to this Agreement.

"Patent Rights" means all rights under patents and patent applications, 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, and any and all patents issuing therefrom (including utility, model and design patents and certificates of invention).

"Patent Term Extensions" shall have the meaning set forth in Section 8.02(c).

"Patient Assistance Program" means a program that reduce (or in certain instances, remove) the patient's out of pocket costs to provide access, affordability and adherence to a given product. Depending on the product, Patient Assistance Programs may include, but are not limited to: co-pay programs, evouchers, free product, PAP product, and bridge programs.

"PDUFA Date" means the goal date set by the FDA to complete its review of an NDA under the Prescription Drug User Fee Act (PDUFA) (without guarantee of approval).

"Permitted Development" means [**].

"Permitted Overrun" shall have the meaning set forth in Section 1.07(d).

"Permitted PolyPid Clinical Trial Activities" means [**]

"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 agreed upon and executed by the Parties in accordance with Section 3.08 below, as may be amended by the Parties from time to time.

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

"PolyPid Indemnitee" has the meaning set forth in Section 11.02.

"PolyPid Invention" means [**].

"Post-Notice Period" shall have the meaning set forth in Section 8.04(d)(i).

"Pre-MFN Price" shall have the meaning set forth in Section 7.02(e)(v).

"Price Reduction" shall have the meaning set forth in Section 12.06(b).

"Pricing and Reimbursement Approvals" means (a) with respect to any jurisdiction in the Territory in which Governmental Authorities (a "Pricing Authority") determine the pricing at which a Product will be sold or reimbursed, the approval, agreement, determination or decision by the applicable Governmental Authorities establishing the pricing and reimbursement status for such Product and (b) any other pricing or reimbursement approvals, determinations, listings or designations that are reasonably required for the commercial launch of the Product in the Territory or that are reasonably required for a service provider (including hospitals and healthcare organizations) to provide healthcare services utilizing the Product.

"Product" means the Product Formulation (without any deviation except for those deviations detailed in the definition of Product Formulation) for any Indication in the Territory, including any number of vials required or used for any Indication as may be approved by the applicable Regulatory Authority from time to time. For the avoidance of doubt, references to "Product" throughout this Agreement (other than in Section 1.07 and in connection with any approved Additional Indication, as applicable) shall be construed as limited to the Product Formulation for any Indication approved by the relevant Regulatory Authority, which the Parties acknowledge the first approved indication within the Indications may be colorectal surgeries.

"Product Formulation" means [**].

"Product Invoices" shall have the meaning set forth in Section 6.01(b).

"Product NDA" shall have the meaning set forth in the definition of "Marketing Authorization Application".

"Product Net Profit" shall have the meaning set forth in Section 7.02(a).

"Product Price" shall have the meaning set forth in Section 6.01(a).

"Product Requirements" shall have the meaning set forth in Section 10.03(a).

"Product Specifications" means the specifications for the Product, as set forth in the MA for each country in the Territory, and the requirements for the Product set forth in the Quality Agreement or otherwise agreed on between the Parties, in each case as may be amended from time to time in accordance with the terms of this Agreement.

"Proposed Resolution" shall have the meaning set forth in Schedule 11.

"Purchase Order" shall have the meaning set forth in Section 6.03.

"Quality Agreement" means an agreement setting forth the applicable quality control and quality assurance responsibilities of each Party related the Product, to be agreed upon and executed by the Parties in accordance with Section 5.01(c) below, as amended by the Parties from time to time.

"Quarterly Revenue and Profit Report" has the meaning set forth in Section 7.02(b).

"Recall" shall have the meaning set forth in Section 3.09.

"Receiving Party" shall have the meaning set forth in Section 9.01(a).

"Redemption Payment" means a single amount that is required to be paid to the IIA pursuant to the IIA Law as a condition to obtaining approval for the transfer, licensing, assignment, sale or other disposition of IIA-funded know-how or related rights outside of Israel, as determined by the IIA in accordance with the applicable statutory formula.

"Reference Volume" shall have the meaning set forth in Section 4.02(b).

"Reference Year" shall have the meaning set forth in Section 4.02(b).

"Regulatory Approval" means any and all approvals, including the MA, Pricing and Reimbursement Approval, NTAP approval, schedule classifications, permits, licenses, filings and certifications of the FDA or HC or any other applicable Regulatory Authority, that are necessary for the Manufacture, Packaging, Commercialization or use of the Product in the Territory.

"Regulatory Authority" means the FDA, HC and any other applicable Governmental Authority with similar regulatory authority in any country within the Territory or any regulatory authority in any jurisdiction outside of the Territory that is involved in granting, maintaining or enforcing Regulatory Approvals for the Product in the Territory.

"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.

"Representatives" shall have the meaning set forth in Section 9.02(a)(iv).

"Rolling Forecast" has the meaning set forth in Section 6.02(a).

"Sales Milestone Events" shall have the meaning set forth in Section 7.01(a)(x).

"Sales Milestone Payments" shall have the meaning set forth in Section 7.01(a)(x).

"Secondary Manufacturer" shall have the meaning set forth in Section 5.06(a).

"Segregate" means, with respect to a Competitive Product, to use commercially reasonable efforts to segregate the Development and all Commercialization and manufacturing activities relating to such Competitive Product, as applicable, from the Development and Commercialization activities with respect to the Product under this Agreement, including ensuring that: (a) no personnel involved in performing the Development, Commercialization or manufacturing, as applicable, of such Competitive Product have access to non-public plans or non-public information relating to the Development or Commercialization of the Product under this Agreement, or any other relevant Confidential Information of the applicable Party; and (b) no personnel involved in performing the Development or Commercialization of the Product under this Agreement have access to non-public plans or information relating to the Development, Commercialization or manufacturing of such Competitive Product; *provided, that*, in either case of (a) or (b), executive leadership personnel may review and evaluate plans and high-level, non-technical summary information regarding the Development and Commercialization of such Competitive Product, solely for the purpose of making strategic portfolio-level decisions with respect to products, including such Competitive Product.

"Sell-off Period" shall have the meaning set forth in Section 12.05(h).

"Selling Parties" shall have the meaning set forth in the definition of "Net Revenues".

"Shelf Life" means, with respect to the Product, the shelf-life of the Product determined by a Regulatory Authority.

"Shipment" means each individual group of unlabeled vials of Products dispatched by PolyPid.

"Shortfall Year" shall have the meaning set forth in Section 4.02(d).

"Specified Material Breach" means [**].

"SSI" shall have the meaning set forth in the definition of "Abdominal SSI Indication."

"Subcontractor" means a Third Party assisting with any Development, Packaging or Commercialization of the Product on a fee-for-service or similar basis on behalf of Azurity or its Affiliates.

"Sublicensee" means a Third Party to whom Azurity has granted any right to exercise any of the rights licensed to Azurity under Section 1.01(a) including the right to market, promote, distribute, or sell the Product anywhere in the Territory, whether such arrangement is characterized as a sublicense, distribution agreement, subcontract, agency agreement or otherwise, provided that the following shall not constitute a Sublicensee: any distributor, wholesaler, reseller, institution, group purchasing organization or logistics provider who both (a) does not materially market or promote the Product and (b) does not have the rights to exercise any rights to Develop the Product (collectively, "Distributors").

"Successful Trial" shall have the meaning set forth in Section 1.07(i).

"Tax Forms" shall have the meaning set forth in Section 7.03(c)(2).

"Term" has the meaning set forth in Section 12.01.

"Territory" means North America including (i) the United States of America, its territories and possessions, including Puerto Rico ("United States") and (ii) Canada, including all of its provinces and territories ("Canada").

"Third Party" means any Person other than: (a) PolyPid, (b) Azurity or (c) an Affiliate of PolyPid or Azurity.

"Third Party Accountant" has the meaning set forth in Section 7.05.

"Third Party Claim" has the meaning set forth in Section 11.01.

"Third Party IP Costs" shall have the meaning set forth in Section 8.04(c).

"United States" has the meaning set forth in the definition of "Territory".

"Upfront Payment" has the meaning set forth in Section 7.01(a)(i).

"USD" or "$" means United States dollars.

"Visual Inspection" shall have the meaning set forth in Section 6.05(a).

"WAC" means wholesaler acquisition cost.

ARTICLE I
LICENSE

Section 1.01 License Terms.

(a) *License Grant*. Subject to the terms of this Agreement, PolyPid hereby grants to Azurity during the Term (subject to Section 12.01 below) an exclusive (even as to PolyPid and its Affiliates) non-transferable (except in connection with a permitted assignment of this Agreement under Section 14.02) license, with the right to grant and authorize sublicenses (through multiple tiers, and subject to the restrictions set forth in Section 1.02), under the Licensed Technology and the Marks to conduct Permitted Development for, Package and Commercialize (collectively, "Exploitation") the Product in the Territory. Azurity shall have no right, title or interest in or to the Licensed Technology or the Marks, except as specifically set forth in this Agreement.

(b) *PolyPid Retained Rights*. Notwithstanding the exclusive rights granted to Azurity in Section 1.01(a), PolyPid and its Affiliates retain the right to practice the Licensed Technology within the scope of the license granted to Azurity under Section 1.01(a) in order to perform, or have performed by a Third Party, PolyPid's obligations under this Agreement.

(c) *Azurity's Technology*. Azurity hereby grants to PolyPid, during the Term, a limited, non-exclusive, non-sublicensable (other than to PolyPid's Affiliates, only for so long as such Affiliate remains an Affiliate of PolyPid) and non-transferable license under Azurity's Technology, solely to the extent necessary for PolyPid to (i) Develop the Product for an Indication (including an Additional Indication in connection with Section 1.07) or (ii) prepare final Packaging, in each case ((i) and (ii)), for use in connection with obtaining Regulatory Approvals in accordance with this Agreement.

Section 1.02 Sublicense Rights.

Azurity shall have the right to sublicense its rights under Section 1.01 to any Third Party or Affiliate, without requiring PolyPid's prior written consent, except that without PolyPid's prior written consent (which PolyPid shall not unreasonably withhold, condition or delay), Azurity shall not[**]. Azurity shall ensure that each sublicense granted by Azurity pursuant to the terms of this Section 1.02 is consistent with the terms and conditions of this Agreement and Azurity 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. Azurity shall provide PolyPid with a copy of each sublicense with each Sublicensee, provided that Azurity may redact such copy at its reasonable discretion to remove any terms and information that are not relevant to this Agreement, that are sensitive financial information or the removal of which is required to otherwise comply with Applicable Law. Without limiting the foregoing, each such sublicense to a Sublicensee shall include the following additional terms and conditions:

(a) the Sublicensee shall be bound by confidentiality obligations substantially similar to those set forth in this Agreement; and

(b) the Sublicensee shall assign or license to Azurity all Information and Data generated by or on behalf of such Sublicensee related to the Product, to the same extent required of Azurity under ARTICLE VIII and Azurity shall promptly assign to PolyPid any such Information, Data or Inventions received from a Sublicensee; and

(c) [**]

For avoidance of doubt, without consent from, or notice to, PolyPid, Azurity may grant a sublicense under any portion of the license granted to Azurity pursuant to Section 1.01(a) to Subcontractors and Distributors for the purposes of such Subcontractor or Distributor, as applicable, to conduct their respective responsibilities and such Subcontractor or Distributor, as applicable, shall not be deemed a Sublicensee.

Section 1.03 Documents and Declarations; Transfer of Licensed Information.

(a) PolyPid shall execute documents, and provide declarations regarding the licenses granted hereunder and reasonably cooperate with Azurity 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 Azurity. Azurity 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 Azurity shall provide any reasonable support required to give effect to such revocation.

(b) *Initial Transfer.* PolyPid shall, and if applicable, shall cause its Affiliates to, transfer to Azurity and, at Azurity's written request, any of Azurity's designees all existing Licensed Information (including all such items listed on Schedule 7) within thirty (30) days after Azurity's written request for the same, solely to the extent necessary or reasonably useful for Azurity to exercise its rights under this Agreement. For the avoidance of doubt, nothing in this Section 1.03(b) shall be construed as a transfer of ownership of any Licensed Information to Azurity or any of its designees.

(c) *Ongoing Transfer.* Without limiting Section 1.03(b), during the Term, PolyPid shall, and if applicable, shall cause its Affiliates to, promptly transfer to Azurity and, at Azurity's written request, any of Azurity's designee(s), all Licensed Information that has not previously been provided pursuant to Section 1.03(b) or otherwise, in each case solely to the extent necessary or reasonably useful for Azurity to exercise its rights under this Agreement.

(d) *Cooperation.* The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Licensed Information in accordance with this Section 1.03. It is understood and agreed that all Licensed Information made available to Azurity hereunder shall be provided in accordance with Applicable Law and, to the extent reasonably practicable, in English. PolyPid shall provide any such Licensed Information in electronic form to the extent the same exists in electronic form, and shall provide copies or an opportunity to inspect (and copy) other materials comprising such Licensed Information that are necessary or reasonably useful for Azurity to exercise its rights under this Agreement (including, for example, relevant patient report forms and other original source data, to the extent not prohibited by Applicable Law). Without limiting the foregoing, PolyPid shall provide to Azurity true and complete copies of all written, graphic or electronic embodiments of Data generated by or on behalf of PolyPid or its Affiliates with respect to the Product to the extent necessary or reasonably useful for Azurity to exercise its rights under this Agreement.

(e) *Assistance*. Upon the request of Azurity, PolyPid shall, and if applicable, shall cause its Affiliates to, reasonably cooperate with and assist Azurity as may be necessary or desirable in order to allow Azurity to understand and utilize the Licensed Information solely for the purposes contemplated in this Agreement. Additionally, upon Azurity's request, PolyPid shall provide reasonable technical assistance, including, upon Azurity's prior notice, making appropriate employees of PolyPid, or its relevant Affiliate, available to Azurity at reasonable times, places and frequency, in each case as mutually agreed by the Parties, for the purpose of assisting Azurity to understand and use the Licensed Information in connection with such permitted activities. For the avoidance of doubt, nothing in this Section 1.03(e) shall require PolyPid to disclose any Excluded Information and such disclosures shall be governed instead by Section 2.01(c) and, if applicable, Section 1.03(f).

(f) *Non-Transferable Licensed Information*. To the extent that PolyPid, in its good faith and reasonable determination, requires that any Licensed Information that cannot be transferred within the meaning of this Agreement pursuant to the IIA Restrictions, is, instead of transferred to Azurity pursuant to this Section 1.03, made available to Azurity or, at Azurity's written request, to any of Azurity's designees, PolyPid will promptly notify Azurity in writing of such requirement and promptly provide Azurity, or if requested, its designees, access thereto in manner requested by Azurity. As requested by Azurity, the Parties will meet and discuss reasonable means of access for Azurity and, if requested, its designees.

Section 1.04 License Restrictions.

(a) Azurity shall not, directly or indirectly, market, promote, distribute, sell or advertise the Products: (i) prior to receipt of all requisite MAs in the Territory (ii) for any indication other than the Indication approved by the Regulatory Authority; (iii) outside the Territory, or (iv) 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, Azurity shall immediately notify PolyPid if, at any time, Azurity becomes aware that any Third Party that received the Product directly or indirectly from Azurity, its Affiliates or Sublicensees (whether as a purchaser, distributor, sub-distributor or otherwise within Azurity's chain of distribution in the Territory) has exported any Products from the Territory or has made such Products available outside the Territory. In such event, Azurity shall identify the Third Party that is the direct or indirect source of such exported Products and shall issue a cease and desist demand or similar notification to such Third Party. This Section 1.04(a) shall apply, *mutatis mutandis*, to PolyPid with respect to Products that are made available in the Territory.

(b) Azurity shall not, and shall ensure that its Affiliates and Sublicensees do not, (i) reverse engineer, decompile, or attempt to derive the composition, formulation or Manufacturing Process of the Product, (ii) duplicate or reproduce the Product, Product Formulation or any component thereof other than as expressly permitted under this Agreement, or (iii) modify or alter the physical composition or formulation of the Product in any way. Nothing in this Section 1.04(b) shall restrict Azurity from adapting or reformatting Licensed Information or documentation provided by PolyPid solely to the extent necessary for Azurity's Permitted Development, Packaging or Commercialization activities under this Agreement (including for purposes of preparing marketing materials, medical education content, or submissions to Regulatory Authorities in the Territory); provided that, Azurity shall be solely responsible and liable for the content, accuracy and consequences of any such adaptation, and PolyPid shall have no liability whatsoever in connection therewith to the extent arising solely from the adapting or reformatting.

Section 1.05 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 1.06 Licensed Marks.

(a) *Commercializing the Mark.* Products shall be Commercialized under the Marks. Subject to the terms and conditions of this Agreement, Azurity shall, and shall ensure that its Affiliates and sublicensees, use the Marks solely in connection with the Exploitation 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 Territory at PolyPid's sole cost and expense, and all goodwill in any such Marks shall accrue to PolyPid. PolyPid shall have the right to exercise quality control over the use of its Marks by Azurity or any Sublicensee to the degree necessary, in the sole opinion of PolyPid, to maintain the validity and enforceability of such Marks and to protect the goodwill associated therewith. Azurity shall, and shall ensure that its Affiliates and Sublicensees shall, not undertake any act that will or reasonably 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 that use of any of the Marks and/or PolyPid's trademarked name and logo by Azurity, its Affiliates or Sublicensees, will or reasonably 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, Azurity shall, upon written notice from PolyPid, promptly take reasonable 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.* Azurity shall, and shall ensure that its Affiliates and Sublicensees shall, use the Marks in accordance with the brand hallmarks provided by PolyPid, and in compliance with all Applicable Laws in the Territory.

(d) Azurity shall use, and shall ensure that its Affiliates and Sublicensees shall use, in connection with the Marks and/or PolyPid's trademarked name and logo, all legends, notices and markings required by Applicable Law. Azurity, its Affiliate and Sublicensees 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.

(e) *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 or Azurity's trademarked name and logo.

Section 1.07 Additional Indications.

(a) *General*. This Section 1.07 governs the process and terms pursuant to which Additional Indications may be pursued and funded. For the avoidance of doubt, the mechanism set out in this Section 1.07 applies exclusively to the pursuit of Additional Indications for the Product Formulation and does not apply to Development activities of Azurity within the existing Indication approved by the applicable Regulatory Authorities, which are governed by Section 1.01(a) and the definition of "Permitted Development." The Parties acknowledge the conduct of Development activities with respect to Additional Indications shall be subject to the requirements of Section 1.07(f). Except as provided in this Section 1.07 with respect to the Product Formulation, neither PolyPid nor its Affiliates, shall conduct any Development or Commercialization, or otherwise exploit, in the Territory (x) any compound or product either (A) using the same logo or trademark used with the Product (other than PolyPid's corporate name and logo), including any Mark or (B) under the same Regulatory Approval or Marketing Authorization of a Product (or any supplement, modification or amendment to such Regulatory Approval or Marketing Authorization), or (y) any Product or Product Formulation, in either case of (x) or (y) for any indication (other than Development of Product for the Abdominal SSI Indication in accordance with this Agreement, for which Azurity has the sole right to Commercialize in the Territory).

(b) *Initiation of Expansion Study*. If either Party desires to pursue an Additional Indication for the Product Formulation in the Territory, such Party shall submit to the CSC a written notice describing in reasonable detail the proposed Additional Indication, the anticipated clinical Development program (including estimated study design and costs based on *bona fide* CRO quotations for adequately powered study(ies) required to obtain the Additional Indication on label), the estimated regulatory pathway, and the anticipated commercial opportunity in the Territory (the "Expansion Notice"). Upon submission of an Expansion Notice to the CSC that complies with the requirements set forth in this Section 1.07(b), the financial evaluation process set forth in Section 1.07(c) shall commence automatically and shall be conducted through the CSC, and neither Party shall have the right to object to, refuse to participate in, or otherwise delay the commencement or conduct of such evaluation process. The sole basis upon which a Party may decline to participate in the financial evaluation process is a *bona fide* dispute that the Expansion Notice does not comply with the requirements set forth in this Section 1.07(b) and any such dispute shall be resolved in accordance with Section 13.01. The Parties shall cooperate in good faith through the CSC [**] to complete the financial evaluation within [**] of the date of the Expansion Notice (the "Evaluation Period"). If the CSC reaches a deadlock at the end of the Evaluation Period with respect to any matter arising under the financial evaluation process, such deadlock shall be resolved in accordance with Section 13.01. For the avoidance of doubt, the mandatory nature of the evaluation process shall not obligate either Party to fund or participate in the applicable expansion study, and a Party's obligation to fund or participate in the applicable expansion study shall be determined solely by reference to the financial thresholds and criteria set forth in Section 1.07(c), and the consequences of the evaluation outcome shall be governed by Section 1.07(g). Notwithstanding the foregoing, the Parties may at any time mutually agree in writing to pursue an Additional Indication for the Product Formulation in the Territory, without conducting, or prior to the completion of, the financial evaluation process set forth in Section 1.07(c) on such terms as described in Section 1.07(d) through Section 1.07(i) below. [**]

(c) *Financial Evaluation Framework.* Prior to either Party's obligation to commit to participation in any expansion study, the Parties shall conduct a financial evaluation of the proposed Additional Indication for the Territory as follows: [**]

(d) *Costs; Overruns; Option to Wind-Down*. If the financial thresholds in Section 1.07(c)(ii) are met or the Parties otherwise mutually agree to pursue the opportunity under an Expansion Notice, (A) the Parties shall agree on a plan (including a budget) for the conduct of the additional Development ("Additional Development") consistent with the Expansion Notice and the costs and activities assumed for the financial evaluation of such Expansion Notice (the "Additional Development Plan" and such budget, the "Additional Development Budget"), and (B) each Party shall use Commercially Reasonable Efforts to complete the activities assigned to it in the Additional Development Plan. Azurity shall pay [**] (the "Additional Development Costs") in accordance with the Additional Development Budget not to exceed an amount that is [**] of such Additional Development Budget (the "Permitted Overrun"). FTE Costs, including the hours and description of activities of the applicable FTEs, shall be documented and invoiced on a Calendar Quarter basis. External Additional Development Costs may be invoiced on a pass-through basis in the amounts invoiced by the applicable Third Party. PolyPid shall, on a Calendar Quarter basis or as otherwise requested by Azurity, keep Azurity apprised of the status, progress, results and expenses in connection with the Additional Development, including a reasonably detailed explanation of any discrepancies between the Additional Development Budget and PolyPid's actual expenses in furtherance of the Additional Development. PolyPid will notify Azurity if it reasonably believes that the Additional Development Costs will or may reasonably exceed the Additional Development Budget and the Parties will discuss the Additional Development Budget and any changes thereto at the CSC. At any time after such a notification or upon Azurity's good faith belief that it will incur costs in excess of the Additional Development Budget (including any Permitted Overrun) (the "Excess Additional Development Costs"), [**]. To the extent not covered under this Agreement, all arrangements under this Section 1.07(d) shall be documented in a written agreement prior to the commencement of any Additional Development. In the event that Azurity is permitted to conduct the Additional Development pursuant to Section 1.07(f), any payment obligations to the IIA arising as a result thereof shall be addressed as provided in Section 1.12(d), and the agreement referred to above shall reflect such obligation. For clarity, but without derogating from Section 5.06(c), Azurity shall not bear any payment obligations of PolyPid to the IIA in the absence of such transfer.

(e) *Cost Reimbursements*. If PolyPid or any of its Affiliates uses, or grants any Third Party the right to use (or has already granted to any Third Party the right to use and such Third Party uses), Data resulting from an applicable Additional Development (the "Additional Development Data") in any jurisdiction outside the United States in a manner to obtain Marketing Authorization for the applicable Additional Indication or otherwise in a manner likely to increase sales for the Additional Indication for such jurisdiction, then PolyPid shall notify Azurity and reimburse Azurity, within forty-five (45) days following receipt of invoice from Azurity, an amount equal to (i) [**] of the Additional Development Costs incurred by Azurity under Section 1.07(d) in connection with such Additional Development Data for use in any jurisdiction outside of the Major European Countries, calculated on a collective basis and not on a per-country basis, and (ii) [**] of the Additional Development Costs incurred by Azurity under Section 1.07(d) in connection with such Additional Development Data for use in any Major European Country. If use of the applicable Additional Development Data is initially for a jurisdiction outside of the Major European Countries, and is subsequently expanded to include any Major European Country, then PolyPid shall pay an additional amount such that the total reimbursement paid to Azurity under Section 1.07(d) equals [**] of the Additional Development Cost incurred by Azurity under Section 1.07(d) in connection with the such Additional Development Data. For avoidance of doubt, if use of the Additional Development Data is initially for one or more Major European Countries and PolyPid reimburses Azurity [**] of the Additional Development Costs incurred by Azurity under Section 1.07(d), PolyPid shall not be required to reimburse Azurity for any additional amount if use of the Additional Development Data is subsequently for any jurisdiction outside of the Major European Countries. For the purposes of this Section, "Major European Country" shall mean any of the following countries: (i) France, (ii) Spain, (iii) Italy, (iv) United Kingdom and (v) Germany.

(f) *Conduct of Expansion Studies*. Subject to Section 1.11 and Section 1.12, the Additional Development shall be led and conducted by PolyPid (or its designee) in compliance with the requirements of the IIA Law. PolyPid shall conduct the Additional Development in accordance with the Additional Development Plan and shall provide Azurity with regular updates on study progress and results through the CSC. Azurity shall provide PolyPid with reasonable cooperation and access to Territory-specific commercial regulatory and clinical data materials to support PolyPid's conduct of any expansion study in the Territory pursuant to this Section 1.07(f). Notwithstanding the foregoing, (A) Azurity may request to conduct the Additional Development itself by delivering written notice to PolyPid, subject to, if applicable, the provisions and procedures set forth in Section 1.12 and (B) the Parties shall cooperate in good faith to structure the Additional Development activities so as to ensure compliance with the IIA Law. If foregoing (A) is satisfied, Azurity shall be permitted to conduct the Additional Development itself.

(g) *Opt-Out; Effect of Non-Participation*.

(i) If the financial thresholds set forth in Section 1.07(c)(ii) are not met following the financial evaluation, neither Party shall have any obligation to fund or otherwise support the applicable expansion study, and each Party's decision whether to proceed shall be entirely voluntary. The Parties may nonetheless mutually agree in writing to proceed with the expansion study for an Additional Indication in accordance with Section 1.07(b) above.

(ii) If either Party elects not to participate in an expansion study for a proposed Additional Indication with respect to a Product Formulation (because the financial thresholds are not met and no mutual written agreement to proceed is reached), then: (A) the proposed Additional Indication shall not be pursued in the Territory; and (B) PolyPid shall not, during the Term, directly or indirectly, pursue, Develop or Commercialize such Additional Indication for the Product Formulation in the Territory without Azurity's prior written consent.

(iii) For the avoidance of doubt, either Party's election not to participate in or fund a particular expansion study which does not meet the financial threshold shall not constitute a breach of this Agreement and shall not affect either Party's rights or obligations with respect to the existing Indication or any other Additional Indications that may be proposed in the future.

(h) [**]

(i) *Post-Trial Filing Obligation*. Following the completion of an expansion study for an Additional Indication in the Territory that yields results which, based on the reasonable scientific judgment of the Parties (acting through the CSC), are sufficient to support the filing of an NDA supplement or comparable regulatory submission with the FDA or HC (as applicable) for such Additional Indication (a "Successful Trial"), Azurity shall [**]. PolyPid shall provide Azurity with all Data, Licensed Information and regulatory support reasonably required to prepare and file such submission. In the event the Parties disagree as to whether the results of an expansion study constitute a Successful Trial, such dispute shall be resolved by the CSC**.**

Section 1.08 Authorized Generics.

Notwithstanding anything in this Agreement to the contrary, **[**]**For the avoidance of doubt, any Authorized Generic Developed or Commercialized by Azurity, its Affiliates or Sublicensees shall be subject to the payment obligations set forth in ARTICLE VI and ARTICLE VII, *mutatis mutandis*, and all sales of an Authorized Generic shall be included in the calculation of Net Revenue for purposes of this Agreement.

Section 1.09 Territorial Integrity.

(a) Azurity agrees that neither it, nor any of its Affiliates or Sublicensees, will research, Develop, make, have made, use, sell, have sold, market, distribute, promote, import, export or otherwise commercialize or exploit Products or the Product Formulation outside of the Territory.

(b) Except as permitted under Section 1.01(b) for the benefit of Azurity, and except as expressly contemplated under Section 1.07 (including in connection with any expansion study that PolyPid or its designee is conducting in the Territory thereunder), PolyPid agrees that neither it, nor any of its Affiliates or licensees or sublicensees, will research, Develop, make, have made, use, sell, have sold, market, distribute, promote, import, export or otherwise commercialize or exploit the Product or the Product Formulation in the Territory without the prior written approval of Azurity.

(c) Except as expressly authorized herein, PolyPid shall not conduct any clinical study or other activities with respect to the Product or Product Formulation in the Territory, without the prior written approval of Azurity (which approval, subject to Section 1.07, shall not be unreasonably, withheld, conditioned or delayed).

Section 1.10 Competitive Products.

(a) *Non-Compete.* [**]

(b) [**]

Section 1.11 Compliance with IIA Law

(a) *Acknowledgment*. The Parties acknowledge that the Licensed Information, the Product and the Product Formulation were developed with the support of the grants provided by the IIA to PolyPid under the IIA Law and that PolyPid is subject to ongoing obligations and restrictions under the IIA Law with respect to the Licensed Technology (including the Product Formulation), including restrictions on the transfer of know-how developed with IIA support outside of Israel (the "IIA Restrictions"). Accordingly, the Parties agree that the conduct of development activities under this Agreement shall be structured so as to ensure PolyPid's continued compliance with the IIA Restrictions.

(b) *PolyPid as Developer of Additional Indications*. All Development activities with respect to Additional Indications (including expansion studies pursuant to Section 1.07) shall be conducted by PolyPid (or its designee) to ensure compliance with the IIA Law, unless the IIA Restrictions do not restrict Azurity or its Affiliate from conducting such Development (e.g., in the case the Redemption Payment has been previously paid (in which case the Parties agree IIA Law does not prohibit Azurity or its Affiliates from conducting such Development) or Azurity establishes an Israeli Affiliate and conducts such Development via such Israeli Affiliate and such Israeli Affiliate received approval from the IIA for the sharing of know-how developed with IIA Grants pursuant to the provisions of Section 1.12(e)) or the IIA has provided its prior written consent to such Development being conducted by Azurity (or such Israeli Affiliate) in accordance with and subject to Section 1.07(f).

(c) *PolyPid IIA Representations*. PolyPid represents, warrants and covenants to Azurity that: (i) as of the Effective Date, PolyPid has received the IIA Grants from the IIA in connection with the Development of the Product and the Product Formulation; (ii) the IIA Grants are the only grants from the IIA that are applicable to, or that would otherwise impose on PolyPid obligations to the IIA with respect to the Product or the Product Formulation; (iii) PolyPid will not during the Term, without the prior written consent of Azurity, which may be granted or withheld in Azurity's sole discretion, seek or obtain additional grants (including any amendments to the IIA Grants) from the IIA, or otherwise take an action with respect to other grants from the IIA, that would reasonably result in the imposition on PolyPid of additional obligations to the IIA with respect to the Product or the Product Formulation or an increase in the Redemption Payment; (iv) PolyPid is in material compliance with its obligations under the IIA Law and the terms of its IIA grants; (v) PolyPid has and will use diligent efforts to take such actions with respect to the IIA that are reasonably necessary to support Azurity's exercise of its rights under this Agreement; and (vi) as of the Effective Date, there are no pending and or to the knowledge of PolyPid threatened proceedings by the IIA against PolyPid relating to the Licensed Technology or the Product. PolyPid shall promptly notify Azurity of any material change in the status of its IIA grants, the IIA Restrictions or obligations that could reasonably be expected to affect Azurity's rights or obligations under this Agreement.

Section 1.12 IIA Approval; Israeli Affiliate.

(a) *IIA Approval Information Rights*. At any time during the Term, upon Azurity's request, PolyPid shall provide Azurity with (i) its good faith estimate of the Redemption Payment amounts applicable at such time under the IIA Grants and reasonable supporting details and documentation supporting such estimate, provided that the Parties acknowledge that the actual amount determined by the IIA may be different from the estimate and (ii) information regarding any other conditions that would be necessary for PolyPid to receive IIA approval to the unlimited and unrestricted transfer of any or all of the know-how developed with IIA Grants outside of Israel and the removal of any IIA Restrictions in connection with, or applicable to, the IIA know-how developed with IIA Grants (the "IIA Transfer Approval"). PolyPid shall consult with Azurity in good faith regarding any strategies or means to minimize the Redemption Payment.

(b) *IIA Transfer Option; Exercise*. At any time during the Term (but no more than once per Calendar Year), Azurity shall have the option (the "IIA Transfer Approval Option"), exercisable by written notice to PolyPid (each such notice, an "IIA Transfer Approval Option Exercise Notice") to require PolyPid to (i) submit an application for an IIA Transfer Approval to the IIA, in form approved by Azurity ("IIA Transfer Application") and (ii) following the final determination by the IIA of the amount of the Redemption Payment required to obtain the IIA Transfer Approval (and notification thereof to Azurity) and Azurity's further written authorization (which authorization shall be separate from Azurity's exercise of the IIA Transfer Approval Option Exercise Notice) (a "IIA Redemption Payment Authorization"), pay, or if requested by Azurity permit Azurity to pay directly, to the IIA the applicable Redemption Payment and Azurity shall reimburse PolyPid for any Redemption Amount paid by Poly Pid as and to the extent provided for in Section 1.12(d), in accordance with and subject to the terms of this Agreement.

(c) *IIA Transfer Approval Option Exercise.* Upon Azurity's delivery to PolyPid of an IIA Transfer Approval Option Exercise Notice, PolyPid shall, and shall cause its representatives to: (i) promptly prepare and submit to the IIA an IIA Transfer Application and any supporting documentation reasonably required to obtain the IIA Transfer Approval, and shall seek and use diligent efforts to obtain the IIA Transfer Approval as expeditiously as reasonably practicable in accordance with the following; (ii) subject to this Section 1.12(c), not take any action, or fail to take any action, that would reasonably be expected to delay, impair or prevent the receipt of the IIA Transfer Approval; (iii) reasonably cooperate with Azurity and any of its representatives with respect to any and all submissions to the IIA in accordance with this Section 1.12; (iv) permit Azurity to review and comment on (and PolyPid shall consider in good faith the views and comments of Azurity in connection with) any documents before submitting such documents to the IIA or any of its representatives in connection with the IIA Transfer Application; provided that, PolyPid shall, in its reasonable discretion, have final decision making authority with respect to the submission of any such documents (other than with respect to whether to file the IIA Transfer Application, and the selection of the IIA know-how transfer procedures under which the IIA Transfer Application will be submitted); (v) permit Azurity and its outside counsel to participate in all material communications with the IIA (including meetings and telephone conferences) relating to such IIA Transfer Application and the IIA Transfer Approval to the extent permissible; (vi) promptly provide Azurity with copies of all filings, written notices and other documents (and summaries of any oral presentations) made or submitted by or on behalf of PolyPid to the IIA or any of its representatives unless restricted by the IIA; (vii) promptly provide any written responses or communications received from the IIA in connection with the IIA Transfer Application unless specifically restricted by the IIA; and (viii) at Azurity's request and sole discretion, as soon as reasonably practicable [**] withdraw any submitted IIA Transfer Application. For the avoidance of doubt, PolyPid shall bear its own internal costs in connection with the foregoing and the IIA Transfer Approval Option is in addition to, and does not limit, Azurity's rights under Section 1.07 or Section 1.11. Azurity acknowledges that the IIA has complete discretion to approve or deny any the IIA Transfer Application and that PolyPid shall not be required to take any action or assume any obligation in connection with the IIA Transfer Application that would be inconsistent with PolyPid's obligations under the IIA Law or any existing requirement of the IIA applicable to PolyPid.

(d) *Redemption Payment; Deduction of Costs*. In connection with the exercise of the IIA Transfer Approval Option and the payment of the Redemption Payment, [**]

(e) *IIA Sharing Approval Option*. At any time prior to the exercise of the IIA Transfer Approval Option and consummation of the activities contemplated under Section 1.12(c), Azurity may notify PolyPid in writing that Azurity is interested in filing an application with the IIA to share the know-how developed with IIA Grants with an Affiliate of Azurity that is established under the laws of Israel (an "Israeli Affiliate", the "IIA Sharing Option"). Promptly following Azurity's delivery to PolyPid of written notice of Azurity's exercise of the IIA Sharing Option, PolyPid and the Israeli Affiliate shall jointly submit to the IIA an application, in form reasonably acceptable to the Parties, for approval to share the rights and obligations of PolyPid under the IIA Grants with the Israeli Affiliate (an "IIA Sharing Application"). The IIA Sharing Application shall provide that PolyPid and the Israeli Affiliate will each be treated by the IIA as a separate entity for purposes of compliance with the IIA Law, including with respect to any royalty payment obligations or other obligations to the IIA. PolyPid and Azurity shall cooperate with each other and to take such actions and provide such information as may be reasonably necessary to support the submission of the IIA Sharing Application.

(f) *Amendments*. Upon (i) the receipt by PolyPid of the IIA approval to the IIA Transfer Application or the IIA Sharing Application, as applicable, and (ii) payment of the applicable Redemption Payment (if any), the Agreement shall be automatically amended as set forth in Schedule 6, without any further action required by either Party. The Parties shall, promptly following the satisfaction of the conditions in the preceding sentence, execute and deliver such additional documents and instruments as may be reasonably necessary or desirable to give effect to the amendments set forth in Schedule 6 and to confirm the removal of the IIA Restrictions. Until such amendment is executed by the Parties, the terms and conditions set forth in Schedule 6 shall be deemed to apply as an amendment to this Agreement.

ARTICLE II
GOVERNANCE

Section 2.01 Central Steering Committee.

(a) *Central Steering Committee*. The Parties shall form a Central Steering Committee (the "Central Steering Committee" or "CSC") to (i) coordinate, oversee and monitor the Marketing Authorization Application, Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization in the Territory, and (ii) to facilitate the exchange of information between the Parties and keep the other Party informed regarding, the Marketing Authorization Application (including any similar application outside the Territory to the extent relevant to the Territory), Medical Affair Activities, Manufacturing, supply, Packaging and Commercialization of the Product and other material activities or events with respect to the Product or Product Formulation planned for or occurring outside the Territory (to the extent affecting the Territory).

(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 Azurity and of up to three (3) representatives of each Party, 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 each Calendar Quarter prior to the entry of a Generic Product in the Territory and no less than once each Calendar Year after the entry of a Generic Product in the Territory (or as more or less frequently as mutually agreed upon by the Parties)) during the Term. Each Party shall bear its own personnel and travel costs and expenses relating to Central Steering Committee meetings. The Central Steering Committee will have a quorum when at least one (1) representative of each Party is present. 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 any applicable information, data and documents relating to the business to be addressed at such meeting. The Central Steering Committee shall be co-chaired by one representative of Azurity and one representative of PolyPid. The co-chairs shall have the responsibilities set forth in Section 2.02, but shall have no additional powers or rights beyond those held by the other Central Steering Committee representatives. Subject to this Section 2.01(c) but notwithstanding anything to contrary in any other section of this Agreement (other than Section 8.04(d)(ii) or Section 9.02(a)(v)), PolyPid shall not be required to share information with Azurity and/or the Central Steering Committee regarding: [**]

(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 related to the Marketing Authorization Application (including any similar application outside the Territory to the extent relevant to the Territory), Medical Affair Activities, Development, Manufacturing, supply, Packaging and Commercialization of the Product or other material activities or events with respect to the Product or Product Formulation planned for or occurring outside the Territory, and any proposed Additional Indication submitted by either Party pursuant to Section 1.07(b) 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. Promptly (but no later than five (5) Business Days) following Central Steering Committee meeting, 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 2.02 Functions and Powers of the Central Steering Committee

The Central Steering Committee shall have solely the powers expressly assigned to it in this ARTICLE II 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 cover the following:

(a) discussing Azurity's Medical Affair Activities and PolyPid's support for those activities;

(b) discussing the Marketing Authorization Application (including any similar application outside the Territory to the extent relevant to the Territory) and monitoring the submission of filings for Regulatory Approvals for the Product in the Territory;

(c) discussing forecasts, the Manufacture, Packaging and supply of the Product for the Territory;

(d) discussing the Business Plan for the Territory, and monitoring, reviewing and recording the Azurity's Commercialization progress;

(e) discussing Development, Manufacturing, regulatory, pricing or commercialization plans and activities for Product outside of the Territory that have, or could reasonably have, a material effect or impact on Azurity's rights under this Agreement, including the planning, initiation or conduct of clinical trials of the Product;

(f) reviewing and evaluating any proposed Additional Indication submitted by either Party pursuant to Section 1.07(b), including overseeing the financial evaluation process set forth in Section 1.07(c) and designing and monitoring the conduct of any expansion study approved thereunder;

(g) discussing, determining and agreeing whether an expansion study constitutes a Successful Trial; and

(h) discussing and approving the Manufacturing Technology Transfer (and plan thereof), including the applicable Secondary Manufacturer; and

(i) such other topics 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 2.03 Decision-Making; Discontinuation

(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 and agreed by all Central Steering Committee members, or (iii) by email confirmation and agreement from all Central Steering Committee members.

(b) In the event an issue arises within the responsibility of the Central Steering Committee on which the Central Steering Committee, after a good faith effort, cannot reach consensus over a period of thirty (30) calendar days, or earlier if the issue at hand is time-sensitive as determined by a Party acting in good faith, such dispute shall be promptly referred for resolution to PolyPid's CEO and to Azurity's CEO (these executives collectively, the "Executives"). The Executives shall discuss within fourteen (14) Business Days following the date of the relevant referral. If the Executives cannot resolve such disagreement in an acceptable manner within a further fourteen (14) Business Day period after such meeting (or such longer period as mutually agreed upon by the Parties), then, and subject to Section 4.04: (i) PolyPid shall have final decision-making authority with respect to [**]and (ii) Azurity shall have final decision-making authority with respect to [**]

(c) The CSC shall not be involved with the day-to-day management of activities to be performed by a Party under this Agreement, except as expressly provided herein. Matters explicitly reserved to the consent, approval or other decision-making authority of a Party or the Parties jointly, as expressly provided in this Agreement, are outside the jurisdiction and authority of the CSC. For the avoidance of doubt, the CSC shall not have the power: (i) to resolve disputes arising out of the interpretation, or involving a breach or alleged breach, of this Agreement, which, for clarity, shall be resolved in accordance with Section 13.01; (ii) to decide to act in a manner that negates any consent rights or other rights specifically allocated to a Party under this Agreement; (iii) to decide to act in a manner that would require a Party to perform any act that is inconsistent with any Applicable Laws; (iv) to determine whether or not any payment obligation is owed by a Party, and whether any milestone event has been achieved under this Agreement; (v) to allocate any intellectual property rights; (vi) to determine that such Party has fulfilled any obligation under this Agreement; or (vii) to make a decision in contravention of any terms and conditions of this Agreement.

(d) *Discontinuation of the CSC.* The CSC shall continue to exist until [**] . Once the CSC is disbanded, the CSC shall have no further rights or obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of any information previously within the scope of the CSC under this Agreement.

Section 2.04 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 2.04(b) and elsewhere in this Agreement or as the Parties may mutually agree in writing. Each Party may change its designated Alliance Manager from time to time upon written 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.

ARTICLE III
DEVELOPMENT, REGULATORY MATTERS AND COMPLIANCE

Section 3.01 Overview.

Except as expressly set forth in this Section 3.01 and otherwise subject to the terms and conditions of this Agreement, as between the Parties, (a) Azurity shall have the sole right to conduct Permitted Development of Products within the Territory (or other Development activities in accordance with and subject to subject to Section 1.07(e)), and (b) PolyPid shall have the sole right to Develop Products outside the Territory and Additional Development activities subject to, and pursuant to Section 1.07. As between the Parties, and except as set forth herein, each Party shall bear all of the costs and expenses incurred in connection with any of the activities performed by such Party (itself or through its Affiliates or Sublicensees) in the course of the Permitted Development of the Products within, with respect to Azurity, the Territory, and in the course of Development with respect to PolyPid, outside the Territory; provided that the costs of any expansion study conducted by PolyPid in the Territory pursuant to Section 1.07(e) shall be borne by Azurity in accordance with Section 1.07(d).

Section 3.02 Marketing Authorization Holder; Maintenance of Regulatory Approvals.

(a) *Regulatory Approval in the United States.* PolyPid shall itself submit the NDA for the Product to the FDA and shall assign the approved Product NDA for an Indication to Azurity as soon as reasonably practical (and in no event later than [**] after final approval is granted). PolyPid shall use Commercially Reasonable Efforts to (A) complete the submission of the Product NDA within four (4) months of the Effective Date and (B) obtain approval of the Product NDA by the PDUFA Date assigned to the Product NDA, including addressing any requests or requirements of the FDA during the review of the Product NDA. Azurity shall accept such transfer without delay and take all actions necessary to effect and maintain the approved Product NDA in Azurity's name (and undertake all post-approval commitments and requirements). The costs of such post-marketing commitments and requirements shall [**] . In the event that PolyPid receives a Complete Response Letter from the FDA for the Product NDA, PolyPid shall use diligent efforts to resolve the circumstances underlying the Complete Response Letter and thereafter obtain approval of the Product NDA. PolyPid shall, to the extent permitted under Applicable Law, promptly notify Azurity of the status of the Product NDA and provide to Azurity all responses, communications or inquiries received or made to the FDA, except those communications or inquiries relating to the DMF. Notwithstanding the foregoing, PolyPid shall not be liable to the extent delays in filing or obtaining the NDA approval are caused solely by the FDA and not by PolyPid.

(b) *Regulatory Approval in Canada.* With respect to the Marketing Authorization for the Product in Canada, (i) Azurity shall prepare, file and prosecute, at its cost, all applications, submissions and responses necessary to obtain Marketing Authorization for the Product in Canada, other than the preparation, filing and submission of the DMF which shall be done by PolyPid and (ii) PolyPid shall provide Azurity with all information and documents necessary for or requested by Azurity in furtherance of foregoing clause (i). Azurity shall use Commercially Reasonable Efforts to obtain Marketing Authorization for the Canada MAA for an Indication, and shall initiate the filing process by submitting the Canada MAA to HC within [**] after compilation of all Licensed Information and documentation required for such filing in accordance with Section 1.03 and the requirements and guidelines of HC. Notwithstanding the foregoing, Azurity shall not be liable to the extent delays in filing or obtaining the Canada MAA are caused solely by HC or to the extent Information necessary for such submission is not available to Azurity. To the extent any additional Development is necessary to obtain Marketing Authorization for the Product in Canada, PolyPid will, subject to clause (B) below, be responsible for conducting such additional Development, including obtaining any necessary data or conducting any necessary clinical studies and (A) subject to clause (B) below, [**]

(c) *Maintenance of Regulatory Approvals.*

(i) Azurity shall maintain throughout the Term, at its sole cost (including, without limitation, PDUFA fees), all Regulatory Approvals required for the Packaging and Commercialization of the Product in the Territory (other than the Drug Master File, which shall be maintained exclusively by PolyPid in accordance with Section 3.02(h)), including, subject to Section 3.02(a), preparing and filing all necessary applications and supporting documentation. PolyPid shall provide Azurity with reasonably requested documentation within its possession or Control to support Azurity's applications in the Territory, provided that, with respect to Excluded Information, the provision of Section 2.01(c) shall apply. The Product NDA (following handover from PolyPid) and other Regulatory Approvals shall be registered in Azurity's name.

(ii) Azurity shall provide PolyPid with a copy of the final registration file and the final Marketing Authorization documents filed with the FDA and HC. In addition, Azurity shall promptly provide PolyPid a complete and accurate record of the registration dossier related to the Regulatory Approvals, including copies of any registrations in the Territory related to the Product and amendments or supplements thereto.

(iii) Any changes to any Marketing Authorization-related documents or to any Regulatory Approvals shall be agreed through the CSC unless such change is required by the FDA, HC or other Applicable Law, in which case, Azurity may make any such changes without submitting the changes to the CSC, but shall be notified to PolyPid through the CSC. Notwithstanding the foregoing, any matters relating to the Drug Master File, including any amendments, supplements or changes thereto, shall be submitted, lead and maintained exclusively by PolyPid in accordance with Section 3.02(h) and shall be notified to Azurity through the CSC, but shall not require CSC approval.

(iv) Except in connection with Section 1.02 or Section 14.02, Azurity shall not [**]

(d) [**]

(e) [**]

(f) *NTAP and Pricing and Reimbursement Approval*.

(i) After receipt of approval by the FDA of the NDA for the Product, Azurity shall use Commercially Reasonable Efforts to prepare and submit to CMS a complete NTAP application for the Product ("Product NTAP Application") [**], including all supporting materials reasonably required to pursue NTAP status. Azurity shall develop and follow a submission plan consistent with CMS deadlines, provide the CSC with drafts of the NTAP application and all material correspondence at least [**] prior to submission for the CSC's review and reasonable comment, and incorporate all reasonable comments (as determined by Azurity acting in good faith). PolyPid shall execute or provide any letters of authorization or manufacturer attestations reasonably required for filing the Product NTAP Application. Azurity shall bear the costs of preparation and submission of the Product NTAP Application and shall lead interactions with CMS regarding the Product NTAP Application. PolyPid shall be provided with copies of all U.S. WAC pricing and coding relevant to NTAP post-launch.

(ii) Azurity shall be responsible for and have the exclusive right to seek and attempt to obtain Pricing and Reimbursement Approvals for the Product in the Territory and to use Commercially Reasonable Efforts to maintain such Pricing and Reimbursement Approvals for the Product in the Territory throughout the Term. Within [**], Azurity shall apply for the Pricing and Reimbursement Approvals required for Commercialization of the Product in Canada, provided that for clarity, Azurity will have the ability to decide which provinces to apply for Pricing and Reimbursement Approval.

(iii) Azurity may, in its sole discretion, establish its resale price and any discount and rebate strategies for the Product in the Territory, and shall reasonably inform PolyPid of such strategies. Azurity shall notify PolyPid of any correspondence relating to NTAP or Pricing and Reimbursement Approvals for the Product received from, or submitted by Azurity to, any Regulatory Authority or relevant healthcare fund in the Territory.

(g) *Importer of Record*. Azurity shall be the importer of record of the Products in the Territory.

(h) *Drug Master File.* Notwithstanding anything to the contrary in this Agreement, PolyPid shall have the exclusive right and responsibility to prepare, file, maintain, amend, supplement and otherwise manage the Drug Master File for the Product in the Territory and worldwide. Without limiting the generality of the foregoing: (i) all correspondence, submissions, responses, meetings and other communications with the FDA, HC or any other Regulatory Authority in the Territory relating to the DMF shall be conducted exclusively (but in consultation and coordination with Azurity, but without having to disclose to Azurity any Excluded Information included in the DMF unless otherwise required or permitted pursuant to Section 2.01(c)) by PolyPid; (ii) PolyPid shall, upon becoming aware, notify Azurity promptly (but no later than [**] of becoming aware) of any material DMF-related submission or amendment that could reasonably be expected to affect the Product NDA, the Canada MAA or any Regulatory Approval held by Azurity in the Territory, and shall consider in good faith any comments provided by Azurity through the CSC in connection therewith; (iii) PolyPid shall promptly (but no later than [**] of receipt) notify Azurity of any material correspondence received from a Regulatory Authority in the Territory relating to the DMF, including any deficiency letters, requests for information or adverse findings; and (iv) PolyPid shall, upon Azurity's reasonable request, provide letters of authorization or other documentation reasonably necessary to enable Azurity to reference or cross-reference the DMF in connection with filing, obtaining or maintaining Regulatory Approval in the Territory. Notwithstanding anything to the contrary, the disclosure of Excluded Information shall be made in accordance with Section 2.01(c) above. All costs and expenses associated with the preparation, filing, maintenance and amendment of the DMF shall be borne solely by PolyPid.

Section 3.03 Regulatory Information Sharing.

(a) Each Party shall, through the CSC, keep the other Party regularly informed about all material regulatory processes for the Products in the Territory and outside the Territory (to the extent applicable to the Territory), as applicable, including: (i) the progress of the registration and other filings processes; (ii) any queries that were submitted by the competent Governmental Authorities; (iii) any assessment reports and; (iv) regulatory guidelines relevant for the Product and for all approvals received. Without limiting the foregoing or other provision of this Agreement, each Party shall notify the other Party promptly, and in any event within [**] of becoming aware of any information, including any correspondence from a Regulatory Authority, or the occurrence of an event that is reasonably likely to adversely impact the Product or Azurity's ability to Exploit such Product in the Territory or the exploitation of the Product by PolyPid outside the Territory, including in connection with filing for and obtaining and maintaining Regulatory Approval from the FDA and HC, filing or maintaining any DMF or establishing facilities or obtaining licenses or other approvals necessary to Manufacture Product for Azurity's Exploitation in the Territory, and the Parties shall thereafter promptly convene a meeting of the CSC to discuss such matter.

(b) In addition, each Party shall notify the other Party of any material questions or decisions relating to the Product received from any Regulatory Authority in the Territory. Subject to Section 3.02(a) and Section 3.02(h), any communication with the Regulatory Authorities in the Territory shall be handled by Azurity and Azurity shall, through the CSC, provide PolyPid copies of its proposed responses. The CSC shall be given a reasonable opportunity to review and comment on Azurity's proposed answers, and Azurity shall implement PolyPid's reasonable comments. In addition, Azurity shall provide PolyPid with copies of any material Regulatory Materials within [**] after receipt.

(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 3.04 Regulatory Audits and Inspection.

(a) *Manufacturers Licenses*. PolyPid shall be responsible for obtaining FDA and HC approval of the Manufacturers listed as applicable to PolyPid in Schedule 8. The Parties recognize that PolyPid is currently only licensed by the Israeli Governmental Authorities for Manufacture of investigational medicinal product and that no FDA or HC authorization to sell any products Manufactured at the facility of such Manufacturer is available as of the Effective Date of this Agreement. PolyPid is also responsible for ensuring (i) that the Manufacturer facility for the active pharmaceutical ingredient of the Product in Schedule 8 at all times complies with all Applicable Laws, including cGMP and holds the applicable approval from FDA and HC and (ii) that, as applicable, the Drug Master File are filed and approved in the Territory. Azurity is responsible for ensuring that the Manufacturer for Finished Packaged Product listed in Schedule 8, obtains the applicable approvals from FDA and HC.

(b) *Inspections.* Subject to the terms of this Section 3.04(b), upon reasonable notice, each Party (the "Inspecting Party") may conduct, no more than once every Calendar Year (or at any time upon reasonable cause) and only during normal business hours, an audit (of no less than [**]) of the other Party's (the "Inspected Party") and its Affiliates, Manufacturers and subcontractor laboratory facilities for the Product, safety, laboratory, packaging and labeling, warehouse and logistics, product, information technology, manufacturing science and technology, training management 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, solely to the extent relating to the Product and to verify compliance with the terms of this Agreement. Such audit shall be conducted upon at least [**] prior written notice to Inspected Party, and shall be scheduled at a time reasonably convenient to Inspected Party so as not to unreasonably interfere with regular operations and shall be completed within [**], provided that shorter reasonable notice shall be acceptable in the event of an audit conducted for reasonable cause. The Inspecting Party may be accompanied by its employees or independent qualified auditors, provided that all such persons are bound by confidentiality obligations no less protective than those set forth in this Agreement. Inspected Party shall provide reasonable access to its facilities, personnel and records, provided they relate to a Product, and shall use reasonable efforts to require its Affiliates, Manufacturers and subcontractor laboratory facilities for the Product to grant similar access. All information obtained during an audit shall be treated as Confidential Information and used solely to verify compliance. The Inspected Party shall bear its own costs of conducting such audit. Notwithstanding the foregoing, in the event that a Party receives an audit or inspection request from a Regulatory Authority that requires access to the other Party's or its respective Affiliates, Manufacturers and subcontractor facilities, records or operations, the other Party shall, and shall require its applicable Affiliate, Manufacturer and subcontractor to cooperate with and accommodate such audit or inspection within the timeframes requested or dictated by such Regulatory Authority. Notwithstanding this Section 3.04(b), where PolyPid is the Inspecting Party such audit or inspection may occur (i) only prior to the transfer of the Product NDA to Azurity pursuant to Section 3.02(a), (ii) solely to the extent necessary for the preparation and filing of the Product NDA or ongoing submissions thereto identifying Azurity's or its Affiliate's packaging facility for the Product, and (iii) only with respect to Azurity's and its Affiliate's packaging facility for the Product.

(c) *Regulatory Audits.* Azurity 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, Azurity shall permit PolyPid's representative to be present at and observe such inspection. Azurity 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, Azurity shall promptly notify PolyPid of any observation noted by any such Regulatory Authority concerning the facility, equipment systems and other cGMP related topics, all as they relate to the Product.

Section 3.05 Meetings with Regulatory Authorities.

Azurity shall, subject to Section 3.02(a) and Section 3.02(h), following PolyPid's assignment of the Product NDA to Azurity, undertake all regulatory responsibility and reporting obligations with respect to the Product for the Indication in the Territory, and shall keep PolyPid informed with respect to same as required pursuant to this Agreement and through the CSC.

Azurity shall provide PolyPid with at least [**] prior written notice (or, to the extent such meeting or discussion is scheduled in less than [**], notice as quickly as practicable) of any meeting or discussion with any Regulatory Authority in the Territory related to the Product (other than meetings or discussions relating exclusively to the Drug Master File, which shall be conducted by PolyPid in accordance with Section 3.02(h)). If PolyPid elects not to, or is unable to, attend a meeting or discussion, Azurity shall provide PolyPid with a written summary thereof promptly following such meeting or discussion. Each Party shall keep the other Party reasonably informed of any material regulatory developments related to Products in the Territory or outside of the Territory. At each regularly scheduled CSC meeting, Azurity shall provide PolyPid with a list and schedule of any meeting with Regulatory Authorities (or related advisory committees specific to the Product) in the Territory planned for the next [**] that relates to the Product.

Section 3.06 Marketing and Promotional Material

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

Section 3.07 Other Required or Requested Changes to Product or Regulatory Approvals

(a) If a Regulatory Authority requires any change to be made to primary Packaging Materials, the Parties shall promptly enter into discussions and mutually agree on all material terms and conditions of such revisions, and PolyPid and Azurity shall thereafter implement such revisions in respect of its activities hereunder. Azurity will provide PolyPid any documentation or other information with respect to the primary Packaging change as PolyPid may reasonably request in order to comply with cGMP or other Applicable Laws. The cost of implementing such agreed upon changes pursuant solely to Regulatory Authority requirements in the Territory shall be borne by [**]; all other costs shall be borne by [**]. In addition, if PolyPid desires to make any changes to the primary Packaging for commercial, regulatory, or other reasons, and such changes may affect or require changes to the Product in the Territory, PolyPid will notify Azurity in writing, and may not make any such changes without Azurity's prior written consent (which shall not be unreasonably withheld, conditioned or delayed).

(b) Notwithstanding anything to the contrary in this Agreement, Azurity may change the secondary Packaging as required for commercial, regulatory, or other reasons. Any such change will be filed with the applicable Regulatory Authorities as required. The cost of implementing such changes shall be borne by Azurity.

(c) Subject to Section 3.07(a), if a Regulatory Authority 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, provided however, that at either Party's request, the Parties shall discuss such requirement and whether to further discuss such requirement with the applicable Regulatory Authority, and upon PolyPid's request thereafter, Azurity shall, in consultation with PolyPid, use reasonable efforts to engage in good faith discussions and negotiations with the applicable Regulatory Authority regarding the scope, timing and manner of implementation of such change, provided, however, that to the extent such discussions would involve disclosure and discussion of Excluded Information in a manner that Azurity is not reasonably required to be involved in, the Parties shall reasonably cooperate to facilitate PolyPid engaging in such discussions directly with the Regulatory Authority in a manner to keep Azurity reasonably apprised of the discussions and situation without unnecessarily disclosing Excluded Information to Azurity. The Parties shall reasonably cooperate with each other in connection with any such discussions. For so long as such discussions or negotiations with the Regulatory Authority are ongoing and the Product may continue to be lawfully marketed and sold in the Territory during such period, PolyPid shall not be required to implement such change until the earlier of (i) the date on which the Regulatory Authority issues a final, non-negotiable directive requiring implementation of the change by a specified date, or (ii) the date on which the Product may no longer be lawfully marketed in the Territory absent implementation of such change; provided that, notwithstanding the foregoing, PolyPid shall use diligent efforts to implement such changes as would reasonably be likely to meet the Regulatory Authority's requirements in such a manner and at a time that would avoid any material interruptions to Azurity's Exploitation of the Product in the Territory, including to the extent requiring PolyPid to use diligent efforts to implement such changes earlier than as required under foregoing clauses (i) and (ii). For clarity, in the event that PolyPid is unable to or otherwise does not implement any such required change (whether following the conclusion of negotiations with the Regulatory Authority or otherwise), then Azurity shall be excused from any obligations to the extent that such obligations are dependent upon supply of Product which complies with Applicable Laws. Notwithstanding the foregoing, Azurity shall not be relieved of its obligations to the extent that Azurity has delayed or prevented the implementation of such change. In addition, Azurity shall use Commercially Reasonable Efforts to mitigate the impact of the relief from its obligations.

(d) If Adverse Events or other issues arise with respect to the safety or efficacy of the Product in or outside of the Territory that jeopardizes the Product's performance or are deemed by the Parties to potentially limit the Product's approved Indication, 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 or outside the Territory or other communication with any Regulatory Authority or entity, if outside the Territory each Party will inform the other, and if in the Territory, the Parties shall mutually discuss how to proceed.

(e) In the event that changes or modifications to the Product Specifications, analytical or stability methods or processes are (i) required by Regulatory Authority or (ii) requested by PolyPid and approved through the CSC, including to conform with Product Specifications outside the Territory, PolyPid shall be responsible, at PolyPid's cost and expense for providing to Azurity all necessary reports and materials for Azurity to prepare and file the Regulatory Materials which Azurity is required to provide to the applicable Regulatory Authorities either pursuant to law or pursuant to the terms of this Agreement, and to obtain approval of such Regulatory Materials, as necessary. If any Regulatory Materials require testing or Information in addition to the Information provided by PolyPid, Azurity shall, to the extent that such testing or Information is required by Applicable Law in the Territory or if otherwise mutually agreed to by the Parties, pay for the costs of such testing to the extent.

Section 3.08 Adverse Event Reporting.

(a) The Parties shall commence negotiations on the Pharmacovigilance Agreement promptly following the Effective Date (but not later than [**] following the Effective Date), execute the Pharmacovigilance Agreement. In the event the Parties cannot mutually agree upon the Pharmacovigilance Agreement within such - [**] period, then either Party may refer the matter for expedited determination by pursuant to Baseball Arbitration Procedure pursuant to Schedule 11. The Pharmacovigilance Agreement will set 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 situations). The Pharmacovigilance Agreement will set forth and describe 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, and this Agreement will control with respect to all other matters.

(b) In accordance with the terms of the Pharmacovigilance Agreement, Azurity shall conduct all pharmacovigilance activities associated with Products in the Territory, maintaining 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. In accordance with the terms of the Pharmacovigilance Agreement, Azurity shall provide to PolyPid, except as prohibited by Applicable Law, data from the Azurity's Adverse Event database for the Products in the Territory. In accordance with the terms of the Pharmacovigilance Agreement, PolyPid shall have the right to conduct all pharmacovigilance activities associated with Products outside of the Territory. Notwithstanding the foregoing, Azurity shall maintain or shall have a Third Party on Azurity's behalf maintain a global Adverse Event database [**], and, except as prohibited by Applicable Law, shall provide PolyPid with safety information in accordance with the terms of the Pharmacovigilance Agreement. Without derogating from the foregoing, Azurity shall grant the European QPPV (the qualified person responsible for Pharmacovigilance) and the marketing authorization holder in Europe, access to information from the global Safety database and additional safety data that may have impact on safety decisions impacting the Commercialization of the Product in Europe, all as described in 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 in accordance with the terms of the Pharmacovigilance Agreement. Azurity is responsible for complying with Applicable Laws governing Adverse Events in the Territory at its sole expense, and PolyPid is responsible for complying with Applicable Laws governing Adverse Events outside of 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.

Section 3.09 Product Recalls or Withdrawal.

(a) In accordance with the terms of the Quality Agreement, if at any time any Regulatory Authority requests a Party to recall the Product or if a voluntary recall of the Product is being considered 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 notify the other Party, as soon as reasonably possible, but in any event within [**]. Any Recall in the Territory shall be carried out by Azurity 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. Azurity shall in all events be responsible for conducting any Recall or market withdrawals with respect to the Product in the Territory. Azurity 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 agrees to notify Azurity within [**] if a Regulatory Authority outside of the Territory has requested a Recall or if PolyPid is considering a Recall outside of the Territory.

(b) *Recall Costs.* The cost and expense of a Recall shall be allocated as follows: [**]

Section 3.10 Assistance.

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

ARTICLE IV
COMMERCIALIZATION

Section 4.01 Commercial Launch; Commercialization of the Product in the Territory.

Except as set forth in this ARTICLE IV, Azurity shall be responsible for, and shall control the conduct of, the Commercialization of the Product in the Territory, at its expense.

(a) *US Launch.* Azurity shall use Commercially Reasonable Efforts to Launch the Product in the United States within [**] following the later of (i) receipt by PolyPid of the MA in the United States, and (ii) PolyPid providing Azurity with sufficient commercial launch quantities of Product in compliance with the NDA as set forth in the Launch Order for shipment into the United States.

(b) *Canada Launch.* Azurity shall use Commercially Reasonable Efforts to Launch the Product in Canada within [**] following the later of (i) approval of the Canada MAA, (ii) pricing being established in target provinces in Canada, and (iii) PolyPid providing Azurity with sufficient commercial launch quantities of Product in compliance with the MA of Canada as set forth in the Launch Order for shipment into Canada.

(c) *Launch Order.* Azurity's obligations in this Section 4.01 are subject to PolyPid supplying the Product set forth in Launch Order for the Territory, in accordance with the terms of this Agreement. For avoidance of doubt, Azurity shall be required to place the Launch Order for the US at least [**] prior to the proposed Launch date in the US, and for Canada at least [**] prior to the proposed Launch date in Canada.

(d) *Marks*. In connection with Azurity's Commercialization of the Product in the Territory, and unless otherwise agreed in writing or required by Applicable Law to use an alternate Mark (which alternate Mark shall be agreed to by PolyPid, such agreement not be unreasonably withheld, delayed or conditioned), Azurity's Commercialization of the Product in the Territory shall be under the Marks. Such use of the Marks may be in conformance with the brand hallmarks provided by PolyPid.

Section 4.02 Minimum Purchase Requirements. [**]

Section 4.03 Business Plan; Diligence.

(a) [**] prior to the first Launch of the Product in the Territory, Azurity shall, through the CSC, provide PolyPid with a proposed and rolling business plan with respect to Azurity's marketing activities, brand strategy and expected sales of the Product in the Territory for the [**](the "Business Plan"). Azurity shall share the updated proposed, and rolling Business Plan on an annual basis through the CSC.

(b) Azurity shall use Commercially Reasonable Efforts to, in accordance with the Business Plan, Commercialize the Product in the Territory.

Section 4.04 No Harmful Actions.

(a) *PolyPid Harmful Actions*. If Azurity believes in good faith that PolyPid and/or any of its Affiliates and/or any Third Party acting under PolyPid's or its Affiliate's authority, is taking or intends to take any action with respect to a Product that could have a material adverse impact upon the Development, regulatory status or Commercialization of any Product in the Territory, then Azurity shall have the right to bring the matter to the attention of the CSC (or to PolyPid in the event the CSC has been disbanded), and the Parties shall discuss in good faith a resolution to such concern within [**] of Azurity's notice to the CSC (or to PolyPid, as applicable). Unless and until such matter has been resolved in favor of PolyPid (including through the Baseball Arbitration Procedure), PolyPid shall cease (and shall cause its Affiliates, sublicensees and other designees to cease) conducting the activities identified by Azurity as causing concern. If the Parties are unable to resolve such concern within such [**] period, then either Party may refer the matter for expedited determination by pursuant to the Baseball Arbitration Procedure pursuant to Schedule 11. [**]

(b) *Azurity Harmful Actions*. If PolyPid believes in good faith that Azurity and/or any of its Affiliates and/or any Third Party acting under Azurity's or its Affiliate's authority, is taking or intends to take any action with respect to a Product that would have a material adverse impact upon the Development, regulatory status or commercialization of any Product outside of the Territory, then PolyPid shall have the right to bring the matter to the CSC (or Azurity in the event the CSC has been disbanded), and the Parties shall discuss in good faith a resolution to such concern within [**] of PolyPid's notice to the CSC (or to Azurity, as applicable). Unless and until such matter has been resolved in favor of Azurity (including through the Baseball Arbitration Procedure), Azurity shall cease (and shall cause its Affiliates, Sublicensees and other designees to cease) conducting the activities identified by PolyPid as causing concern. If the Parties are unable to resolve such concern within such [**] period, then either Party may refer the matter for expedited determination pursuant to the Baseball Arbitration Procedure pursuant to Schedule 11.

ARTICLE V
MANUFACTURE, SUPPLY AND PACKAGING

Section 5.01 Agreement to Supply Product.

(a) Except as permitted pursuant to Section 3 of Schedule 2, Azurity shall purchase, and PolyPid shall supply, all of Azurity's, its Affiliates' and Sublicensees' requirements of Product from PolyPid in accordance with and subject to the terms of this Agreement. Therefore, subject to the terms hereof, Azurity agrees to purchase exclusively from PolyPid, and PolyPid agrees to supply for, and sell exclusively to Azurity 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 Regulatory Approvals to subcontract any part of the Manufacturing Process for the Product to be sold in the Territory; (c) the Third Party has obtained all required Regulatory Approvals for the Manufacturing Process for the Product to be sold in the Territory and such subcontracting or conduct of the Manufacturing Process is permitted under the applicable Marketing Authorizations for the Territory (or PolyPid has obtained, or is in the process of obtaining and obtains prior to the commencement of commercial supply from such Third Party, the necessary amendments to the applicable Marketing Authorizations to permit such subcontracting or Manufacturing Process); and (d) PolyPid notifies Azurity in writing of such subcontract, and any subcontract is consistent with the terms and conditions of this Agreement and PolyPid shall be solely responsible for all of its subcontractors' activities and any and all failures by its subcontractors to comply with the terms of this Agreement.

(b) All Product supplied by PolyPid to Azurity shall be supplied in vials, unlabeled and bulk-packaged by PolyPid for shipment or such other form as mutually agreed by the Parties during the Term. Upon receipt of Product, Azurity shall be responsible for Packaging each individual vial in accordance with the Packaging Specifications, the Quality Agreement, cGMP, all serialization requirements and other Applicable Laws and using the Packaging Materials approved by PolyPid.

(c) *Failure to Supply Terms.* The Parties agree to the additional supply terms with respect to failures to supply the Products set forth in Schedule 2 attached hereto (the "Failure to Supply Terms").

Section 5.02 Quality Assurance.

(a) The Parties shall commence negotiations on the Quality Agreement promptly following the Effective Date, and shall enter into a Quality Agreement no later than [**] following the Effective Date. In the event the Parties cannot mutually agree upon the Quality Agreement within such [**] period, then either Party may refer the matter for expedited determination by pursuant to the Baseball Arbitration Procedure pursuant to Schedule 11.

(b) Release procedures with respect to the Product shall be defined in the Quality Agreement, which shall include, among other items, that (i) PolyPid will provide to Azurity, prior to delivery of the Product to Azurity, a Certificate of Analysis showing the results of the testing by PolyPid (or an approved and qualified subcontractor) indicated that the Product complies with each requirement of the Product Specification with such testing conducted according to validated and appropriately documented test methods, certificate of conformity and a summary of any deviations and investigations, in English, for Azurity's review and for release purposes, and release and delivery by PolyPid of Product shall be made only after Azurity's review and approval thereof (ii) PolyPid will be responsible for review of the test results and supporting data, the Certificate of Analysis, certificate of conformance and Batch records and the PolyPid qualified person (or their authorized representative) shall certify each Batch released to Azurity and (iii) final release of Product to market is the responsibility of Azurity.

(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, including that PolyPid will be responsible for annual stability activities, and any other requirements for the Product as shall be specified in 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, and this Agreement will control with respect to all other matters.

Section 5.03 Shipping Validation; Transportation Studies.

Azurity is solely responsible, at its cost, for designing, executing, and maintaining all shipping validation and transportation qualification activities for the Product (including lane risk assessment, packaging design/qualification, thermal mapping, stress and real-world simulation per applicable ISTA/ASTM guidance, and ongoing requalification), documenting and retaining protocols/reports, and ensuring that distribution conditions maintain Product quality throughout the supply chain (from the pick-up of the Product Ex Works, PolyPid's Manufacturing site or storage facility).

Section 5.04 Packaging.

(a) Azurity shall be responsible for selecting, auditing, and qualifying the external packager/packaging vendors (including URS, IQ/OQ/PQ, and change control) to ensure they meet cGMP and applicable regulatory/standards requirements.

(b) Azurity shall ensure that it or its designee Packages the unlabeled vials of the Product in accordance with the Packaging Specifications, the Quality Agreement, cGMP and other Applicable Laws.

(c) Azurity shall be responsible, at its sole cost, for all levels of serialization including design, validation and any subsequent set-up activities that will be required and shall perform the serialization activities in compliance with the Drug Supply Chain Security Act (DSCSA).

Section 5.05 Priority of Supply. [**]

Section 5.06 Manufacturing Technology Transfers [**]

ARTICLE VI
PRODUCT PRICE, FORECASTS, ORDERS AND CAPACITY

Section 6.01 Product Price.

(a) PolyPid shall sell, and Azurity shall purchase (in each case pursuant to the terms and conditions of this Agreement) each Product at [**] USD per one unlabeled and unpacked vial (5g) of Product (the "Product Price"). The Product Price is[**]. For the avoidance of doubt, the Product Price shall be payable by Azurity regardless of the commercial results of Azurity's Commercialization activities in the Territory, and except as provided in this Agreement PolyPid shall have no obligation to share in, bear, reimburse or otherwise assume any portion of any losses, liabilities, costs or expenses incurred by Azurity or its Affiliates or Sublicensees in connection with the Exploitation of the Product in the Territory.

(b) PolyPid will invoice Azurity the Product Price within [**] following the delivery (as per Section 6.04 and Schedule 2**)** of the Products in unlabeled vials. The Product Price invoices ("Product Invoices") shall contain the number of units of the Product provided during the relevant period and be in a form reasonably acceptable to Azurity. Payment of all Product Invoices will be due within [**] from receipt of the Product Invoice. All payment shall be made by wire transfer of immediately available funds.

(c) In the event that Azurity disputes any part of a Product Invoice provided by PolyPid, Azurity shall pay the undisputed portion of the Product Invoice in accordance with the applicable payment terms specified in the Agreement and shall promptly provide written notice regarding such dispute to PolyPid within [**] after receipt of the applicable invoice (an "Invoice Dispute"). If the Parties fail to resolve the Invoice Dispute, they shall refer the dispute to the executives of the Parties for their resolution pursuant to Section 13.01. If the executives of the Parties fail to resolve the Invoice Dispute within [**] after the matter was referred to them, then, upon the request of either Party, the Parties shall use reasonable efforts to have such disputes resolved on an expedited basis pursuant to Section 13.03.

Section 6.02 Forecasts and Orders.

(a) [**]

(b) *Manufacturing Capacity.* Without limiting PolyPid's obligations in the Failure to Supply Terms, PolyPid shall keep Azurity regularly informed of its Manufacturing capacity for the Product, and shall promptly notify Azurity if at any time PolyPid anticipates that it will not be able to Manufacture and supply to Azurity the amount of Product set forth in the Rolling Forecast (including the non-binding portion of the Rolling Forecast), and shall provide Azurity its best estimate of the timing and quantities of the Product that it will be able to supply.

(c) *Orders in Excess of Binding Portion of Rolling Forecast.* If Azurity's orders for the Product exceed the amount forecasted by Azurity in the binding portion of the Rolling Forecast, PolyPid shall use Commercially Reasonable Efforts to accept the order in excess of the binding portion of the Rolling Forecast. If PolyPid does so accept such excess, that portion of the order shall be become binding on the Parties pursuant to this Agreement. For clarity, subject to the previous sentence, it shall not be a breach of this Agreement if PolyPid fails to provide Azurity with such excess amount.

(d) *Safety Stock.* PolyPid agrees to maintain on hand sufficient safety stock of components (including API and excipients) related to the Manufacturing and supply of the Product to meet Azurity's Product requirements as set forth in Rolling Forecasts, and in no event less than[**]Azurity agrees to maintain on hand at least [**]

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

Section 6.03 Purchase Order.

Azurity's purchase orders for the Products (each a "Purchase Order") shall set forth (i) the quantity or amount ordered provided that quantity ordered is a multiple of a full Batch; and (ii) the requested delivery date, which date shall be no less than [**] from the date of such Purchase Order is received by PolyPid. [**]. PolyPid shall accept each Purchase Order within [**] of its receipt, except that PolyPid may reject any Purchase Order for failure to comply with the Rolling Forecast or the terms of this Agreement. In the event that PolyPid rejects a Purchase Order, it will notify Azurity in writing, including in reasonable detail its rationale for rejection. If PolyPid does not confirm acceptance or rejection of a Purchase Order within such [**] period, Azurity shall notify PolyPid of such failure to respond and PolyPid shall have an additional [**] to accept or reject such Purchase Order and if PolyPid does not confirm acceptance or rejection of a Purchase Order within such additional [**], the Purchase Order shall be deemed accepted. Without limiting PolyPid's obligations in the Failure to Supply Terms, if PolyPid is unable to deliver the entire amount of any Purchase Order by the requested delivery date, PolyPid shall promptly notify Azurity of such inability and when it expects to delivery such Purchase Order quantities. Each Purchase Order accepted by PolyPid under this Section 6.03 shall be deemed a "Firm Purchase Order". The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in any Purchase Order, confirmation, invoice, or other business forms used by the Parties for the purpose of ordering, acknowledging, invoicing or shipping the Products.

Section 6.04 Delivery.

(a) PolyPid shall deliver the Products ordered pursuant to a Purchase Order to Azurity, [**]. The Product shall be delivered with a minimum remaining Shelf Life from the time the Products ordered pursuant to a Purchase Order is [**] as follows: [**] (the "Minimum Shelf Life"). Each Shipment of Product shall be accompanied by a Certificate of Compliance and a Certificate of Analysis confirming that such Products were Manufactured in accordance with the Product Specifications, that such Products meet the Minimum Shelf Life, and any further manufacturing requirements specified in the Quality Agreement. Title and risk of loss will pass to Azurity [**]

(b) PolyPid shall deliver to Azurity, at the time of delivery of each Shipment, all documentation originating from the Manufacturer that is required to enable Azurity to export the Product from Israel or the Secondary Manufacturer (if applicable) to the Territory, and which are customarily issued by or on behalf of the Manufacturer under Applicable Law.

(c) Azurity shall pick-up Product within [**] after the date on which PolyPid notifies Azurity that the applicable Products are [**]

Section 6.05 Rejection of Product for Failure to Conform to Specifications.

(a) Azurity shall visually inspect the Products upon receipt thereof and Azurity shall have [**] 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 Azurity or anyone on its behalf (such inspection, the "Visual Inspection", such notice being a "Defect Notice" and such Products or Shipment "Defective Product"). Notwithstanding the foregoing, with respect to Defective Products, Azurity or its designees shall have the further right to reject Products by providing a Defect Notice within [**] following Azurity's discovery of a Defective Product which could not have been reasonably been determined to be Defective during the Visual Inspection. 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 Azurity with the results of such review within [**] after its receipt of the Defect Notice. Should Azurity 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 Azurity (or anyone acting on Azurity's behalf), then Azurity 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. PolyPid shall, deliver replacement Product to Azurity for the Defective Product, at PolyPid's expense, no later than [**] from Azurity's request.

(c) If the Parties fail to agree as to whether a Product is Defective for reasons not attributable to Azurity (or anyone acting on Azurity'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) Azurity, if the findings indicate the Product is either not Defective or the Defect is attributable to Azurity; (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, Azurity 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 this Section 6.05, no Product supplied by or on behalf of PolyPid to Azurity may be returned by Azurity after it has been delivered to Azurity.

ARTICLE VII
COMPENSATION

Section 7.01 Milestone Payments.

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

(i) $15,000,000 on the date of execution by both Parties of this Agreement (the "Upfront Payment").

(ii) $15,000,000 on the date of the Filing Acceptance of the Product NDA.

(iii) [**]

(iv) [**]

(v) [**]

(vi) [**]

(vii) [**]

(viii) [**]

(ix) Upon Net Revenues in the Territory for the Product for any Calendar Year period first reaching: [**]

Section 7.02 Product Net Profit Sharing

(a) *Product Net Profit.* During the Term, Azurity will pay to PolyPid the Applicable Percentage of Azurity's or its Affiliates' or Sublicensees' Net Profits on the Products ("Product Net Profit"), as further described in this Section 7.02. For purposes of this Section 7.02, "Applicable Percentage" means: [**]

(b) [**]

(c) [**]

(d) [**]

(e) *MFN Pricing Impact on Profit Share*. [**]

Section 7.03 Payment Terms.

(a) *Exchange Rate; Manner and Place of Payment*. All payments hereunder shall be payable in USD. All payments owed under this Agreement shall be made by wire transfer to a bank account designated by the Party to be paid, unless otherwise specified in writing by such Party. If any currency conversion will be required in connection with the calculation of any payment hereunder, such conversion will be made by the paying Party at the prevailing exchange rate listed in the Wall Street Journal on the date or dates on which such consideration is paid.

(b) *Late Payments*. [**]

(c) *Taxes*.

(1) Except as provided in this Section 7.03(c)(1) and Section 7.03(c)(3), each Party shall be responsible for paying any income or similar taxes imposed on payments received by such Party under this Agreement.

(2) If any withholding or deduction for or on account of tax is required by Applicable Law to be made from any payment by Azurity under this Agreement, Azurity shall be entitled to make such withholding or deduction. PolyPid shall no later than [**] prior to the relevant payment date (or such shorter period as is reasonably agreed requested by Azurity or required under Applicable Law) provide all valid, complete and duly executed Form 8-3-6 or any other form and all such information and documentation as may reasonably be required to enable Azurity to apply any available exemption, relief, or reduced rate of withholding ("**Tax Forms**"); provided that Azurity shall provide written notice of any such required Tax Forms sufficiently in advance to enable the timely payments of any withholding or deduction required to be made by Azurity pursuant to this Section 7.03(c). [**]

(3) Any payment made by Azurity under this Agreement is exclusive of any value added tax, sales tax, consumption tax, and other similar taxes (each, an "Indirect Tax") imposed upon such payment under Applicable Law to the extent no refunds or credits of such Indirect Taxes are available to the PolyPid. Azurity shall be responsible for the payment of Indirect Taxes levied on account of any payments made to PolyPid under this Agreement. Azurity is entitled to receive a proper tax invoice as required under Applicable Law where any Indirect Tax amount is shown separately. In addition, the Parties shall cooperate in accordance with and subject to Applicable Law to minimize Indirect Taxes in connection with this Agreement. Notwithstanding the foregoing, if there is an increase in the Indirect Taxes that are applicable on any amounts payable to PolyPid under this Agreement pursuant to Applicable Law by reason of or following an assignment by PolyPid of its rights to another Person under this Agreement pursuant to Section 14.02, a change in Tax residency of PolyPid, or a change in the tax classification of PolyPid following a reorganization of PolyPid, then Azurity will not be responsible for such incremental Indirect Taxes.

(4) The Parties expressly agree that, for purposes of all applicable tax laws (including Israeli tax law, Irish tax law and U.S. federal, state and local tax law), this Agreement constitutes a license and supply arrangement, and shall not be characterized as creating a partnership, joint venture, or any other arrangement under which the Parties are deemed to carry on a business in common. The payments made by Azurity to PolyPid pursuant to Section 7.02 are intended by the Parties to constitute variable consideration for the license granted under Section 1.01(a) and for the supply of Product under ARTICLE VI, and shall not be characterized as a distribution of profits between partners or participants in a joint venture for any tax purpose. Neither Party shall take any position on any tax return, report, or filing, or in any proceeding before any taxing authority, that is inconsistent with this characterization, unless required to do so by a final, binding determination of a competent taxing authority.

Section 7.04 Monthly Reports.

[**]

Section 7.05 Records and Audits.

During the Term and for a period of **[**]** thereafter or such longer period as required in order for the other Party (the "Auditing Party") to comply with Applicable Law, each Party (the "Audited Party") shall keep complete and accurate records in sufficient detail to permit the Auditing Party to confirm the completeness and accuracy of the information presented in each Quarterly Revenue and Profit Report, Product Invoices, or of such other payments made under this Agreement (the "Accounting Records"). The Audited Party shall permit the Auditing Party, and/or an independent, certified public accountant (the "Third Party Accountant") reasonably selected by the Auditing Party and reasonably acceptable to the Audited Party, 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 the Audited Party's normal business hours, and (i) no more than once in any **[**]** period, (ii) upon at least **[**]**prior written notice by the Auditing Party to the Audited Party and (iii) for a period covering not more than the preceding **[**]** (and in no event may the same period be audited more than once). As a condition to examining any records of the Audited Party, such Third Party Accountant will sign a nondisclosure agreement reasonably acceptable to the Audited Party in form and substance. Any and all records of the Audited Party examined by such Third Party Accountant (including as set forth in any Audit Report) will be deemed the Audited Party's Confidential Information. Upon completion of the audit, the Third Party Accountant will provide both the Audited Party and the Auditing Party with a written report disclosing whether the applicable reports are correct or incorrect, the specific details concerning any discrepancies, and the corrected amount due (the "Audit Report"). If such Audit Report concludes that such payments were underpaid by the Audited Party to the Auditing Party for the period with respect to which the audit/inspection was performed (the "Audited Period"), the Audited Party shall pay the Audited Party the amount of any such underpayments for the Audited Period, plus interest at the rate set out in Section 7.03(b), within **[**]**of the date the Auditing Party delivers to the Audited Party such report so concluding that such payments were underpaid for the Audited Period. If such Audit Report concludes that such payments were overpaid by the Audited Party to the Auditing Party for the Audited Period, the Auditing Party shall pay to the Audited Party the amount of any such overpayments for the Audited Period, plus interest at the rate set out in Section 7.03(b), within **[**]**of the date the Auditing Party delivers to the Audited Party such report so concluding that such payments were overpaid for the Audited Period. The Auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment by the Audited Party by more than **[**]**of the amount due to the Auditing Party for Audited Period. In such case, the Audited Party shall bear the full cost of such audit.

ARTICLE VIII
PATENTS AND TRADEMARKS

Section 8.01 Ownership of Inventions.

Inventorship of Inventions shall be determined in accordance with the rules of inventorship under Applicable Laws in the United States, regardless of where such Invention was made.

(a) Azurity (or its Affiliate) shall solely own all Azurity Inventions.

(b) PolyPid (or its Affiliate) shall solely own all PolyPid Inventions. All PolyPid Inventions shall be deemed included in Licensed Information, and any Patent Rights covering PolyPid Inventions shall be deemed included in Licensed Patent Rights. Azurity hereby assigns, and shall cause its Affiliates and Sublicensees to assign, to PolyPid all right, title and interest in and to any Invention that constitutes a PolyPid Invention pursuant to this Section 8.01(b), and shall execute all documents and take all actions reasonably necessary to give effect to and perfect such assignment.

(c) The Parties (or their respective Affiliates) shall jointly own all Joint Inventions in equal undivided shares. PolyPid's rights in Joint Inventions shall be deemed included in Licensed Information, and PolyPid's interest in any Joint Patent shall be deemed included in Licensed Patent Rights. Subject to the exclusive rights and licenses granted under, and the other restrictions set forth in, this Agreement, each Party may practice and exploit any Joint Invention and/or any Joint Patent including in connection with its development, manufacture and/or commercialization of products, without the consent of, or a duty of accounting to, the other Party, and each Party hereby waives any right it may have under Applicable Law to require such consent or accounting. If Applicable Laws only allow one Party to own the Joint Invention, the owning Party shall grant, and hereby grants, to the other Party a non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up, worldwide license with the right to grant sublicenses (including to other Party's licensee(s) and through multiple tiers of sublicensees) to such Joint Invention for all purposes, subject to the exclusive rights and licenses granted under, and the other restrictions set forth in, this Agreement.

Section 8.02 Maintenance of Patents or Marks.

(a) During the Term, PolyPid shall, at PolyPid's cost and expense and to the extent commercially reasonable, maintain and protect the Licensed Patent Rights and the Marks in the Territory; *provided however,* that upon written request by PolyPid, Azurity shall, at PolyPid's sole cost and expense and reasonable request, provide such assistance as may be necessary to enable PolyPid to comply with the administrative formalities necessary to maintain the Licensed Patent Rights and the Marks.

(b) PolyPid shall keep Azurity reasonably informed of the progress with regard to the filing, prosecution and maintenance of Licensed Patent Rights and Marks in the Territory, and corresponding patents and trademarks outside the Territory to the extent having effect on the Territory. PolyPid shall not make statements applicable to inside or outside the Territory that are inconsistent or that would otherwise adversely affect the intellectual property filings or registrations outside or inside the Territory, respectively. PolyPid shall consult with Azurity as to the filing, prosecution and maintenance of the Licensed Patent Rights and Marks in the Territory reasonably prior to any deadline, submission to or action with any patent or trademark office, and shall furnish to Azurity copies of all material draft patent and trademark applications, and other material correspondence with respect to, such Licensed Patent Rights and Marks (and corresponding patents and trademarks outside the Territory to the extent having effect on the Territory) reasonably in advance of the submission thereof to any patent or trademark office. PolyPid shall consider in good faith any reasonable and timely comments provided by Azurity in connection with PolyPid's prosecution and maintenance of such Licensed Patent Rights and Marks in the Territory; provided that PolyPid shall retain final decision-making authority with respect to the filing, prosecution and maintenance of all Licensed Patent Rights and Marks unless Azurity assumes responsibility therefor as described below. If PolyPid desires to abandon or cease prosecution or maintenance of any such Licensed Patent Right or Mark in any country in the Territory, PolyPid shall provide written notice to Azurity of such intention promptly after PolyPid makes such determination, but in no event later than [**]prior to any deadline that must be met in order to avoid such abandonment, and Azurity shall have the right, but not the obligation, to assume responsibility for prosecution and maintenance of such Licensed Patent Right or Mark which shall be at Azurity's cost and expense; provided that: Azurity may offset any such costs and expenses it incurs for such prosecution and maintenance from any payment owed to PolyPid under this Agreement. Any Licensed Patent Right or Mark prosecuted or maintained by Azurity pursuant to this Section 8.02(b) shall remain the sole property of PolyPid, and Azurity's assumption of prosecution or maintenance shall not confer upon Azurity any ownership interest therein. Azurity shall consult with PolyPid in advance regarding the prosecution strategy and arguments to be advanced with respect to such Licensed Patent Right or Mark, and shall consider in good faith PolyPid's reasonable and timely input, including PolyPid's input on the potential impact of such strategy and arguments on PolyPid's patent portfolio and prosecution strategy for the Products outside the Territory. At the written request of Azurity, PolyPid shall promptly execute such documents and take such actions as are reasonably necessary to enable Azurity to assume responsibility for prosecution and maintenance in the event of abandonment by PolyPid as described above, subject to Azurity's compliance with the requirements of this Section 8.02(b).

(c) PolyPid shall have the first right, but not the obligation, to obtain patent term extensions, supplementary protection certificates, and equivalents thereof (collectively, "Patent Term Extensions") with respect to any Licensed Patent Rights with respect to a Product in the Territory, and Azurity shall reasonably cooperate with PolyPid in connection therewith at PolyPid's cost and expense. If PolyPid elects not to obtain or maintain any such available Patent Term Extensions with respect to any Licensed Patent Rights in the Territory, PolyPid shall provide written notice to Azurity of such intention promptly after PolyPid makes such determination, but in no event later than [**]prior to any deadline that must be met in order to avoid forfeiture of such Patent Term Extensions, and Azurity shall have the right, but not the obligation, to obtain and/or maintain such Patent Term Extensions with respect to such Licensed Patent Rights at Azurity's cost and expense provided that Azurity shall consult with PolyPid in advance regarding the strategy for obtaining or maintaining such Patent Term Extensions and shall consider in good faith PolyPid's reasonable and timely input, including PolyPid's input on the potential impact on PolyPid's patent portfolio and prosecution strategy outside the Territory.

For the avoidance of doubt, Azurity's assumption of responsibility for obtaining or maintaining any Patent Term Extensions pursuant to this Section shall not transfer to Azurity any ownership interest in the underlying Licensed Patent Rights or any such Patent Term Extensions, and all such rights shall remain the sole property of PolyPid.

Section 8.03 Prosecution of Infringement.

(a) During the Term, each Party shall give prompt (and in any case no later than five (5) Business Days after becoming aware of any such action) notice to the other of any Third Party act that may infringe the Licensed Patent Rights or the Marks in the Territory and shall cooperate with each other to terminate such infringement without litigation. A notice under 42 U.S.C. § 262(l) or 21 U.S.C. § 355 (as such laws may be amended from time to time during the Term) with respect to a Product will constitute an act of infringement of a Licensed Patent Right, regardless of its content. Azurity shall have the first right, but not the obligation, to initiate proceedings or take other action it believes appropriate, at its own expense, to enforce or defend the Licensed Patent Rights or Marks against any such Third Party with respect to such activities in the Territory (each, an "Enforcement Action"), using outside counsel reasonably acceptable to PolyPid (such acceptance not to be unreasonably withheld, conditioned or delayed). If Azurity does not initiate an Enforcement Action or otherwise take steps with respect to such action or infringement within [**] from the date of written notice from PolyPid to do so, then PolyPid shall be entitled, but shall not be obliged, to initiate an Enforcement Action or take other action it believes appropriate against such Third Party, at its own expense.

(b) *Conduct of Enforcement Actions*. The Party conducting an Enforcement Action shall have control over its conduct, including settlement thereof; provided, however, that the Party conducting such Enforcement Action shall: (i) keep the other Party reasonably informed of the status and strategy of such Enforcement Action, including providing copies of all material pleadings, submissions and correspondence; (ii) consult with the other Party in advance regarding the strategy and arguments to be advanced in such Enforcement Action, and shall consider in good faith the other Party's reasonable and timely input, taking into account the other Party's expertise in the Product and the potential impact of such strategy and arguments on prosecution or enforcement of the Licensed Patent Rights or Marks inside or outside the Territory; and (iii) not settle any such Enforcement Action in a manner that would materially adversely affect the rights or interests of the other Party without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In any event, the Parties shall assist one another and cooperate in any such Enforcement Action at the other's reasonable request (including joining or being named as a party plaintiff as requested by the other Party and furnishing a power of attorney for such purpose, providing access to relevant documents and other evidence (including laboratory notebooks), and making its employees or the inventors available at reasonable business hours). PolyPid shall (i) inform and consult with Azurity, and conduct enforcement actions outside the Territory, as described in foregoing clauses (i), (ii) and (iii) with respect to PolyPid's or its sublicensees' enforcement or defence of the Patent Rights or trademarks with respect to the Product outside of the Territory (to the extent having effect on Territory) and (ii) shall not make statements applicable to inside or outside the Territory that are inconsistent or that would otherwise adversely affect the intellectual property filings or registrations outside or inside the Territory, respectively.

(c) *Recovery*. Azurity and PolyPid shall each recover their respective actual out-of-pocket expenses including reasonable attorneys' fees associated with any Enforcement Action against infringers undertaken pursuant to Section 8.03(a) or settlement thereof from any resulting amount received in a settlement, by award of a court, or pursuant to another dispute resolution mechanism. After reimbursement of each Party's out-of-pocket expenses, any remaining amount shall be allocated as follows: the remaining amount shall be shared [**]by PolyPid and [**]by Azurity. The Party conducting the Enforcement Action shall pay the other Party's share of such amount at the same time as the next Product Net Profit payment due.

(d) The Parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning the Licensed Patent Rights or the Marks within the Territory and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party).

Section 8.04 Infringement Claimed by Third Parties.

(a) In the event a Third Party commences, or threatens to commence, a judicial or administrative proceeding in the Territory against a Party to this Agreement and such proceeding pertains to the Product or Product Formulation infringing or misappropriating any intellectual property right (including any Patent Right or Information) of a Third Party (an "Infringement Action"), the Party against whom such Infringement Action is threatened or commenced shall give prompt notice to the other Party. With respect to any such Infringement Action, the Parties shall first attempt to negotiate in good faith an amicable resolution with respect thereto with the appropriate Third Party if such negotiations are commercially reasonable under the circumstances.

(b) With respect to the defense of any Infringement Action: (i) if Azurity is entitled to seek, and exercises its rights to obtain, indemnification for such Infringement Action pursuant to ARTICLE XI, then the terms of ARTICLE XI shall govern and control the defense of such Infringement Action and the payment obligations of PolyPid in connection with such Infringement Action; provided that, PolyPid shall not settle such Infringement Action in a manner that would reasonably be expected to adversely affect any Product or Azurity's rights hereunder, without the prior written consent of Azurity, which consent shall not be unreasonably withheld, conditioned or delayed; and (ii) if Azurity has not sought to exercise its rights to obtain indemnification for such Infringement Action pursuant to ARTICLE XI (if applicable) and the Parties cannot settle such Infringement Action through amicable resolution with the appropriate Third Party within a reasonable period of time after the receipt of the notice above, the Party that is subject to such Infringement Action shall have the right to direct and control the defense thereof, at its own expense (subject to Section 8.04(c)) with counsel of its choice; provided, however, that the other Party may participate in the defense and/or settlement thereof, at its own expense with counsel of its choice. In any event, the Party that is defending the Infringement Action agrees to keep the other Party hereto reasonably informed of all material developments in connection with any such Infringement Action. The Party controlling such defense shall consult with the other Party in advance regarding the defense strategy and arguments to be advanced, and shall consider in good faith the other Party's reasonable and timely input, taking into account the other Party's expertise in the Product and the potential impact of such strategy and arguments on prosecution, enforcement or defense of the Licensed Patent Rights or Marks inside or outside the Territory. Each Party agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would reasonably be expected to adversely affect any Product, or the manufacture, use or sale of any Product, with respect to the other Party's permitted exploitations of such, without the prior written consent of such other Party, which shall not be unreasonably withheld, conditioned or delayed. At Azurity's request, PolyPid shall join as a party to any Infringement Action or proceeding brought by Azurity or its Sublicensee to enforce any Licensed Technology, to the extent PolyPid is a necessary party to such action.

(c) *Recovery, Offset and Liability Allocation*. In the event that Azurity has not sought to exercise its rights to obtain indemnification for such Infringement Action pursuant to ARTICLE XI and Azurity is the defending Party and incurs reasonable out of pocket expenses (including reasonable attorneys' fees and court costs, and any settlement costs or damages) in defending or in connection with any Infringement Action in the Territory pursuant to Section 8.04(b) ("Third Party IP Costs") Azurity shall have the right to deduct fifty percent (50%) of such Third Party IP Costs from the Milestone Payments and the Product Net Profit payments otherwise payable by Azurity to PolyPid pursuant to Section 7.01 or Section 7.02; provided that (i) such deduction shall not apply to the Product Price payable pursuant to Section 6.01, or any other amounts payable to PolyPid under this Agreement other than Milestone Payments or Product Net Profit, (ii) other than in the case such Infringement Action is a result of any breach or inaccuracy of any representation, warranty or covenant made by PolyPid under this Agreement or arises from the subject matter of Excluded Information, the aggregate amount deducted in any Calendar Quarter shall not exceed fifty percent (50%) of the aggregate Milestone Payments and Product Net Profit otherwise payable to PolyPid for such Calendar Quarter, and (iii) any part of the 50% of the Third Party IP Costs that cannot be fully deducted in a given Calendar Quarter may be carried forward to future Calendar Quarters until fully recovered, subject to the same per-quarter cap. Azurity shall provide PolyPid with reasonable documentation supporting any Third Party IP Costs for which it seeks deduction under this Section 8.04(c). For clarity, in the event that Azurity elects to seek indemnification pursuant to Section 11.01 with respect to a certain Infringement Action (and accordingly, the provisions of this Section 8.04 shall not apply except as expressly set forth in this Section 8.04), PolyPid shall bear and be responsible for 100% of the Third Party IP Costs in connection with its indemnification of Azurity for Infringement Actions pursuant to Section 11.01.

(d) *Infringement Determination Notice; Post-Notice Liability Allocation*.

(i) If, following receipt of notice of an Infringement Action for the infringement of a Third Party's Patent Right pursuant to Section 8.04(a) where such Infringement Action is either (A) against PolyPid and Azurity is not otherwise indemnifying PolyPid pursuant to ARTICLE XI or (B) against Azurity for which PolyPid is indemnifying Azurity pursuant to this Section 8.04 or pursuant to ARTICLE XI, and in either case of (A) or (B) PolyPid delivers written notice to Azurity (an "Infringement Determination Notice") [**]

(ii) The Infringement Determination Notice shall include [**]

(e) *Third Party Agreements*. Azurity shall have the right to seek, negotiate and enter into agreements or other arrangements with Third Parties to obtain rights, whether by license, acquisition or otherwise, to intellectual property and other subject matter of Third Parties that pertain to the Product and Azurity's exercise of its rights and obligations under this Agreement. [**]

ARTICLE IX
CONFIDENTIALITY

Section 9.01 Confidentiality.

(a) The Party receiving any Confidential Information hereunder (the "Receiving Party") agrees that, during the Term and for a period of [**] thereafter, 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 disclosing Party (the "Disclosing Party"), except to the extent expressly agreed in writing by the Disclosing Party. In addition, Receiving Party shall maintain in confidence all Confidential Information of the Disclosing Party to the same extent such Receiving Party maintains and protects its own proprietary information of similar kind and value, and, in any event, using no less than a reasonable standard of care. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Disclosing 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 (to the extent such Receiving Party or its Affiliate has the right to use and disclose such information) at the time of disclosure by the Disclosing 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 Representatives in breach of this Agreement;

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

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

Section 9.02 Authorized Disclosure.

(a) Notwithstanding the obligations set forth in Section 9.01, Receiving Party may disclose Disclosing Party's Confidential Information and the terms of this Agreement to the extent:

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

(ii) such disclosure is reasonably necessary in enforcing the Receiving Party's or performing its obligations or exercising its rights under this Agreement;

(iii) such disclosure is reasonably necessary in Regulatory Materials in the Territory that the Receiving Party has the right to make under this Agreement;

(iv) such disclosure is reasonably necessary to (A) its or its Affiliates' employees, agents, consultants, contractors, advisors, or representatives (collectively "Representatives") and (B) actual or potential licensees or sublicensees, in each case 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;

(v) 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 (a) prior to disclosure, such Third Party must be bound by written obligations of confidentiality and non-use similar to those contained in this Agreement, and (b) [**]

(vi) 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) Each Party shall be responsible for any breaches of confidentiality by any of its Affiliates, licensees or sublicensees, Representatives, advisors and Third Parties (to whom it discloses Confidential Information pursuant to Section 9.02(a) and Section 9.03).

(c) Notwithstanding the foregoing, in the event a Receiving Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 9.02(a)(i), Section 9.02(a)(v) or Section 9.02(a)(vi), 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. If the Disclosing Party is unable to obtain a protective order or other remedy, the Receiving Party shall disclose only that portion of such Confidential Information that it is advised by counsel is legally required to be disclosed; provided that, any Confidential Information so disclosed shall retain its status as Confidential Information for all other purposes other than such legally required disclosure.

Section 9.03 Publicity; Public Statements; Terms of Agreement.

(a) The Parties agree that the terms of this Agreement are the Confidential Information of both Parties, provided that each Party may disclose the existence and/or terms of this Agreement: (a) to its Representatives, advisors (including financial advisors, attorneys and accountants), potential and existing investors, lenders, collaboration partners or acquirers, and others, on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof; or (b) to the extent necessary to comply with Applicable Laws and court orders, including securities laws or regulations or pursuant to the listing rules of any recognized stock exchange on which the such Party's or its Affiliate's securities are traded; provided that in the case of clause (b) the Disclosing Party shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the Disclosing Party's legal counsel, to comply with securities laws, regulations or such listing rules) allow the other Party a reasonable opportunity to oppose with the body initiating the process and, to the extent allowable by Applicable Law, to seek limitations on the portion of the Agreement that is required to be disclosed.

(b) The Parties have agreed in principle upon the initial press release to announce the execution of this Agreement in substantially the form attached hereto as Exhibit A, 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 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 [**] 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. Notwithstanding the foregoing, neither Party is required to seek the permission of the other Party (i) to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 9.03(b) or (ii) in the event a public disclosure is required by Applicable Law, provided that, to the extent legally permissible, such Party shall give reasonable prior advance notice of the proposed text of such public disclosure to the other Party for its prior review.

(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) Azurity acknowledges that PolyPid is a public company whose shares are publicly traded on the NASDAQ (ticker symbol PYPD). Accordingly: (a) PolyPid's Confidential Information may be considered as "inside information" pursuant to US securities laws and regulations and Azurity undertakes not to use any Confidential Information in violation of the applicable securities laws; and (b) PolyPid may be required to make certain disclosures, filings, press releases or publications under Applicable Laws, which may include the terms and conditions of this Agreement and/or the engagement hereunder.

(e) Without limiting Section 9.03(d) and notwithstanding anything to the contrary in this Section 9.03 or elsewhere in this Agreement, PolyPid may make public statements, disclosures, filings, press releases or publications regarding [**]; provided that PolyPid first provides Azurity a copy of the proposed disclosure at least [**]in advance of such disclosure, and provided further that if Azurity reasonably demonstrates, within [**]of PolyPid providing the copy, that the public disclosure of previously undisclosed information will materially adversely affect the Exploitation of a Product being Exploited in the Territory, PolyPid shall remove from the disclosure such specific previously undisclosed information as Azurity reasonably requested to be removed; provided further that PolyPid may disclose such information as required by Applicable Law. To the extent that, at any point during the Term, Azurity becomes a public company or is otherwise subject to disclosures pursuant to the U.S. Securities and Exchange Commission or any exchange, the provisions of this Section 9.03(e) shall apply to Azurity, *mutatis mutandis*.

Section 9.04 Publication.

(a) Subject to the obligations under Section 9.01 and Section 9.03(a), Azurity (or its designee) shall have the right, subject to the conditions set forth in this Section 9.04(a), to publish and present the results of Development activities in the Territory with respect to the Product and pursuant to the terms of this Agreement, including the results of any clinical study of a Product, conducted by or under the authority of Azurity or any of its Affiliates in the Territory (including in Territory Journals (as defined below), even if such publication is distributed outside the Territory); provided, however, that (i) Azurity shall notify PolyPid in writing of any such publication or presentation (including the subject matter therein) at least [**]prior to the expected date of publication and (ii) PolyPid (including its Affiliates, as applicable) and its work and contributions shall be appropriately mentioned, acknowledged and reflected in such publication or presentation in accordance with accepted scientific practice and to the extent applicable. Any publications by Azurity regarding the results of Development activities in the Territory with respect to the Product in any global or international journals which are not Territory Journals shall require PolyPid's prior written consent, not to be unreasonably withheld or delayed; provided that, Azurity shall, in coordination with PolyPid, be entitled to publish publications regarding the Product (A) in journals in the Territory mainly intended for readers in the Territory or (B) in journals that are based in the Territory (e.g., headquartered in the Territory) other than [**](such journals in (A) and (B), "Territory Journals").

(b) Subject to the obligations under Section 9.01 and Section 9.03(a), PolyPid (or its designee) shall have the right to publish and present the results of Development activities conducted within or outside the Territory with respect to a Product, including the results of any clinical study of a Product, conducted by or under the authority of PolyPid or any of its Affiliates and any other publication covering Development activities conducted by Azurity (or any of its Affiliates) pursuant to Section 9.04(a), in any journals which are not Territory Journals; provided, however (i) PolyPid shall notify Azurity in writing of any such publication or presentation (including the subject matter therein) at least [**]prior to the expected date of publication and (ii) Azurity (including its Affiliates, as applicable) and its work and contributions shall be appropriately mentioned, acknowledged and reflected in such publication or presentation in accordance with accepted scientific practice and to the extent applicable. Any publications regarding the results of Development activities in the Territory with respect to the Product in any Territory Journals shall require Azurity's prior written consent, not to be unreasonably withheld or delayed.

(c) Without limiting Section 9.04(a) and Section 9.04(b), the Parties shall reasonably cooperate with each other to coordinate their strategies for publishing the results of any clinical study of a Product.

Section 9.05 Equitable Relief.

Each Party acknowledges that its breach of this ARTICLE IX may 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 IX by the other Party.

ARTICLE X
REPRESENTATIONS AND WARRANTIES; COVENANTS

Section 10.01 Mutual Representations and Warranties.

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

(a) *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 performs its obligations hereunder.

(b) *Due Authorization; Binding Obligations*. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate actions on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal and valid obligation binding upon it and is enforceable in accordance with its terms, except that the enforcement of the rights and remedies created hereby is subject to bankruptcy, insolvency, reorganization and similar laws of general application affecting the rights and remedies of creditors and that the availability of the remedy of specific performance or of injunctive relief is subject to the discretion of the court before which any proceeding therefor may be brought.

(c) *No Conflict*. The execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the transactions contemplated pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Applicable Law existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation or by-laws (or other organizational documents) of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a material default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

(d) *No Violation*. Neither such Party nor any of its Affiliates is under any obligation to any Person, contractual or otherwise, that is in violation of the terms of this Agreement.

(e) *No Consents*. No authorization, consent, approval of a Third Party nor any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or, to such Party's knowledge will be, necessary for the (i) valid execution and delivery of this Agreement by such Party; or (ii) the consummation by such Party of the transactions contemplated hereby.

(f) *Debarment.* It is not and has not been debarred or suspended by any Governmental Authority, and none of its or any of its Affiliates' officers, directors, employees, agents, representatives, independent contractors, or any other Person acting for or on behalf of it or any of its Affiliates who were or will be involved in the Development, Manufacture or Commercialization of Products prior to the Effective Date are, or have been, debarred or suspended by any Governmental Authority; each Party covenants that when performing its activities pursuant to this Agreement, it will not employ any personnel or use a subcontractor or consultant or other Person 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. In the event that such Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to such Party or any of its Affiliates with respect to any activities relating to any Products, such Party will promptly notify the other Party in writing and such Party will cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to the applicable Products.

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

(i) It represents, warrants and covenants that it complies with the Ethical Business Conduct Laws and neither it 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.

(ii) Each Party acknowledges that the other Party has in place codes of conduct and other policies and procedures directed to compliance with Applicable Law, including Anti-Corruption Laws and each Party agrees to adhere in all material respects to its own existing codes, policies and procedures during the Term and in connection with activities conducted pursuant to this Agreement.

(iii) it hereby covenants to give regular training on these issues to its employees throughout the Term.

Section 10.02 Additional Representations, Warranties and Covenants of Azurity.

(a) *Compliance*. Azurity 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 the Regulatory Approvals including the MA and Pricing and Reimbursement Approvals and all Commercialization activities carried out under this Agreement.

(b) *Requisite Approvals.* Azurity represents, warrants and covenants to PolyPid that it holds or shall timely procure and shall cause its Sublicensees and distributors to hold in good standing all Regulatory Approvals and all licenses, permits and approvals required by the Regulatory Authorities to Exploit the Product in the Territory, including without limitation, MA and Pricing and Reimbursement Approvals, excluding any such Regulatory Approvals, licenses, permits and approvals required to be obtained by PolyPid under this Agreement.

(c) Azurity covenants and agrees that, except as otherwise specified in this Agreement, it will assume all responsibility for Exploiting the Product in the Territory including obtaining all necessary Regulatory Approvals, and any other requirements relating to the Exploitation of the Product, including import, sale and distribution of the Product imposed by Applicable Law.

Section 10.03 Additional Representations, Warranties and Covenants of PolyPid.

(a) *Product Representations and Warranties*. PolyPid represents, warrants and covenants to Azurity that on and after the Effective Date: (i) the Product delivered pursuant to this Agreement, at the time of delivery and during the Shelf Life (provided Azurity, its Affiliates and Sublicensees comply with applicable storage requirements), shall comply with the Product Specifications, Manufacturing Standards, the Quality Agreement, and Applicable Law; (ii) at the time of Manufacture and delivery to Azurity the Product will be free from any defects, liens and encumbrances and Azurity shall receive good and marketable title to the Product; and (iii) at the date of Manufacture and delivery of the Product, that PolyPid has the right to Manufacture and label the Product (items (i) through (iii), collectively, the "Product Requirements").

(b) *Manufacturing Facilities.* The operation of the manufacturing facilities for the Product supplied to Azurity under this Agreement shall be in compliance with: (i) the Manufacturing Standards; (ii) the Quality Agreement and (iii) any further manufacturing, packaging or other standards agreed in writing by the Parties.

(c) *No Conflicting Grant of Licensed Technology.* PolyPid represents and warrants that on the Effective Date, (a) it Controls all right, title and interest in and to the Licensed Technology and the Marks, (b) it has not granted any license under the Licensed Technology or the Marks for any Product for the Indication in the Territory to any Third Party and (c) PolyPid is not a party to any contract or agreement with a Third Party pursuant to which PolyPid in-licenses or otherwise acquires Control of Patent Rights, or Information that is necessary to Develop, Manufacture, Commercialize or otherwise Exploit any Product in the Territory.

(d) *Rights in Products, Licensed Technology 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 or unenforceable, in whole or in part;

(ii) it has the full right, power and authority to grant the license under Section 1.01(a);

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

(iv) to PolyPid's knowledge, there is no actual, pending, alleged or threatened infringement by a Third Party of any of the Licensed Technology or Products; and

(v) the Licensed Technology is free and clear of all liens, claims, security interests or other encumbrances of any kind and, during the Term, PolyPid shall not permit any of the Licensed Technology to become encumbered by any liens, claims, security interests or other encumbrances.

(e) Schedule 4 contains a complete list of the Licensed Patent Rights in existence as of the Effective Date and all applicable renewals, annuities, and other fees have been duly and timely paid with respect to the Patent Rights listed on Schedule 4.

(f) *Sanctions*. PolyPid represents and warrants to Azurity that it will not engage in any "covered data transactions" involving "data brokerage" of any information received from Azurity under this Agreement with a "country of concern" or a "covered person," within the meaning ascribed to each term under Executive Order 14117 and rules issued thereunder, including 28 C.F.R. Part 202.

(g) *No Infringement or Misappropriation*.

(i) Neither PolyPid, its Affiliates, nor its or their respective current or former employees have misappropriated any of the Licensed Information from any Third Party, and PolyPid is not aware of any claim by a Third Party that such misappropriation has occurred.

(ii) To the knowledge of PolyPid, the use of the Licensed Technology in the performance of the activities under this Agreement, and the Development, Manufacture and Commercialization or other exploitation of Products and Product Formulations, in each case, as contemplated to be conducted under this Agreement, does not (A) infringe any issued Patent Right of any Third Party or the claims of any published Third Party patent application if such claims were to issue in their current form, (B) misappropriate any Information of any Third Party, or (C) otherwise violate any intellectual property right of any Third Party.

(h) *Third Party Agreements*. Each Existing Third Party Agreement is set forth on Schedule 10. PolyPid shall not take, or fail to take, any action within its reasonable control that comprises or would result in an amendment, modification, breach, termination or diminution of PolyPid's rights under an Existing Third Party Agreement (or Azurity's rights under this Agreement), in each case to the extent reasonably likely to adversely affect the Product in the Territory or Azurity's rights or obligations under this Agreement without Azurity's prior written consent. PolyPid shall not enter into any agreement with a Third Party that would conflict in any respect with this Agreement, would be reasonably likely to materially adversely affect the Product in the Territory or would adversely affect Azurity's rights or obligations under this Agreement. Each counterparty to an Existing Third Party Agreement is a reputable company in the biopharmaceutical industry and as of the Effective Date is in, and is required to conduct its activities under the applicable Existing Third Party Agreement in, compliance with all Applicable Laws (including, as applicable, cGMP and other regulatory requirements imposed by a Regulatory Authority with respect to the manufacture, testing or supply of Product (or components or raw materials therefor) for the Territory). The Existing Third Party Agreements, taken together, are sufficient and adequate to permit and enable PolyPid to Manufacture Product and supply the Product to Azurity in accordance with the terms of this Agreement throughout the Term and no Existing Third Party Agreement contains any exclusivity, non-compete, or other provision that would restrict PolyPid's ability to supply the Product to Azurity or otherwise adversely affect Azurity's rights under this Agreement or requires the consent of any counterparty in connection with the execution or performance of this Agreement. To PolyPid's knowledge, no counterparty to an Existing Third Party Agreement is subject to any bankruptcy, insolvency, or similar proceeding or other decree or order or has indicated an inability to perform its material obligations thereunder. For clarity, nothing in this Section 10.03(h) restricts PolyPid from entering into, amending or performing agreements in the ordinary course of business or with respect to products, technologies or territories other than the Product in the Territory, provided that PolyPid complies with this Section 10.03(h).

(i) *Disclosures*. PolyPid has made available to Azurity: (a) all material information pertaining to the IIA Grants; (b) all Existing Third Party Agreements, except for such Existing Third Party Agreements that cannot be made available due to confidentiality obligations of PolyPid prohibiting such disclosure and that are set forth on Schedule 10) (along with a description of the nature of such Existing Third Party Agreement); and (c) material Information, including Regulatory Materials, in its possession or Control regarding or related to the Product or Product Formulation (other than the Excluded Information), including any adverse Information with respect to the use of the Product or Product Formulation, and in each case ((a) through (c)), all such materials pertaining to the IIA Grants, Existing Third Party Agreements, and other Information are true, complete and correct in all material respects. After the Effective Date, PolyPid will continue to make available to Azurity true, complete and correct copies of any material information or documentation pertaining the IIA Grants, Existing Third Party Agreements, except for such Existing Third Party Agreements that cannot be made available due to confidentiality obligations prohibiting such disclosure, and other material Information in its possession or Control regarding or related to the Product or Product Formulation (other than the Excluded Information). Except with respect to information that has been disclosed or otherwise made available to Azurity in writing or during the due diligence process (i.e. discussed during Azurity's visits to PolyPid sites on February 4th and 5th, 2026), neither PolyPid nor any of its Affiliates, as of the Effective Date, (i) has knowledge of any scientific or technical facts or circumstances that would reasonably be expected to materially adversely affect the Product or Product Formulation or the scientific, therapeutic or commercial potential of the Product or Product Formulation or (ii) is aware of any information that would reasonably be expected to materially adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for Regulatory Approval for the Product in the Territory.

Section 10.04 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) Without derogating from the generality of the above, each Party represents and warrants that such Party and its Affiliates and their employees, officers, directors, agents or representatives, have not and will not make or offer or promise to make any payment in violation of any Anti-Corruption Laws, anti-bribery practices or Applicable Laws. Each Party shall not, and shall ensure that its Affiliates and their employees, officers, directors, agents or representatives, shall not, give, offer or promise to give, or authorize the giving directly or indirectly through any other Person, of any money or thing of value to any employee, representative or official of any government, hospital, health center, medical center or governmental entity, for the purpose of inducing or rewarding favorable action or the exercise of influence by such employee, representative, official or party, in relation to the business or affairs of PolyPid, Azurity or the engagement hereunder.

(c) Notwithstanding the foregoing, each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to audit the other Party's books and records in the event that a suspected violation of any Anti-Corruption Law needs to be investigated (in such Party's reasonable, good-faith discretion). Such audit shall be conducted by such Party's audit team comprised of qualified auditors who have received anticorruption training.

Section 10.05 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 XI
INDEMNIFICATION

Section 11.01 Azurity Indemnified by PolyPid.

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

(a) any negligence or willful misconduct on the part of PolyPid or any PolyPid Indemnitee;

(b) any breach of any representations, warranties or covenants by PolyPid in Section 1.11(c) or ARTICLE X above;

(c) the Manufacturing, Development, Commercialization and other exploitation of the Product by PolyPid, its Affiliates or sublicensees outside of the Territory; and

(d) 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, provided that Azurity has sought indemnification pursuant to this Section 11.01 to the exclusion of Section 8.04;

provided that, the indemnity set forth in this Section 11.01 shall not apply to the extent that Azurity has an indemnification obligation for such Third Party Claim pursuant to clauses (a) or (b) of Section 11.02.

Section 11.02 PolyPid Indemnified by Azurity.

Azurity 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 Losses which PolyPid Indemnitee may incur or suffer as a result of such Third Party Claim, arising out of or based upon:

(a) any negligence or willful misconduct on the part of Azurity or any Azurity Indemnitee;

(b) any breach of any representations, warranties or covenants by Azurity in ARTICLE X above; and

(c) the Exploitation of the Product by Azurity, its Affiliates or Sublicensees in the Territory;

provided that the indemnity set forth in this Section 11.02 shall not apply to the extent that PolyPid has an indemnification obligation for such Third Party Claim pursuant to Section 11.01.

Section 11.03 Claims and Proceeding.

In the event that any person (an "Indemnitee") entitled to indemnification under Section 11.01 or Section 11.02 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 sole 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) subject to Section 11.04 below, 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 and Indemnitor has agreed in writing to take on such expense, 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 11.03, 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 estimated amount of Loss and relevant details thereof.

Section 11.04 Indemnitor May Settle.

Notwithstanding anything to the contrary, the Indemnitor shall have the right to settle or compromise any claim against the Indemnitee without the consent of the Indemnitee provided that the terms thereof: (a) provide for the unconditional release of the Indemnitee; (b) require the payment of compensatory monetary damages by Indemnitor only and do not adversely affect the rights of the Indemnitee; and (c) expressly state that neither the fact of settlement nor the settlement agreement shall constitute, or be construed or interpreted as, an admission by the Indemnitee of any issue, fact, allegation or any other aspect of the claim being settled. No Indemnitee shall pay or voluntarily permit the determination of any liability which is subject to any such action while the Indemnitor is negotiating the settlement thereof or contesting the matter, except with the prior written consent of the Indemnitor, which consent shall not be unreasonably withheld, conditioned or delayed. If the Indemnitor fails to give Indemnitee notice of its intention to defend any such action as provided herein, the Indemnitee involved shall have the right to assume the defense thereof with counsel of its choice, at the Indemnitor's expense, and defend, settle or otherwise dispose of such action pursuant to Section 11.03.

Section 11.05 Limitation of Liability. [**]

Section 11.06 Insurance. [**]

ARTICLE XII
TERM; DEFAULT AND TERMINATION

Section 12.01 Term.

This Agreement shall commence as of the Effective Date and shall, subject to the early termination provisions as specified herein, expire twenty (20) years from the Effective Date (the "Term"). Upon expiration (but not early termination) of this Agreement, Azurity's license under Section 1.01(a) shall become perpetual, irrevocable and fully paid up.

Section 12.02 Termination by Either Party.

In addition to the early termination rights of each Party as expressly indicated in this Agreement, either Party may terminate this Agreement**:** [**]

Section 12.03 [**]

Section 12.04 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.

Section 12.05 Effect of Termination.

Upon the termination (but not expiration) of this Agreement by either Party, the following shall occur:

(a) The licenses under Section 1.01 of this Agreement and all other rights granted to either Party hereunder shall automatically terminate and (i) all of PolyPid's rights to the Licensed Technology, the Data and Marks shall continue to be the sole property of PolyPid and (ii) all of Azurity's rights to the Azurity Technology shall continue to be the sole property of Azurity;

(b) Azurity shall promptly assign to PolyPid (at no cost to PolyPid, except in the event of termination by Azurity under Section 12.02 (PolyPid's breach or insolvency), in which case at PolyPid's cost and expense) all right, title and interest in and to any PolyPid Inventions and Data constituting Licensed Information, in each case that have not previously been assigned to PolyPid pursuant to Section 8.01 or otherwise, and shall execute all documents and take all actions reasonably necessary to give effect to and perfect such assignments; (ii) except in connection with activities under Section 12.05(h), Azurity shall, and shall cause its Affiliates and Sublicensees to, immediately cease all use of the Marks and PolyPid's trademarked name and logo, and shall not thereafter use any trademark, trade name, or domain name that is the same as or confusingly similar to the Marks or PolyPid's trademarked name and logo; and (iii) Azurity shall deliver to PolyPid all tangible embodiments of Licensed Information (other than Product in connection with activities under Section 12.05(h)) and [**].

(c) Without limiting a Party's right to claim damages for breach of this Agreement, neither Party shall be entitled to receive any form of compensation and/or remuneration and/or other payments in connection with or as a result of termination or expiration of this Agreement for any reason, including without limitation, any compensation for investments made by such Party, for building a distribution network, for lost profits of such Party, for goodwill, etc.

(d) Upon termination of this Agreement, the survival or termination of sublicenses granted by Azurity to Sublicensees shall be determined in accordance with Section 1.02(c). Without limiting the foregoing, where a sublicense survives termination in accordance with Section 1.02(c) and the relevant Sublicensee is deemed a direct licensee of PolyPid, such Sublicensee shall only be responsible for any payments that become due under the direct license with PolyPid solely as a result of such Sublicensee's activities after the effective date of such termination and any breach by the Sublicensee occurring prior to the effective date of such termination, and shall not be responsible for any Milestone Payments already paid by Azurity, or that have accrued, prior to the effective date of such termination and, unless the Sublicensee agrees in writing, such direct license with PolyPid shall not grant the Sublicensee any rights, or obligate the Sublicensee to obligations, broader than those granted under the applicable sublicense as in effect immediately prior to termination of this Agreement.

(e) *Regulatory Matters*.

(i) without derogating from Section 3.02(d), all Regulatory Materials shall be assigned to PolyPid at no cost to PolyPid (except in event of termination by Azurity under Section 12.02, in which case it shall be at PolyPid's sole cost and expense). Azurity shall make any required filings with the Regulatory Authorities to the extent necessary and sufficient for PolyPid to market and sell the Product in the Territory (provided that in event of termination by Azurity under Section 12.02, such filings shall be at PolyPid's sole cost and expense). Azurity shall upon request and where applicable, at PolyPid's cost, provide to PolyPid confirmatory assignments and all such other documents and assistance as PolyPid may reasonably request in relation to all Licensed Technology and the Marks; or

(ii) without derogating from Section 3.02(d), to the extent any Regulatory Approvals are not, by law, assignable to PolyPid, then Azurity shall, at no cost to PolyPid (except in the event of termination by Azurity under Section 12.02 (PolyPid's material breach or insolvency), in which case at PolyPid's sole cost and expense): (A) grant PolyPid full unencumbered access to and right to use all Azurity Regulatory Materials in respect of the Product (including signing and filing all necessary cross-reference letters); (B) upon the request of PolyPid, voluntarily file with the appropriate authorities all documents that may be required in connection with the surrender, cancel and rescind or cause to be surrendered, cancelled and rescinded all Regulatory Approvals for the Product which Azurity may have obtained; and (C) if requested by PolyPid, provide reasonable cooperation to PolyPid for a period not to exceed [**] after the effective date of expiration or termination in effecting the cancellation of any identification of Azurity with any authorities or Regulatory Approvals applicable to the Product.

(f) 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 6.01(c) above after termination or expiration of this Agreement;

(g) Receiving Party will return to the Disclosing Party, or destroy at the Disclosing Party's election, all Confidential Information of the Disclosing Party, and Receiving Party will cease to make use of the other Party's Confidential Information, except that (i) Receiving Party will not have an obligation to return or destroy or to cease to make use of any information to the extent it is required for regulatory or compliance purposes; (ii) Receiving Party will not 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 ARTICLE IX shall continue to apply; and (iii) each Party may retain one copy of the Confidential Information of the other Party solely to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement;

(h) [**]

Section 12.06 Effect of Expiration [**]

Section 12.07 Survival.

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. The obligations and rights of the Parties under the following Articles and Sections Section 1.01(a) (only upon expiration); Section 1.02(c) (only with respect to such sublicenses which are to survive following termination of the Agreement, in circumstances detailed therein); Section 1.04 (except with respect to the restrictions therein with respect to the Manufacturing Process, solely to extent necessary to exercise Azurity's rights under Section 12.06 in the case that PolyPid elects clause (B) of Section 12.06(b)); Section 1.05; Section 1.10(a) (for the period set forth therein); Section 1.10(b); Section 3.02(d) (only upon termination, solely with respect to procedures that are pending as of the effective date of termination); ARTICLE V and ARTICLE VI (only upon expiration and solely with respect to Manufacture and supply by PolyPid in accordance with Section 12.06); Section 6.01(c); ARTICLE VII (solely for purposes of a final accounting); Section 8.01; Section 8.04 (with respect to claims or proceedings arising prior to the effective date of expiration or termination); ARTICLE IX (for the period set forth therein); ARTICLE XI (including the insurance tail obligation set forth in Section 11.06); Section 12.05 (only upon termination); Section 12.06 (only upon expiration); this Section 12.07; ARTICLE XIII; Section 14.02; Section 14.06; Section 14.09; Section 14.10; Section 14.11; Section 14.12; and Section 14.14, and the Definitions Section (to the extent applicable to such surviving provisions), 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 as set forth in such agreements.

ARTICLE XIII
GOVERNING LAW AND DISPUTE RESOLUTION

Section 13.01 Dispute Resolution

In the event of any dispute between the Parties (other than with respect to intellectual property matters under ARTICLE VIII), the senior executives of PolyPid and Azurity 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, except with respect to (i) disputes arising under Section 3.02(b), Section 3.08(a), Section 4.04(a), Section 4.04(b), Section 5.02, [**], and Section (c)(iii) of Schedule 9 that are specified as subject to baseball arbitration (each an "Baseball Arbitration Matter") which will be resolved pursuant to the proceedings set forth in Schedule 11 (the "Baseball Arbitration Procedure") and (ii) Invoice Disputes arising under Section 6.01(c), which will be resolved pursuant to the proceedings set forth in Section 13.03, such dispute shall be finally settled in accordance with Section 13.02.

Section 13.02 Governing Law and Jurisdiction

This Agreement shall be governed by, and construed and enforced in accordance with, the laws of [**], 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 competent courts located in [**], 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.

The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement.

Section 13.03 Expedited Arbitration.

Any Invoice Disputes shall be finally resolved by binding expedited arbitration administered by the International Chamber of Commerce under its Expedited Procedure Rules then in effect, except as modified herein. The arbitration shall be conducted in English before a single arbitrator seated in [**]. The arbitrator shall be appointed by the ICC within [**] after commencement of the arbitration. Judgment on the award may be entered in any court of competent jurisdiction.

Section 13.04 Interim Relief.

Notwithstanding anything in this ARTICLE XIII to the contrary, each Party shall have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other similar interim or conservatory relief, as necessary to protect the rights or property of such Party, pending the resolution of the dispute.

ARTICLE XIV
MISCELLANEOUS

Section 14.01 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 14.02 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, PolyPid may only assign this Agreement to a Third Party to whom all right, title and interest in and to the Licensed Technology is also assigned. 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 14.03 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 14.04 Force Majeure.

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 any other reason which is completely beyond the control of the Party, (collectively a "Force Majeure"). In the case of a Force Majeure, the affected Party shall (a) as soon as reasonably practicable 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. Suspension of performance shall be of no greater scope and no longer duration than necessary to resolve such Force Majeure.

Section 14.05 Further Actions.

Upon the terms and subject to the conditions hereof, each of the Parties hereto shall use its Commercially Reasonable Efforts to 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 14.06 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.

[**]
with a copy to:
[**]

If to Azurity: Azurity Pharmaceuticals Ireland Ltd.

[**]
with a copy to:
[**]

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 14.07 Independent Contractors.

It is expressly agreed that PolyPid and Azurity 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 Azurity 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 14.08 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.

Section 14.09 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, the word “or” is disjunctive but not necessarily exclusive and the singular shall include the plural and vice versa. The term “including” as used herein means including, without limiting the generality of any description preceding such term. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement.

Section 14.10 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 14.11 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. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same.

Section 14.12 Severability.

In case any provision of this Agreement shall be invalid, illegal or unenforceable, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and 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 14.13 Termination Due to Regulatory Impossibility or Infeasibility.

Nothing in this Agreement shall obligate either Party to act in violation of Applicable Laws. To the extent that developments in Applicable Laws prohibit or prevent a Party from carrying out, or make it infeasible for a Party to carry out, its obligations under this Agreement, the Parties will discuss in good faith such development and potential alternatives.

Section 14.14 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.

(Signature Page Follows)

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
Date: July 17, 2026

Azurity Pharmaceuticals Ireland Ltd.

By: /s/ Ronald L. Scarboro
Name: Ronald L. Scarboro
Title: Chief Executive Officer
Date: July 17, 2026

SCHEDULE 1

[**]

SCHEDULE 2

FAILURE TO SUPPLY TERMS [**]

SCHEDULE 3

AZURITY FORECASTS FOR PRODUCT[1] [**]

1

SCHEDULE 4

EXISTING LICENSED PATENT RIGHTS[**]

SCHEDULE 5

PRODUCT MARKS[**]

SCHEDULE 6

IIA-RELATED AMENDMENTS

1. IIA Transfer Approval Option Amendments. Following the (i) receipt by PolyPid of the applicable IIA approval and (ii) payment of the applicable Redemption Payment (if any), the Agreement shall be, and is hereby deemed, amended as follows:

    a. All references to "Permitted Development" or "conduct Permitted Development" shall be replaced with "Development", "Developed", "Developing" or "Develop", as the case may be.

    b. The definition of "Data" shall be deleted in its entirety and replaced with the following:

    ""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. For the avoidance of doubt, any Data or Information made by Azurity, its Affiliates, Sublicensees or subcontractors in the conduct of Commercialization of the Product other than Doxy Specific Data and Information shall be solely owned by, and the Confidential Information of, Azurity."

    c. The definition of "PolyPid Invention" shall be deleted in its entirety and replaced with the following:

    ""PolyPid Invention" means any Invention (a) made solely or jointly by one or more employees, consultants or contractors of PolyPid or any of its Affiliates, (b) made jointly by one or more employees, consultants or contractors of PolyPid or any of its Affiliates on the one hand, and one or more Third Parties on the other or (c) that is a Doxy-Specific Invention."

    d. The penultimate sentence of Section 1.07(d) shall be deleted.

    e. Section 1.07(f) shall be deleted in its entirety and replaced with the following:

    "PolyPid shall conduct the Additional Development in accordance with the Additional Development Plan and shall provide Azurity with regular updates on study progress and results through the CSC. Azurity shall provide PolyPid with reasonable cooperation and access to Territory-specific commercial regulatory and clinical data materials to support PolyPid's conduct of any expansion study in the Territory pursuant to this to Section 1.07(e). Notwithstanding the foregoing, Azurity may request to conduct the Additional Development itself by delivering written notice to PolyPid and Azurity or any of its Affiliates shall be permitted to conduct the Additional Development."

    f. Section 8.01(b) shall be deleted in its entirety and replaced with the following:

    "PolyPid (or its Affiliate) shall solely own all PolyPid Inventions. All PolyPid Inventions shall be deemed included in Licensed Information, and any Patent Rights covering PolyPid Inventions shall be deemed included in Licensed Patent Rights."

g. PolyPid hereby assigns, and shall cause its Affiliates and sublicensees to assign, to Azurity all right, title and interest in and to any Invention that was assigned to PolyPid pursuant to Section 8.01(b) as a result of clause (c) of the definition of PolyPid Invention as PolyPid Invention was defined prior to the changes in this Schedule 6 taking effect, and shall execute all documents and take all actions reasonably necessary to give effect to and perfect such assignment.

2. IIA Sharing Approval Option. Following Azurity's exercise of the IIA Sharing Option, (i) Section 1 of this Schedule 6 shall apply and (ii) the Parties shall discuss and agree in good faith such additional modifications that are necessary or appropriate to ensure that the provisions of this Agreement that seek to allocate responsibility between Azurity and PolyPid for conduct or payments arising from the IIA Law are modified accordingly.

3. Additional Terms.

a. The Parties shall take such actions, and make such additional modifications to the Agreement, as are necessary or appropriate to effect the contemplated amendments herein.

b. Except as expressly modified by this Schedule 6, or as otherwise modified pursuant to Section 3.a. of this Schedule 6, the terms of the Agreement remain and shall remain in full force and effect without amendment or other modification.

SCHEDULE 7

LICENSED INFORMATION[**]

SCHEDULE 8

MANUFACTURER FACILITIES[**]

SCHEDULE 9

ROYALTY PAYMENTS TO THE IIA[**]

(i)

SCHEDULE 10

EXISTING THIRD PARTY AGREEMENTS[**]

SCHEDULE 11

BASEBALL ARBITRATION PROCEDURE

With respect to any Baseball Arbitration Matters, either Party shall have the right, upon written notice to the other Party (such notice, a "Baseball Arbitration Notice"), to refer such matter for resolution by final, binding arbitration in the manner described in this Schedule 11 and administered by a single independent arbitrator of recognized standing with relevant experience in pharmaceutical licensing disputes (a "Baseball Arbitrator"). The Baseball Arbitrator shall be mutually agreed to by the Parties within **[**]**of the Baseball Arbitration Notice; provided that if the Parties are unable to agree on an Baseball Arbitrator within **[**]** (or such other time period as may be agreed by the Parties) after a Party provides the other Party the Baseball Arbitration Notice, then Baseball Arbitrator shall be appointed by JAMS (or such other appointing authority as the Parties may agree) upon application by either Party. The Parties shall use their best efforts to cause the Baseball Arbitrator to be selected and retained within**[**]**after a Party provides the other Party the Baseball Arbitration Notice.

Within **[**]**of retention of the Baseball Arbitrator, each Party shall submit to the Baseball Arbitrator (a) a written statement of its proposal for resolution of the Baseball Arbitration Matter, together with any supporting evidence it considers relevant (each, a "Proposed Resolution") and (b) such other information as may be requested by the Baseball Arbitrator within **[**]**after such request by the Baseball Arbitrator. Each Party's Proposed Resolution, and any additional information provided to the Baseball Arbitrator by such Party, shall be simultaneously provided to the other Party. There shall be no *ex parte* communications with the Baseball Arbitrator. The seat, or legal place, of the baseball arbitration shall be New York City, New York.

The Baseball Arbitrator will be instructed to select one or the other of the two Proposed Resolutions submitted by the Parties within **[**]**after the receipt of each Party's Proposed Resolution, or the receipt of such other information as the Baseball Arbitrator may request pursuant to the paragraph above, and to select the Proposed Resolution, on the balance of the evidence presented, that is most reasonable under the circumstances. The Baseball Arbitrator shall select only one of the Proposed Resolutions (without making any changes to such Proposed Resolution) and shall render such Proposed Resolution as the Baseball Arbitrator's final decision and award. Notwithstanding anything to the contrary in this Agreement, the Baseball Arbitrator shall not have the authority to render any decision other than selecting one Proposed Resolution submitted by a Party pursuant to this Schedule 11. The Baseball Arbitrator shall promptly notify the Parties of its determination in writing, and such decision and award shall be final and binding on the Parties, and judgment on the award may be entered in any court of competent jurisdiction, if applicable. **[**]**

SCHEDULE 12

IIA GRANT [**]

SCHEDULE 13

IIA MANUFACTURING GRANT[**]

EXHIBIT A

INITIAL PRESS RELEASE

PolyPid Announces Exclusive Partnership with Azurity Pharmaceuticals for the Commercialization of D-PLEX100 in the U.S. and Canada

- PolyPid to potentially receive over $320 million in upfront and milestone payments, including $30 million in upfront and near-term milestone payments, plus tiered royalties ranging from mid-teen to mid-twenties percentages
- Azurity, a private global pharmaceutical company, to commercialize D-PLEX100 upon approval in the U.S. and Canada for the prevention of surgical site infections, leveraging its first-in-class commercial model. PolyPid to manufacture and supply D-PLEX100
- Azurity will also fund clinical development of D-PLEX100, supporting the potential label expansion in the U.S. and Canada beyond SSI indications for abdominal surgery
- Partnership follows positive Phase 3 SHIELD II results, demonstrating achievement of the primary endpoint and a 60% relative risk reduction at the secondary endpoint in SSI incidence, with PolyPid's NDA submission to the FDA recently completed
- U.S. launch targeted for the first quarter of 2027

PETACH TIKVA, Israel, X, Month, 2026 -- PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins, today announced that it has entered into an exclusive commercial partnership agreement (the "Agreement") with Azurity Pharmaceuticals ("Azurity"), a privately held specialty pharmaceutical company, for the commercialization of D-PLEX100 in the United States and Canada for the prevention of surgical site infections ("SSIs").

Under the terms of the Agreement, PolyPid will receive an upfront payment of $15 million due upon signing and an additional near-term milestone payment of $15 million payable upon U.S. Food and Drug Administration ("FDA") acceptance of the D-PLEX$_{100}$ New Drug Application ("NDA"), which is expected in August 2026. PolyPid is eligible to receive up to approximately $300 million in additional regulatory, development, and sales-based milestone payments. Upon commercialization, the Company will manufacture and supply D-PLEX100 to Azurity for a transfer price and will be entitled to tiered royalties ranging from mid-teen to mid-twenties percentages.

In addition to the upfront and milestone payments, as part of the collaboration, the parties may agree to jointly pursue potential label expansion of D-PLEX100 in the U.S. and Canada into additional SSI indications beyond abdominal, with Azurity providing funding for these additional clinical development programs. PolyPid will retain global commercial rights to D-PLEX100 outside of the U.S. and Canada, manufacturing rights worldwide, and full ownership of its PLEX platform, Kynatrix™ technology and associated pipeline assets.

“This partnership is a defining step in PolyPid’s transition into a commercial-stage company, and Azurity is the right partner to bring D-PLEX100 to U.S. and Canadian patients, hospitals and surgeons,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “We believe that Azurity’s first-in-class commercial model and demonstrated commercial execution will be invaluable in expanding access to D-PLEX100, if approved. Importantly, this collaboration represents a meaningful validation of our unique platform, and allows us to fully realize the U.S. and Canadian commercial value of D-PLEX100 while putting us in a position of financial strength to continue investing in our Kynatrix technology, pipeline, and the next generation of therapies.”

“At Azurity, we believe meaningful innovation is measured by the difference a therapy makes in the realities of patient care,” said Ronald Scarboro, Chief Executive Officer of Azurity Pharmaceuticals. “D-PLEX$_{100}$ is a differentiated therapy addressing an important unmet need, and we are excited to partner with PolyPid to help bring it to patients in the United States and Canada, if approved. Our commercial model was built to support specialized therapies like this-connecting the right treatment to the right healthcare professionals and patients through efficient, focused execution. Together, we believe we can expand access to an important new option while exploring opportunities to broaden its impact in the years ahead.”

About D-PLEX$_{100}$

D-PLEX$_{100}$, PolyPid’s lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site with the goal of preventing abdominal surgical site infections (“SSIs”). Following the administration of D-PLEX$_{100}$ into the surgical site, PolyPid’s delivery technology, Kynatrix, is designed to pair with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in a high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. In the Phase 3 SHIELD II trial, D-PLEX$_{100}$ recently demonstrated positive results in achieving its primary end point and a 60% (p= 0.0013) relative risk reduction at the secondary end point in SSI incidence following abdominal colorectal surgery with large incisions. D-PLEX$_{100}$ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins. The Company develops long-acting, controlled-release drugs designed to deliver therapy precisely at the site of care, addressing critical unmet medical needs across a wide and diverse pipeline spanning surgical care, metabolic diseases, and beyond. PolyPid’s lead product, D-PLEX$_{100}$, successfully met its primary and all key secondary endpoints in the landmark Phase 3 SHIELD II trial for the prevention of surgical site infections. Guided by a commitment to precision and innovation, PolyPid is redefining how therapies perform and raise the standard of patient care. For additional Company information, please visit http://www.polypid.com and follow us on Twitter (X) and LinkedIn.

About Azurity Pharmaceuticals

Azurity Pharmaceuticals is a privately held global pharmaceutical company dedicated to redefining medicine for the real world. Azurity’s first-in-class enterprise model challenges the status quo by rethinking how therapies are designed, delivered, and accessed. With more than 50 medicines across 10 therapeutic areas, Azurity’s mission is fueled by a growing portfolio that reaches millions of people in more than 50 countries. Learn more at www.azurity.com

Forward-looking Statements

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PolyPid Announces Exclusive Partnership with Azurity Pharmaceuticals for the Commercialization of D-PLEX100 in the U.S. and Canada

- PolyPid to potentially receive over $320 million in upfront and milestone payments, including $30 million in upfront and near-term milestone payments, plus tiered royalties ranging from mid-teen to mid-twenties percentages
- Azurity, a private global pharmaceutical company, to commercialize D-PLEX100 upon approval in the U.S. and Canada for the prevention of surgical site infections, leveraging its first-in-class commercial model. PolyPid to manufacture and supply D-PLEX100
- Azurity will also fund clinical development of D-PLEX100, supporting the potential label expansion in the U.S. and Canada beyond SSI indications for abdominal surgery
- Partnership follows positive Phase 3 SHIELD II results, demonstrating achievement of the primary endpoint and a 60% relative risk reduction at the secondary endpoint in SSI incidence, with PolyPid's NDA submission to the FDA recently completed
- U.S. launch targeted for the first quarter of 2027

PETACH TIKVA, Israel, July 21, 2026 -- PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins, today announced that it has entered into an exclusive commercial partnership agreement (the "Agreement") with Azurity Pharmaceuticals ("Azurity"), a privately held specialty pharmaceutical company, for the commercialization of D-PLEX100 in the United States and Canada for the prevention of surgical site infections ("SSIs").

Under the terms of the Agreement, PolyPid will receive an upfront payment of $15 million due upon signing and an additional near-term milestone payment of $15 million payable upon U.S. Food and Drug Administration ("FDA") acceptance of the D-PLEX$_{100}$ New Drug Application ("NDA"), which is expected in August 2026. PolyPid is eligible to receive up to approximately $300 million in additional regulatory, development, and sales-based milestone payments. Upon commercialization, the Company will manufacture and supply D-PLEX100 to Azurity for a transfer price and will be entitled to tiered royalties ranging from mid-teen to mid-twenties percentages.

In addition to the upfront and milestone payments, as part of the collaboration, the parties may agree to jointly pursue potential label expansion of D-PLEX100 in the U.S. and Canada into additional SSI indications beyond abdominal, with Azurity providing funding for these additional clinical development programs. PolyPid will retain global commercial rights to D-PLEX100 outside of the U.S. and Canada, manufacturing rights worldwide, and full ownership of its PLEX platform, Kynatrix™ technology and associated pipeline assets.

"This partnership is a defining step in PolyPid's transition into a commercial-stage company, and Azurity is the right partner to bring D-PLEX100 to U.S. and Canadian patients, hospitals and surgeons," said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. "We believe that Azurity's first-in-class commercial model and demonstrated commercial execution will be invaluable in expanding access to D-PLEX100, if approved. Importantly, this collaboration represents a meaningful validation of our unique platform, and allows us to fully realize the U.S. and Canadian commercial value of D-PLEX100 while putting us in a position of financial strength to continue investing in our Kynatrix technology, pipeline, and the next generation of therapies."

"At Azurity, we believe meaningful innovation is measured by the difference a therapy makes in the realities of patient care," said Ronald Scarboro, Chief Executive Officer of Azurity Pharmaceuticals. "D-PLEX$_{100}$ is a differentiated therapy addressing an important unmet need, and we are excited to partner with PolyPid to help bring it to patients in the United States and Canada, if approved. Our commercial model was built to support specialized therapies like this-connecting the right treatment to the right healthcare professionals and patients through efficient, focused execution. Together, we believe we can expand access to an important new option while exploring opportunities to broaden its impact in the years ahead."

About D-PLEX$_{100}$

D-PLEX$_{100}$, PolyPid's lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site with the goal of preventing abdominal surgical site infections ("SSIs"). Following the administration of D-PLEX$_{100}$ into the surgical site, PolyPid's delivery technology, Kynatrix, is designed to pair with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in a high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. In the Phase 3 SHIELD II trial, D-PLEX$_{100}$ recently demonstrated positive results in achieving its primary end point and a 60% (p= 0.0013) relative risk reduction at the secondary end point in SSI incidence following abdominal colorectal surgery with large incisions. D-PLEX$_{100}$ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins. The Company develops long-acting, controlled-release drugs designed to deliver therapy precisely at the site of care, addressing critical unmet medical needs across a wide and diverse pipeline spanning surgical care, metabolic diseases, and beyond. PolyPid's lead product, D-PLEX$_{100}$, successfully met its primary and all key secondary endpoints in the landmark Phase 3 SHIELD II trial for the prevention of surgical site infections. Guided by a commitment to precision and innovation, PolyPid is redefining how therapies perform and raise the standard of patient care. For additional Company information, please visit http://www.polypid.com and follow us on Twitter (X) and LinkedIn.

About Azurity Pharmaceuticals

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