Exhibit 10.28  
Certain information identified by bracketed asterisks ([\*\*\*]) has been omitted from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed. The omitted information will be filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted information.  
LICENSE AGREEMENT  
by and between  
DURECT CORPORATION  
and  
INNOCOLL PHARMACEUTICALS LIMITED  
dated  
December 21, 2021  
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 EXECUTION COPY  
CONFIDENTIAL  
 LICENSE AGREEMENT  
This LICENSE AGREEMENT (the “Agreement”) is effective as of December 21, 2021 (the “Effective Date”) by and between Innocoll Pharmaceuticals Limited, a company incorporated in Ireland having company number 395965 and having its registered office at 70 Sir Xxxx Xxxxxxxx’x Xxxx, Xxxxxx 0, X00 X000, Xxxxxxx (“INNOCOLL”), and Durect Corporation, a Delaware corporation having a place of business at 00000 Xxxx Xxxx, Xxxxxxxxx, Xxxxxxxxxx 00000 (“DURECT”). INNOCOLL and DURECT may each be referred to herein by name or, individually, as a “Party” and, collectively, as the “Parties.”  
BACKGROUND  
A.DURECT owns and controls rights in and to the pharmaceutical product known as POSIMIR®, which comprises bupivacaine and DURECT’s proprietary carrier materials and systems known as the SABER® formulation platform technology; and  
B.INNOCOLL desires to obtain the right to commercialize Licensed Product in the Field in the Licensed Territory (each, as defined below), and DURECT desires to grant INNOCOLL such rights, all on the terms and conditions of this Agreement.  
NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein below and other consideration, the receipt and sufficiency of which is hereby acknowledged, INNOCOLL and DURECT hereby agree as follows:  
ARTICLE 1  
DEFINITIONS; INTERPRETATION  
The following capitalized terms shall have the meanings given in this Article 1 or elsewhere in this Agreement when used in this Agreement:  
1.1“Active Ingredient”  
means bupivacaine [(i.e., (RS)-1-Butyl-N-(2,6-dimethylphenyl) piperidine-2-carboxamide)].  
1.2“Affiliate”  
means with respect to a Person, any other Person controlling, controlled by or under common control with such first Person, for so long as such control exists. For purposes of this Section 1.2 only, “control” means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.  
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 1.3“Annual Net Sales”  
means, with respect to a calendar year, the aggregate Net Sales throughout the Licensed Territory during such calendar year.  
1.4“Applicable Law”  
means, with respect to a Person’s activities under this Agreement, any and all laws, ordinances, orders, rules, rulings, directives and regulations of any kind whatsoever of any governmental authority (including the FDA), national securities exchanges or securities listing organizations applicable to such Person’s activities.  
1.5“Assigned Trademark”  
means the trademark listed on Exhibit 1.5.   
1.6“Business Day”  
means any day other than a Saturday, Sunday or any other day on which commercial banks in San Francisco, California or Dublin, Ireland are authorized or required by law to remain closed.  
1.7“Commercialization”  
means, with respect to a pharmaceutical product (including Licensed Product), any and all processes and activities conducted to prepare for and establish and maintain sales for such product, including offering for sale, detailing (including physician targeting), promoting, marketing, advertising, pricing, seeking and securing reimbursement, branding, selling, storing of finished products, transporting and distributing such product. For clarity, Commercialization includes (a) medical support planning, medical affairs activities, medical education activities and other activities traditionally conducted by medical scientific liaisons, health economics and outcomes researchers and other individuals having similar functions, including gathering and maintaining user feedback and establishing and maintaining one or more call centers in connection therewith, (b) the conduct of any Post-Approval Activities, including all regulatory matters in support thereof or otherwise necessary to maintain any NDA Approval. “Commercialize” and “Commercialized” has a correlative meaning.  
1.8“[\*\*\*]”  
means with respect to [\*\*\*] by a Party with respect to an agreed [\*\*\*] as such Party would [\*\*\*] taking into account the [\*\*\*] of such Party’s [\*\*\*], including, with respect to a [\*\*\*], or otherwise [\*\*\*], those efforts and [\*\*\*] as applied by [\*\*\*] and resources to [\*\*\*] (as applicable) of its own products that are at a [\*\*\*], taking into account performance of [\*\*\*] issues. [\*\*\*] shall be [\*\*\*], and it is anticipated that the [\*\*\*] and may change over time, reflecting changes in the [\*\*\*] and [\*\*\*] involved.  
1.9“Control” or “Controlled”  
means, with respect to any material, information or Intellectual Property right, that either Party including its Affiliates (a) owns or (b) has a license to such material, information, or Intellectual Property right and, in each case (a) and (b), has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without giving rise to any violation of the terms of any written agreement with any Third Party. Notwithstanding anything to the contrary in this Agreement, in the event that a Third Party merges or consolidates with or acquires DURECT, or DURECT transfers to a Third Party all or substantially all of its assets to which this Agreement relates (such Third Party and its Affiliates immediately prior to such merger, consolidation or transfer (the “Acquisition Transaction”), collectively, the “Acquiring Entities”), the following shall not be deemed to be Controlled by DURECT for purposes of this Agreement: (a) any subject matter (and  
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 associated Intellectual Property rights) owned or controlled by any Acquiring Entity immediately prior to the effective date of such Acquisition Transaction, and (b) any subject matter (and associated Intellectual Property rights) independently developed or acquired by or on behalf of any Acquiring Entity after an Acquisition Transaction, without accessing or practicing or reliance on any subject matter within the Licensed Technology or Confidential Information of INNOCOLL.  
1.10“Cover”  
means, with respect to any subject matter, the Development, Manufacture, use, sale, offering for sale, import or other Exploitation of such subject matter would infringe a Valid Claim of a Patent (in the absence of a license under or ownership of such claim) at the time and in the jurisdiction thereof. For clarity, with respect to a Valid Claim which is a pending claim of an application, such claim shall be deemed issued as then prosecuted for purposes of determining whether subject matter “infringes”. “Covered” or “Covering” have their correlative meanings.  
1.11“Data”  
means any and all information, data, and results of research, preclinical studies, including in vitro and in vivo studies, clinical trials and other testing resulting from the Development, Manufacture or Commercialization of Licensed Product, including biological, chemical, pharmacological, toxicological, pharmacokinetic, preclinical, clinical, CMC, analytical, quality control, mechanical, software, electronic and other data, results and descriptions.  
1.12“Develop”  
means all internal and external research, development, and regulatory activities related to pharmaceutical products (including Licensed Product), including (a) research, toxicology, nonclinical, and preclinical testing and activities, clinical trials, drug substance and drug product process development, product and process characterization, product and process qualification and validation, qualification and validation and stability testing of product from development, qualification, or validation batches, quality assurance and quality control of development, qualification, or validation batches, clinical studies, statistical analysis, and report writing and (b) preparation, submission, review, and development of Data or information for the purpose of submission to the FDA to obtain authorization to conduct clinical trials or to obtain, support, or maintain Regulatory Approval of a pharmaceutical product, and interacting with FDA following receipt of Regulatory Approval in the United States for such pharmaceutical product regarding the foregoing, including all other activities necessary or reasonably useful or otherwise requested or required by the FDA as a condition or in support of obtaining or maintaining a Regulatory Approval. Further, Development includes importing or exporting (including having imported or having exported) pharmaceutical products for purposes of development. “Developing,” “Development” and “Developed” will be construed accordingly.  
1.13“Exploit” or “Exploiting” or “Exploited” or “Exploitation”  
means to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, a product (including Licensed Product).  
1.14“FDA”  
means the United States Food and Drug Administration, or any successor agency thereto.  
1.15“Field”  
means all uses and applications in humans.  
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 1.16“Financial Exhibit”  
means Exhibit 1.16.  
1.17“First Commercial Sale”  
means the first arm’s length sale of the Licensed Product by or on behalf of INNOCOLL or its Affiliates or sublicensees to a Third Party in the Licensed Territory; for clarity excluding any pre-launch activities, including advertising, education, product-related public relations, health care economic studies, governmental affairs activities for reimbursement and formulary acceptance, sales force training, transfers for use in Development, compassionate use (including named-patient programs) or as samples or use in a clinical trial.  
1.18“IND”  
means Investigational New Drug application No. 66,086 for the Licensed Product.  
1.19“Intellectual Property”  
means all Patents, copyrights, design rights, trademarks, trade secrets, Know-How, and all other intellectual property rights (whether registered or unregistered) and all applications and rights to apply for any of the foregoing.  
1.20“Invention”  
means any new and useful process, article of manufacture, compound, composition of matter, formulation or apparatus, or any improvement thereof, discovery or finding, whether or not patentable.  
1.21“Know-How”  
means (a) any commercial, technical, scientific, or other know-how or information, knowledge, practices, instructions, skills, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, records, improvements, modifications, techniques, assays, physical, chemical or biological materials, designs, protocols, formulas, Data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, analytical and quality control data, Manufacturing data and know how, regulatory data, study designs, and protocols), dosage regimens, control assays, assay standards and references, cells, cell lines, animal models, product specifications, marketing, pricing and distribution costs, processes, methods, utilities, formulations, compositions of matter, articles of Manufacture, creations, discoveries, findings, algorithms, technology, profiles, strategies, plans, results in any form whatsoever, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.  
1.22“Licensed Know-How”  
means all Know-How (a) Controlled by DURECT during the Term, and (b) necessary or reasonably useful to maintain the NDA Approval for or Exploit the Licensed Product in the Field in the Licensed Territory.  
1.23“Licensed Patents”  
means any Patent(s) (a) Controlled by DURECT during the Term (b) which Cover the Licensed Product, and (c) are necessary or reasonably useful to Exploit the Licensed Product in the Field in the Licensed Territory, including the Patents listed on Exhibit 1.23.  
1.24“Licensed Product”  
means any pharmaceutical product for injection or infiltration or similar manner of administration (a) comprising the Active Ingredient as the sole active pharmaceutical ingredient and (b) comprising [\*\*\*], including the product described on Exhibit 1.24 (the “Initial Product”) and any Reformulations thereof. For clarity, Licensed Product shall exclude  
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 any product Controlled by INNOCOLL as of the Effective Date and any modification, revision, reformulation or improvement to any such product made after the Effective Date, so long as such modification, revision, reformulation or improvement does not use or incorporate [\*\*\*].   
1.25“Licensed Technology”  
means the Licensed Know-How and Licensed Patents.  
1.26“Licensed Territory”  
means the United States of America, including all of its territories and possessions.  
1.27“Manufacture”  
means, with respect to any pharmaceutical product (including Licensed Product), any and all processes and activities conducted for the manufacture, production or processing of such pharmaceutical product, including manufacturing or having manufactured and formulating active pharmaceutical ingredients for incorporation into pharmaceutical product, packaging, physical and regulatory labeling, storing of finished products and other finishing activities, quality control and assurance testing, in each case, with respect to such pharmaceutical product and including the right to have one or more Third Parties conduct such activities. “Manufacturing” has a correlative meaning.  
1.28“NDA”  
means New Drug Application No. 204803 filed with the FDA for Licensed Product.  
1.29“NDA Approval”  
means the FDA approval of the NDA.  
1.30“Net Sales”  
means, with respect to any period, the [\*\*\*] by INNOCOLL, its Affiliates or sublicensees (each, a “Selling Party”) to Third Parties (including [\*\*\*]) in [\*\*\*], less the following deductions [\*\*\*]:  
(a) [\*\*\*];  
(b) [\*\*\*], including [\*\*\*];  
(c) [\*\*\*] relating to Licensed Product;  
(d) [\*\*\*];  
(e) [\*\*\*]) [\*\*\*]; and  
(f) [\*\*\*];  
provided that, in each case (a) through (g), (i) [\*\*\*] is calculated [\*\*\*] and in accordance [\*\*\*], and (ii) [\*\*\* is directly [\*\*\*] such that [\*\*\*], and (iii) no [\*\*\*] above shall be [\*\*\*].   
In the event that the Licensed Product is Commercialized in combination with one or more products which are themselves not the Licensed Product under this Agreement for a single price, the Net Sales for the Licensed Product will be calculated by [\*\*\*] of the other product(s) in the combination sale. If the fair market value for any product sold in combination with the Licensed  
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 Product cannot be reasonably determined, the price attributed to such product will be [\*\*\*]. Where any reduction in the invoice price or deduction (described in clauses (a) through (g), inclusive) therefrom is based on [\*\*\*]in which the [\*\*\*]is included, the [\*\*\*]therefrom will be on [\*\*\*](excluding any [\*\*\*]).  
In the event that a Selling Party makes any adjustments to the above deductions after the associated Net Sales have been reported pursuant to Paragraph II(c) of the Financial Exhibit, the adjustments [\*\*\*]. Net Sales shall not include [\*\*\*]between or among [\*\*\*], so long as such [\*\*\*]to be based only on any subsequent [\*\*\*].  
With respect to any sale of Licensed Product in the Licensed Territory for any consideration other than monetary consideration, Net Sales for such transactions will be calculated [\*\*\*] (calculated as the would realize from an [\*\*\*]of an identical [\*\*\*]and at the same time and place [\*\*\*].  
Notwithstanding anything to the contrary herein, Net Sales shall not include [\*\*\*].  
For clarity, Net Sales shall be calculated in accordance with [\*\*\*].  
1.31“Orange Book Eligible Patent”  
means an issued Patent in the Territory that Covers the (a) Initial Product, or (b) any approved method of use of the Initial Product.  
1.32“Patent”  
means any of the following: (a) any issued patent, including inventor’s certificates, substitutions, extensions, confirmations, reissues, re-examination, renewal or any like governmental grant for protection of inventions; and (b) any pending application for any of the foregoing, including any continuation, continued prosecution application, divisional, substitution, continuation-in-part, provisional and converted provisional applications, in each case (a) or (b) existing at any time during the Term.  
1.33“Person”  
means any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.  
1.34“Post-Approval Activities”  
means any non-clinical or clinical activities conducted after the NDA Approval, including commitments required by the FDA as a condition of NDA Approval.  
1.35“Product-Specific Licensed Patent Claim”  
means any Valid Claim of a Licensed Patent that Covers Licensed Product and recites [\*\*\*] and the Active Ingredient as necessary elements of such claim.   
1.36“Prosecution”  
means, with respect to a Patent, the filing, preparation, prosecution (including conducting all correspondence and interactions with the USPTO) and seeking, conducting and defending any interferences, inter partes reviews, reissue proceedings, reexaminations, (and similar proceedings), and maintenance thereof, including obtaining patent term extensions, or their equivalents with respect thereto. When used as a verb, “Prosecute” means to engage in Prosecution.  
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 1.37“Reformulations”  
means[\*\*\*].  
1.38“Regulatory Approval”  
means, with respect to a particular country or other regulatory jurisdiction, all approvals, product or establishment licenses, registrations, or authorizations (including approval of a marketing authorization application) of all applicable regulatory authorities in such country or jurisdiction necessary for the commercial marketing or sale of a pharmaceutical product in such country or other regulatory jurisdiction for one (1) or more indications.  
1.39“Regulatory Exclusivity”  
means, with respect to a Licensed Product in the Territory, any exclusive marketing right, data protection, or other exclusive right, other than a Licensed Patent, conferred by FDA with respect to such Licensed Product.  
1.40“Regulatory Material”  
means regulatory applications (including the IND and NDA), submissions, notifications, communications, correspondence, registrations (including the NDA Approval) or other filings made to, received from or otherwise conducted with the FDA (including minutes of meetings with the FDA) that are Controlled by DURECT and are necessary or reasonably useful to Exploit Licensed Product in the Licensed Territory.  
1.41“Retained Territory”  
means all countries and territories throughout the world other than the Licensed Territory.  
1.42“Royalties”  
means the royalty payments payable to DURECT during the Royalty Term pursuant to Paragraph II of the Financial Exhibit (Exhibit 1.16).  
1.43“[\*\*\*] DMF”  
has the meaning set forth in Section 5.3.  
1.44“[\*\*\*]”  
means any [\*\*\*].   
1.45“Third Party”  
means any Person other than INNOCOLL, DURECT or their respective Affiliates.  
1.46“Third Party Licensee”  
means Third Parties who have been or during the Term are granted the right to Exploit Licensed Product in the Retained Territory by DURECT.  
1.47“Third Party Payments”  
shall mean the pro rata portion reasonably attributable to the Exploitation of Licensed Products of all payments (including for royalties, lump sum payments, upfront payments, costs, damages, judgements and awards) which INNOCOLL or its Affiliates or sublicensees pay to a Third Party for a license under Patents or Know-How owned or controlled by such Third Party that are necessary for the Exploitation of the Licensed Products in the Field in the Licensed Territory.  
1.48“Transaction Agreements”  
means, individually and collectively, the PV Agreement, Quality Agreement, Data Exchange Agreement, Initial Product Supply Agreement, Retained Territory Supply Agreement, Excipient Supply Agreement and CMO Excipient Supply Agreement, in each case, once executed.  
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 1.49“USPTO”  
means the United States Patent and Trademark Office, or any successor agency thereto.  
1.50“Valid Claim”  
means a claim of (a) an issued, unexpired, and in-force Patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which holding no appeal can be taken, or for which the applicable time for appeal has expired, and has not been held or admitted to be invalid or unenforceable through re-examination, inter partes review, post grant review or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending Patent application that has not been finally abandoned, finally rejected, or expired; but, if a claim of a pending patent application has not issued within [\*\*\*] after the earliest date from which such claim takes priority, then such claim will cease to constitute a Valid Claim for the purposes of this Agreement unless and until such claim issues.  
1.51Additional Definitions  
. Each of the following definitions has the meanings defined in the corresponding Section of this Agreement indicated below:  
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1.52Interpretation  
. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the word “will” shall be construed in the imperative having the same meaning as the word “shall”; (c) the word “day” or “year” means a calendar day or year; (d) the word “notice” requires notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (e) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); (f) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or”; (g) provisions that require that a Party or the Parties “agree,” “consent” or “approve” or the like shall require that  
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 such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words of any gender include the other gender; (i) words using the singular or plural number also include the plural or singular number, respectively; (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; and (k) neither Party nor its Affiliates shall be deemed to be acting “on behalf of” or “under authority of” the other Party hereunder.  
ARTICLE 2  
LICENSES / ALLIANCE MANAGEMENT  
2.1License Grant  
. Subject to the terms and conditions of this Agreement, DURECT hereby grants to INNOCOLL:  
(a)an exclusive license (even as to DURECT and its Affiliates), sublicensable through multiple tiers (subject to Section 2.1(b)), under the Licensed Technology to:  
(i)Develop Licensed Products in accordance with this Agreement for Commercialization in the Field in the Licensed Territory,  
(ii)Manufacture Licensed Products in the Licensed Territory, Germany or another mutually agreed upon jurisdiction in accordance with this Agreement for Development and for Commercialization in the Field in the Licensed Territory, and  
(iii)Commercialize and otherwise Exploit Licensed Products in the Field in the Licensed Territory.   
(b)INNOCOLL shall have the right to sublicense through multiple tiers under the rights granted to it in Section 2.1(a) to any of its Affiliates and Third Parties, provided that INNOCOLL shall ensure that each of its sublicensees is bound by a written agreement that is consistent with, and subject to the applicable terms and conditions of, this Agreement, and provide DURECT with a copy of such sublicense agreement within [\*\*\*] after the execution of such sublicense agreement. [\*\*\*]  
2.2No Other Rights  
. Each Party acknowledges that the rights and licenses granted under this Article 2 and elsewhere in this Agreement, including with respect to Licensed Know-How and Licensed Patents, are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted, whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights that are not specifically granted herein are reserved to the owner thereof.  
2.3Negative Covenants  
.   
(a)INNOCOLL hereby covenants not to practice, and not to permit or cause or assist any Affiliate, or permit or cause or assist any Third Party to practice, any Licensed Technology  
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 for any purpose other than as expressly authorized in this Agreement. Without limiting the generality of the foregoing, INNOCOLL hereby covenants, on behalf of itself and its Affiliates (and shall require any sublicensee under 2.1(b)), not to Exploit, Develop or seek Regulatory Approval for (i) Licensed Product outside the Licensed Territory or (ii) any product comprising [\*\*\*] with an active pharmaceutical ingredient other than the Active Ingredient.  
(b)DURECT hereby covenants on behalf of itself and its Affiliates and its Third Party Licensees not to, or permit or cause or assist any Third Party to Develop for Commercialization in the Licensed Territory, or Commercialize or seek Regulatory Approval in the Licensed Territory for (i) any Licensed Product or (ii) any product comprising [\*\*\*] that is intended for administration by intra- or peri-incisional delivery to treat or ameliorate post-surgical pain.  
2.4Excluded Activities  
.  
(a)During the Term, INNOCOLL agrees that neither it, nor any of its Affiliates or sublicensees, [\*\*\*].  
(b)During the Term, DURECT agrees that neither it, nor any of its Affiliates or Third Party Licensees, [\*\*\*].  
2.5Alliance Managers  
. Promptly after the Effective Date, each Party shall appoint an individual to act as alliance manager for that Party (each, an “Alliance Manager”). The Alliance Managers shall be the primary point of contact for the Parties with respect to the activities to be conducted under this Agreement. The name and contact information for the Alliance Managers, as well as any replacement(s) chosen by either Party in their sole discretion from time to time, shall be promptly provided to the other Party in writing.   
ARTICLE 3  
DEVELOPMENT; REGULATORY MATTERS  
3.1Development  
.   
(a)General. As between the Parties, from and after the Effective Date, INNOCOLL shall be solely responsible, [\*\*\*], for and use [\*\*\*] to take steps necessary or customary to maintain the NDA Approval for the Initial Product, including conducting applicable Post-Approval Activities. As between the Parties, and except as expressly provided elsewhere in this Agreement, INNOCOLL shall have sole responsibility for liaising with and managing all interactions with the FDA with respect to the Licensed Product in the Field in the Licensed Territory, as well as maintaining the IND and NDA Approval for the Initial Product and conducting applicable Post-Approval Activities. For clarity, INNOCOLL shall have no regulatory rights or responsibilities in the Retained Territory.  
(b)Reformulations. The Parties understand and agree that INNOCOLL may, but shall not be required to, Develop, Manufacture and Commercialize Reformulation(s). If INNOCOLL  
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 elects to so Develop, Manufacture and Commercialize any Reformulation, the Development, Manufacture and Commercialization thereof shall be at INNOCOLL’s sole cost.  
(c)Label Expansion. [\*\*\*].  
3.2Assignment of Regulatory Filings  
.   
(a)Simultaneous with the execution of this Agreement, DURECT shall transfer and assign to INNOCOLL IND No. 66,086, NDA No. 204803, any supplements thereof and all correspondence to or from and all submissions to the FDA with respect to the IND and/or NDA. To the extent there are other Regulatory Materials Controlled by DURECT and obtained or maintained by DURECT that are necessary or reasonably useful for the Exploitation of Licensed Product in the Field in the Licensed Territory, the Parties will take reasonable steps to ensure that INNOCOLL has access to such Regulatory Materials. Accordingly, from and after such transfer and assignment, INNOCOLL shall use [\*\*\*], at its sole cost, to maintain the NDA Approval. For clarity, DURECT shall have no obligation to transfer or assign the [\*\*\*] DMF. Following the assignment of the above Regulatory Materials, [\*\*\*] shall have the right to list or delist applicable Patents, including Licensed Patents, in the FDA Approved Drug Product List with Therapeutic Equivalence Evaluations (the “Orange Book”) for the Licensed Product(s).  
(b)Without limiting Section 2.1 and notwithstanding the transfer and assignment of any Regulatory Materials to INNOCOLL pursuant to Section 3.2(a), DURECT shall have the right to use and/or reference all information, including Data, contained in such Regulatory Materials, subject to Section 2.3(b).  
3.3Technology Transfer  
. Promptly following the Effective Date, DURECT shall provide electronic copies to INNOCOLL, for no additional consideration or cost reimbursement for the non-physical transfer, of all:  
(a)Data Controlled by DURECT and its Affiliates that are necessary or reasonably useful for the Development, Manufacture, and Commercialization of Licensed Product in the Field in the Licensed Territory; and   
(b)Licensed Know-How in reasonably sufficient detail in order for a reasonably skilled Person to practice such Know-How within the scope of the license granted to INNOCOLL in Section 2.1, and in a format and method agreed to by the Parties’ IT departments (e.g., FTP, physical hard disk).  
(c)DURECT shall provide such Data and Licensed Know-How in electronic form to the extent the same exists in electronic form, and shall provide originals or copies as reasonably requested. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of Data and Licensed Know-How. All Data provided by DURECT pursuant to this Section 3.3 shall be deemed Licensed Know-How, subject to the license granted to INNOCOLL in Section 2.1. For clarity, INNOCOLL shall have the right to use the Data, including the Data in the IND and NDA, for any purpose in the Licensed Territory.   
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 3.4Data Exchange Agreement  
. Upon request from either Party and in connection with the potential Exploitation of Licensed Product in the Retained Territory, the Parties shall negotiate in good faith, or DURECT shall use [\*\*\*] to facilitate a negotiation between INNOCOLL and a Third Party Licensee to enter into, a data exchange agreement on reasonable and customary terms for the Parties (or INNOCOLL and such Third Party Licensee) to exchange their respective Data concerning Licensed Products obtained in their respective Territories (“Data Exchange Agreement”).  
3.5Pharmacovigilance Agreement  
. Upon request from either Party and in connection with the potential Commercialization of Licensed Product in the Retained Territory, the Parties shall negotiate in good faith, or DURECT shall use [\*\*\*] to facilitate a negotiation between INNOCOLL and a Third Party Licensee to enter into, one or more safety exchange or pharmacovigilance, safety data access agreements (each, a “PV Agreement”) on reasonable and customary terms to ensure compliance with safety reporting requirements of the FDA and regulatory authorities in the Retained Territory by providing detailed procedures regarding the collection, exchange and management of safety data relating to Licensed Product, including but not limited to the establishment and maintenance of a safety database, collection and reporting, and maintenance of core safety information, and each Party (or INNOCOLL and such Third Party Licensee) will have access to such database, the right to query and otherwise use the data (including primary data) included therein. The Parties acknowledge that responsibility for pharmacovigilance (including safety data reporting and management) with respect to Licensed Product in the Licensed Territory will transfer from DURECT to INNOCOLL upon transfer of the IND and NDA to INNOCOLL, however, it is understood and agreed that if DURECT Commercializes Licensed Product, whether itself or through a Third Party Licensee, in the Retained Territory, INNOCOLL by virtue of this Agreement, has no obligation to be the global safety database holder for the Licensed Product.  
ARTICLE 4  
COMMERCIALIZATION  
4.1Commercialization  
.  
(a)Within the Licensed Territory. INNOCOLL shall have the exclusive right to Commercialize Licensed Product in the Field in the Licensed Territory, and shall Commercialize Licensed Product in the Field in the Licensed Territory in accordance with Applicable Law. In connection with the foregoing, INNOCOLL shall use [\*\*\*] to Commercialize Licensed Product in the Field in the Licensed Territory.   
(b)Within the Retained Territory. As between the Parties, DURECT shall have the exclusive right, but not the obligation, to Commercialize Licensed Product in the Retained Territory, itself or through one or more Third Party Licensees.  
(c)Reporting. Within [\*\*\*] following the Effective Date, INNOCOLL shall provide DURECT a written plan for the Commercialization of the Licensed Product for the following [\*\*\*] period, (which plan shall be in the level of detail used internally by INNOCOLL for its own operational planning purposes, the “Commercialization Plan”). Within [\*\*\*] following the end of each calendar year during the Term, INNOCOLL shall provide DURECT with an updated  
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 Commercialization Plan for the following [\*\*\*] period. Each Commercialization Plan shall set forth in a reasonable level of detail the Commercialization activities and timelines for those activities to be performed with respect thereto, including information and level of detail that INNOCOLL uses for its own internal planning purposes. Each Commercialization Plan shall further include an annual, non-binding forecast, for DURECT internal purposes only. All Commercialization Plans shall be the Confidential Information of INNOCOLL.  
(d)Resources. Throughout the Term of this Agreement, INNOCOLL will have and maintain commercially reasonable Commercialization capabilities, including with respect to, but not limited to, personnel (including sales representatives and medical science liaisons) and operating capital, for the Commercialization of Licensed Product, in accordance with the Commercialization Plan.  
(e)Compliance. INNOCOLL shall be solely responsible, in its sole discretion, for all federal, state and local government purchasing, pricing or reimbursement programs and private purchasing, pricing or reimbursement programs with respect to Licensed Product sold by INNOCOLL in the Field in the Licensed Territory, including using [\*\*\*] to execute agreements and file other appropriate reports and other documents with regulatory agencies and private entities for coverage of Licensed Product under state, federal or other health care programs and to list Licensed Product under such agreements. INNOCOLL shall be responsible for seeking and using [\*\*\*] to obtain and maintain such federal, state and local government reimbursements for Licensed Product in the Field in the Licensed Territory. INNOCOLL shall be solely responsible for responding to all state and federal regulations on pricing transparency. DURECT will use [\*\*\*] to cooperate with INNOCOLL by providing any reasonably requested existing information and supporting documentation in DURECT’s Control required to support all government and payor pricing calculations including product classifications or state regulations/legislation related to government pricing, Medicaid liabilities or pricing transparency regulations (current and future).  
4.2Trademarks  
.  
(a)Assigned Trademark. DURECT hereby assigns the Assigned Trademark and any and all associated goodwill to INNOCOLL. INNOCOLL agrees to use the Assigned Trademark solely in connection with its Commercialization of the Licensed Product in the Licensed Territory and it will not use the Assigned Trademark outside of the Licensed Territory, except any incidental use arising from on-line Commercialization or for Manufacturing activities for the Licensed Territory.  
(b)DURECT Trademark Matters. For clarity, (i) no right to any trademarks or domain names other than the Assigned Trademark and the domain name “xxx.XXXXXXX.xxx” is transferred to INNOCOLL, (ii) the Parties (or their designees) shall coordinate the use of related trademarks and domain names inside and outside of the Licensed Territory consistent with industry practices and (iii) nothing herein is intended to prevent DURECT or its Affiliates (or any Person authorized, directly or indirectly, by DURECT or its Affiliates) from utilizing any related trademark (e.g., the Posimir xxxx) or domain name in the Retained Territory (e.g., xxx.xxxxxxx.xx or xxx.xxxxxxx.xx) including incidental use arising from on-line Commercialization activities.  
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 (c)Trademark Prosecution/Enforcement. As between the Parties, INNOCOLL shall control the prosecution and enforcement of and use [\*\*\*] to maintain the Assigned Trademark in the Licensed Territory [\*\*\*], and DURECT shall retain ownership and control the prosecution, maintenance and enforcement of the foreign trademarks corresponding to the Assigned Trademark in the Retained Territory. The Parties shall cooperate fully and coordinate with each other with respect to the prosecution, maintenance and enforcement of the Assigned Trademark in the Licensed Territory and such trademark in the Retained Territory, respectively.   
ARTICLE 5  
SUPPLY  
5.1Product Supply Agreements  
.   
(a)Initial Product Supply Agreement. As of the Effective Date, DURECT shall assign to INNOCOLL and INNOCOLL shall accept assignment from DURECT that certain Agreement for Commercial Manufacturing and Packaging of Initial Product dated [\*\*\*] (as amended, the “Initial Product Supply Agreement”) between DURECT and [\*\*\*] (the “CMO”); provided that DURECT shall (i) retain all obligations and liabilities, other than those listed on Exhibit 5.1 (including the validation activities reimbursement), arising under the Initial Product Supply Agreement prior to the Effective Date and (ii) sell and/or transfer to INNOCOLL and INNOCOLL shall purchase and/or obtain from DURECT the protocols, processes, equipment and materials used in the Development and Manufacture of the Initial Product, including saleable inventories of Initial Product, work in progress, components and raw materials, in each case, as described on Exhibit 5.1, at the price described therein (which, for clarity, is DURECT’s fully-allocated cost of acquisition thereof).   
(b)Retained Territory Supply Agreement. Upon DURECT’s reasonable request, INNOCOLL agrees, in its sole discretion, to [\*\*\*].   
5.2Excipient Supply Agreement  
. Promptly following the Effective Date, the Parties shall negotiate in good faith a separate agreement (the “Excipient Supply Agreement”), together with a quality assurance agreement (the “Quality Agreement”), pursuant to which DURECT will supply [\*\*\*] to the CMO and/or INNOCOLL for incorporation in Licensed Product in the Field in the Licensed Territory. The Excipient Supply Agreement will contain the key terms set forth in Exhibit 5.20.  
5.3Drug Master File  
. DURECT has [\*\*\*].  
5.4Supply  
. Except as otherwise expressly provided herein, as between the Parties, INNOCOLL shall be responsible for the Manufacture and supply of the Licensed Product to support its and its Affiliates’ and sublicensees’ activities hereunder, including all related regulatory matters associated therewith.  
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 ARTICLE 6  
ECONOMIC TERMS  
6.1Expenses  
. Except as otherwise expressly provided herein, each Party shall be responsible for and, as between the Parties, bear all costs and expenses incurred in conducting the activities for which it is responsible.  
6.2Upfront Fee  
. In partial consideration of the rights granted to INNOCOLL hereunder, INNOCOLL shall pay to DURECT an initial fee in the amount of Four Million Dollars ($4,000,000) (“Upfront Fee”) payable within [\*\*\*] after the Effective Date. Such Upfront Fee shall be non-refundable, and shall not be creditable against any other amount due hereunder.  
6.3Other Payments  
. INNOCOLL shall make the other payments to DURECT as set forth in the Financial Exhibit (Exhibit 1.16).  
6.4Payment Method  
. All payments due under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the payee Party. All payments hereunder shall be made in the legal currency of the United States of America, and all references to “$” or “Dollars” shall refer to United States dollars. Except as otherwise provided herein, all payments due to either Party under this Agreement shall be due and payable within [\*\*\*] of the receipt of invoice from the other Party.  
6.5Taxes  
. DURECT will pay any and all taxes levied on account of any payments made to it under this Agreement. If any payment under this Agreement is subject to withholding tax under Applicable Law, INNOCOLL shall have the right to withhold any and all such taxes, which taxes shall be paid to the appropriate taxing authority for the account of DURECT. INNOCOLL shall remit to DURECT an amount net of such withholding taxes. The Parties agree to cooperate to minimize any withholding taxes (including providing each other with any exemption certificates or other documentation establishing that no taxes are due, or such taxes are due at a reduced rate).   
6.6Acknowledgement  
. The Parties acknowledge that the economic terms and conditions set forth herein were negotiated and agreed to and represent a fair and equitable allocation of the value from Licensed Product in the Field in the Licensed Territory. The Parties further acknowledge that there is considerable value in the Licensed Technology that is consistent with the economic terms and conditions herein.  
ARTICLE 7  
  
INTELLECTUAL PROPERTY  
7.1Ownership of Inventions  
. Without limiting Section 4.2(a), each Party shall retain ownership of its Intellectual Property rights existing as of the Effective Date, or developed or acquired by or on behalf of it independent of any activities under this Agreement, and nothing in this Agreement shall assign any ownership to the other Party with respect to such Intellectual Property rights. Notwithstanding the foregoing, subject to the licenses and other rights provided herein:  
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 (a)[\*\*\*];  
(b)[\*\*\*];  
(c)[\*\*\*];  
(d)notwithstanding anything to the contrary in clauses (a)-(c) of this Section 7.1, DURECT shall exclusively own all Inventions, regardless of inventorship, comprising an improvement of or modification to [\*\*\*];  
(e)Each Party shall cause its employees, agents and contractors to be bound by a written agreement whereby such employees, agents and contractors assign, or are required to assign, all intellectual property rights developed by any such employees, agents and contractors in the course of their employment or engagement with the respective Party to such Party;  
(f)Disclosure of Inventions. Each Party shall promptly disclose to the other any Inventions made in the course of activities conducted pursuant to this Agreement; and  
(g)Inventorship of Inventions and other Intellectual Property made pursuant to this Agreement shall be determined in accordance with the patent laws of the United States.   
7.2Ownership of Data  
. As between the Parties, subject to the licenses and other rights provided herein, all right, title and interest to Data developed or generated by [\*\*\*]. For clarity, as between the Parties, [\*\*\*]. For clarity, all such Data, to the extent [\*\*\*].  
7.3Prosecution of Licensed Patents  
. As between the Parties, [\*\*\*] shall control the Prosecution of all Licensed Patents, including [\*\*\*] Patents. [\*\*\*] shall reasonably cooperate with [\*\*\*] to permit and enable [\*\*\*]to Prosecute the Licensed Patents[\*\*\*]. With respect to each Product-Specific Licensed Patent Claim, [\*\*\*]. If [\*\*\*] intends to abandon or cease prosecution or maintenance of any Licensed Patent in the Licensed Territory, [\*\*\*] shall provide prior notice to [\*\*\*] of such intention, which notice must be given at least [\*\*\*] in advance of the next deadline to take any action necessary to maintain existing rights in any such Licensed Patent. Upon [\*\*\*]’s election, [\*\*\*] shall permit [\*\*\*] to assume prosecution and maintenance of such Licensed Patent using counsel of [\*\*\*]’s choosing. [\*\*\*].   
7.4Defense of Third Party Infringement Claims  
. If Licensed Product becomes the subject of a Third Party’s claim or assertion of infringement of a Patent relating to the Development, Manufacture, or Commercialization of Licensed Product in the Field in the Licensed Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing (such agreement not to be unreasonably withheld, conditioned or delayed by either Party), [\*\*\*] (the “Defending Party”). Neither Party shall enter into any settlement of any claim described in this Section 7.4 that adversely affects the other Party’s rights or interests hereunder without such other Party’s written consent, which consent shall not be  
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 unreasonably withheld, conditioned or delayed. The other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party’s request and expense.   
7.5Enforcement of Licensed Patents  
.  
(a)Notice. In the event that (i) either Party receives a notice letter pursuant to 21 U.S.C. §§ 355(b)(3) or 355(j)(2)(B) of a paragraph IV certification to one or more patents listed in the Orange Book for Licensed Product, or (ii) reasonably believes that any Licensed Patent (A) is being infringed by a Third Party or (B) is or will become subject to a declaratory judgment action arising from such infringement, in each case ((i) or (ii)) in the Field in the Licensed Territory by a product containing the Active Ingredient (an “Infringing Product”), such Party shall promptly notify the other Party.  
(b)Patent Enforcement of Orange Book Listed Patents. As between the Parties, [\*\*\*] shall have the sole right (but not the obligation), at its expense, to control the enforcement (including settlement) of or to defend any declaratory judgment action arising from any Infringing Products infringing (i) the Licensed Patents listed in the Orange Book as of the Effective Date and (ii) any Product-Specific Licensed Patent Claims of any Licensed Patent listed in the Orange Book after the Effective Date with respect to Infringing Products (each, an “Orange Book Enforcement Action”) in the Field in the Licensed Territory.   
(c)Patent Enforcement of Platform Patents. With respect to an Infringing Product, if either (1) a claim of a Licensed Patent not listed in the Orange Book or (2) a claim of a Licensed Patent listed in the Orange Book after the Effective Date that is not a Product-Specific Licensed Patent Claim is infringed (as determined by either Party in good faith) by such Infringing Product or is subject to a declaratory judgment action arising from such Infringing Products (each, a “Platform Enforcement Action” and together with an Orange Book Enforcement Action, an “Enforcement Action”) in the Field in the Licensed Territory, the Parties shall discuss and determine in good faith, if applicable, whether (in the case of an infringement action) to bring such Platform Enforcement Action and, if applicable, which Party or if both Parties will have the right to bring such Platform Enforcement Action with respect to such Infringing Products and which Party or Parties will bear the cost of such action. For clarity, in the event that the Parties are unable to agree on any Platform Enforcement Action, in the case of an infringement action, then neither Party shall bring such action, and, in the case of a declaratory judgment action, then [\*\*\*] shall have the right to defend such action at its expense. The Enforcing Party or Parties agree not to settle any Platform Enforcement Action or make any admissions or assert any position in such Platform Enforcement Action, in a manner that would materially adversely affect the validity, enforceability or scope of any Licensed Patent, [\*\*\*], without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.   
(d)Cooperation. The Party commencing, controlling or defending any Enforcement Action under this Section 7.5 (the “Enforcing Party”) shall keep the other Party reasonably informed of the progress of any such action, and such other Party shall have the right to participate with counsel of its own choice [\*\*\*] to the extent permitted by law. In any event, the other Party shall reasonably cooperate with the Enforcing Party in any Enforcement Action[\*\*\*]. DURECT  
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 and INNOCOLL each acknowledges and understands that such cooperation may include the retention, collection and production of documents as reasonably requested by INNOCOLL (where INNOCOLL is the Enforcing Party) or DURECT (where DURECT is the Enforcing Party) [\*\*\*]. The Enforcing Party shall have the right to join the other Party, and such other Party shall join and hereby agrees to be joined, as a party in any Enforcement Action if necessary to bring or maintain such action.   
(e)Recoveries. Any recovery, including, but not limited to damages or other monetary awards received as a result of any Enforcement Action pursuant to this Section 7.5 shall be used first to reimburse each Party’s documented, out-of-pocket costs and expenses (including court, attorneys’ and professional fees) incurred in connection with such Enforcement Action, and the remainder of the recovery shall be shared as follows: (i) to the extent such recovery represents lost sales, such recoveries shall be retained by INNOCOLL and treated as Net Sales hereunder and INNOCOLL shall pay the applicable percentage of such recoveries to DURECT, and (ii) for all other recoveries [\*\*\*] of such recovery shall be paid to the Enforcing Party and [\*\*\*] of such recovery shall be paid to the other Party.  
7.6Patent Marking  
. INNOCOLL shall use [\*\*\*] to xxxx (or cause to be marked) Licensed Product marketed and sold hereunder with appropriate Licensed Patent numbers or indicia in accordance with Applicable Law.  
ARTICLE 8  
CONFIDENTIALITY  
8.1Confidentiality; Exceptions  
. Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, the Parties agree that the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential or proprietary information or materials furnished to it by the other Party pursuant to this Agreement (collectively, “Confidential Information”). Notwithstanding the foregoing, Confidential Information shall not be deemed to include information or materials to the extent that it can be established by written documentation by the receiving Party that such information or material:  
(a)was already known to or possessed by the receiving Party without any obligation of confidentiality, at the time of its disclosure to the receiving Party hereunder;  
(b)was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party hereunder;  
(c)became generally available to the public or otherwise part of the public domain after its disclosure hereunder other than through any act or omission of the receiving Party in breach of this Agreement;  
(d)was independently developed by or for the receiving Party (including its contractors, suppliers or clinical research organizations (“CROs”)) without use of or reference to the  
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 other Party’s Confidential Information as demonstrated by documented evidence prepared by the receiving Party contemporaneously with such independent development; or  
(e)was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.  
8.2Authorized Use and Disclosure  
. Each Party may use and disclose Confidential Information of the other Party as follows: (a) under appropriate confidentiality provisions substantially equivalent to those in this Agreement in connection with the performance of its obligations or exercise of rights granted to such Party in this Agreement; (b) to the extent such disclosure is reasonably necessary for the Prosecution of Patents (including applications therefor) in accordance with this Agreement, complying with the terms of agreements with Third Parties subject to appropriate confidentiality provisions consistent with those in this Agreement, prosecuting or defending litigation, complying with applicable governmental regulations, filing for, conducting preclinical or clinical trials, obtaining and maintaining Regulatory Approvals (including the NDA Approval) for Licensed Product under this Agreement, or otherwise required by Applicable Law or any listing agreement with or rules of a national securities exchange, provided, however, that if a Party is required by Applicable Law to make any such disclosure of the other Party’s Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its [\*\*\*] to secure confidential treatment of such Confidential Information required to be disclosed; (c) in communication with existing and potential contractors, suppliers, CROs, investors, acquirers, consultants, advisors (including financial advisors, lawyers and accountants) and others on a need to know basis, in each case, under appropriate confidentiality provisions and a written agreement substantially equivalent to those of this Agreement; or (d) to the extent mutually agreed to by the Parties in writing.  
8.3Prior Agreements  
. This Agreement supersedes the Confidentiality Agreement between DURECT and INNOCOLL dated [\*\*\*] (the “Prior CDA”) with respect to information disclosed thereunder. All information or materials disclosed or provided by DURECT to INNOCOLL under the Prior CDA shall be deemed Confidential Information of DURECT (subject to the exceptions set forth herein) and shall be subject to INNOCOLL’s confidentiality obligations under this Article 8. All information disclosed by INNOCOLL under the Prior CDA shall be deemed Confidential Information of INNOCOLL (subject to the exceptions set forth herein) and shall be subject to DURECT’s confidentiality obligations under this Article 8.  
8.4Technical Publications  
. Each Party shall submit to the other Party any proposed publication or public disclosure containing clinical or scientific results relating to Licensed Product in the Field at least [\*\*\*] in advance to allow that Party to review such proposed publication or disclosure. The reviewing Party shall notify the requesting Party in writing during such [\*\*\*] reviewing period if the reviewing Party wishes to (a) remove its Confidential Information from such proposed publication or presentation, in which event the requesting Party shall remove such Confidential Information from its proposed publication or presentation; or (b) request a reasonable delay in publication or  
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 presentation in order to protect patentable subject matter, in which event the requesting Party shall delay the publication or presentation for a period of no more than [\*\*\*] to enable patent applications to be filed in accordance with Section 7.1 protecting Inventions disclosed in such publication or presentation. For clarity, if the reviewing Party fails to notify the requesting Party during the [\*\*\*] reviewing period as provided under this Section 8.4, the requesting Party shall be free to proceed with the proposed publication or presentation.   
8.5Publicity  
.  
(a)Confidential Terms. Each Party agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to advisors (including consultants, financial advisors, attorneys and accountants), potential acquirers, and others, including potential and actual (sub)licensees under the Licensed Technology on a need to know basis (which means in the case of DURECT’s potential and actual licensees of the Licensed Technology with redaction of the financial obligations of INNOCOLL), in each case under circumstances that reasonably protect the confidentiality thereof, or to the extent necessary to comply with the terms of agreements with Third Parties, or to the extent required by Applicable Law, including securities laws and regulations. Notwithstanding the foregoing, each Party may issue a press release to announce the execution of this Agreement, provided that such press release is provided to the other Party [\*\*\*] in advance of publication and the issuing party considers all reasonable comments from the non-issuing Party in good faith. Thereafter, DURECT and INNOCOLL may each disclose to Third Parties the information contained in such press releases or disclosed in SEC filings without the need for further approval by the other.  
(b)Publicity and Public Disclosure Review. The Parties acknowledge the importance of supporting each other’s efforts to publicly disclose results and significant developments regarding Licensed Product in the Field and other activities in connection with this Agreement, and each Party may make such disclosures from time to time subject to review and approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed. Such disclosures may include achievement of significant events in the Commercialization of Licensed Product. When a Party elects to make any such public disclosure under this Section 8.5(b), it will give the other Party reasonable notice to review and comment on such statement, it being understood that if the reviewing Party does not notify the requesting Party in writing within a [\*\*\*] period or such shorter period if required by Applicable Law of any reasonable objections, as contemplated in this Section 8.5(b), such disclosure shall be deemed approved, and in any event the reviewing Party shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. Nothing in this Agreement shall limit a Party’s right to make disclosures as required by Applicable Law or any listing agreement with or rules or regulations of a national securities exchange.  
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 ARTICLE 9  
REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION  
9.1General Representations and Warranties  
. Each Party represents and warrants to the other Party that as of the Effective Date:  
(a)it is duly organized and validly existing under Applicable Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;  
(b)it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;  
(c)this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound;  
(d)it is not aware of any action, suit or inquiry or investigation instituted by any Person which questions or threatens the validity of this Agreement or the solvency of its business; and  
(e)it shall, at all times during the Term, comply with all Applicable Laws relating to its activities under this Agreement.  
Each Party covenants to the other Party that it shall (i) not knowingly use in any capacity, in connection with the performance of its obligations under this Agreement or with respect to a Licensed Product or the Licensed Technology, any individual or entity who or that has been debarred or suspended under 21 U.S.C. §335(a) or any foreign equivalent thereof, or who is the subject of a conviction described in such section or any foreign equivalent thereof, and (ii) inform the other Party in writing immediately upon becoming aware if it or any individual or entity who or that is performing activities hereunder on its behalf is debarred, suspended or is the subject of a conviction described in 21 U.S.C. §335(a) or any foreign equivalent thereof, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to its knowledge, is threatened, relating to such debarment or conviction.  
9.2DURECT Representation, Warranties and Covenants  
. DURECT further represents and warrants and covenants to INNOCOLL that, except as set forth on the schedule of exceptions in the Exhibit 9.2, as of the Effective Date:  
(a)[\*\*\*].  
(b)[\*\*\*];  
(c)[\*\*\*];  
-26-  
 (d)[\*\*\*];  
(e)[\*\*\*];  
(f)[\*\*\*];  
(g)[\*\*\*];  
(h)[\*\*\*];  
(i)[\*\*\*]; and  
(j)[\*\*\*].  
For purposes of this Section 9.2, [\*\*\*].  
9.3Disclaimer of Warranties  
. EXCEPT AS SET FORTH IN THIS AGREEMENT AND THE EXPRESS WARRANTIES OF ANY OTHER TRANSACTION AGREEMENT (ONCE EXECUTED), DURECT AND INNOCOLL EXPRESSLY DISCLAIM ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT (INCLUDING THE LICENSED PRODUCT AND LICENSED TECHNOLOGY), INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.  
9.4Indemnification  
.  
(a)Indemnification by DURECT. DURECT hereby agrees to defend, hold harmless and indemnify (collectively, “Indemnify”) INNOCOLL and its Affiliates, and its and their agents, directors, officers and employees (the “INNOCOLL Indemnitees”) from and against any liability or expense (including reasonable legal expenses and attorneys’ fees) (collectively, “Losses”) resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a “Third-Party Claim”) against any INNOCOLL Indemnitee, arising out of (i) a breach of any of [\*\*\*], (ii) the [\*\*\*] by any [\*\*\*], or (iii) [\*\*\*] (1) prior to [\*\*\*] and (2) after [\*\*\*]. DURECT’s obligation to Indemnify the INNOCOLL Indemnitees pursuant to this Section 9.4(a) shall not apply to the extent [\*\*\*].  
(b)Indemnification by INNOCOLL. INNOCOLL hereby agrees to Indemnify DURECT and its Affiliates, and its and their agents, directors, officers and employees (the “DURECT Indemnitees”) from and against any and all Losses resulting from Third-Party Claims against any DURECT Indemnitees arising out of (i) a breach of any of [\*\*\*], (ii) the [\*\*\*], or (iii) the [\*\*\*] of any [\*\*\*]. INNOCOLL’s obligation to Indemnify the DURECT Indemnitees pursuant to this Section 9.4(b) shall not apply to the extent [\*\*\*].  
(c)Procedure. To be eligible to be Indemnified hereunder, the indemnified Party shall provide the indemnifying Party with prompt notice of the Third-Party Claim giving rise to the  
-27-  
 indemnification obligation pursuant to this Section 9.4 and the exclusive ability to defend (with the reasonable cooperation of the indemnified Party). The indemnifying Party shall have the right to settle or compromise any Third-Party Claim against the indemnified Party without the consent of the indemnified Party provided that the terms thereof: [\*\*\*]. In all other cases, the indemnified Party and indemnifying Party must agree to enter into any proposed settlement. The indemnified Party shall have the right to participate, [\*\*\*], in the defense of any claim or suit that has been assumed by the indemnifying Party, provided that the indemnifying Party shall have no obligations with respect to any Losses resulting from the indemnified Party’s admission, settlement or other communication without the prior written consent of the indemnifying Party.  
9.5Insurance  
. Each Party shall obtain and maintain, during the Term and for [\*\*\*] thereafter, reasonable insurance, as outlined on Exhibit 9.5, with financially stable and reputable insurers. Each Party shall furnish to the other Party on request evidence of its liability insurance setting forth the limits of the liability insurance maintained. The limits of insurance coverage will not affect or limit the liability or indemnity obligations of either Party stated elsewhere in this Agreement or as required by law.  
9.6Limitation of Liability  
. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, OTHER THAN BY REASON OF A BREACH OF ARTICLE 7 (INTELLECTUAL PROPERTY) OR ARTICLE 8 (CONFIDENTIALITY) ABOVE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT (WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY) FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY, INCIDENTAL OR PUNITIVE DAMAGES, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.7 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION OBLIGATIONS OF EITHER PARTY UNDER SECTION 9.4 ABOVE TO THE EXTENT A THIRD PARTY RECOVERS ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY, INCIDENTAL OR PUNITIVE DAMAGES FROM AN INDEMNITEE.   
ARTICLE 10  
TERM AND TERMINATION  
10.1Term  
. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 10, shall continue until the last to expire Royalty Term in the Territory (the “Term”). Upon expiration (but not earlier termination) of this Agreement, the licenses granted to INNOCOLL hereunder will be irrevocable, royalty-free and fully paid-up.  
10.2Termination  
.  
(a)Termination for Convenience. INNOCOLL shall have the right to terminate this Agreement for convenience upon six (6) months’ prior written notice to DURECT referencing this Section 10.2(a).   
-28-  
 (b)Termination for Safety or Efficacy. Notwithstanding anything contained herein to the contrary, INNOCOLL shall have the right to terminate this Agreement at any time in the event that INNOCOLL reasonably believes that there are potential safety or efficacy concerns affecting the Licensed Products, by giving thirty (30) days’ advance written notice to DURECT; provided that, at least thirty (30) days prior to providing DURECT with any such notice of termination, INNOCOLL will notify DURECT of the facts and circumstances giving rise to such right of termination, and if requested by DURECT, discuss in good faith possible alternatives to termination.  
(c)Termination for Patent Challenge. If INNOCOLL or any of its Affiliates initiates a challenge under any court action or proceeding, or before the USPTO (except for a case where such actions undertaken by an Affiliate of INNOCOLL that first becomes such an Affiliate as a result of an acquisition of all or any part of INNOCOLL or any of its Affiliates, where such new Affiliate was participating in the challenge prior to such acquisition and immediately ceases such actions following such acquisition), of the validity, patentability or enforceability of any Licensed Patent, or initiates a reexamination or similar proceeding of any Licensed Patent, or directly assists any Third Party to conduct any of the foregoing activities, but excluding where INNOCOLL is involuntarily joined to any challenge or any ordinary course patent prosecution by or on behalf of INNOCOLL (each, a “Challenge”), DURECT will have the right to terminate this Agreement immediately following thirty (30) days’ written notice to INNOCOLL referencing this Section 10.2(c) and the specific facts giving rise to the termination, unless INNOCOLL or its applicable Affiliate has filed a motion to dismiss such action within [\*\*\*] following receipt of such notice. In any event, INNOCOLL shall notify DURECT at least [\*\*\*] prior to initiating any such Challenge. In the event that any sublicensee of INNOCOLL or its Affiliates to the Licensed Patents initiates a Challenge, upon the written request from DURECT, INNOCOLL shall promptly terminate the applicable sublicense agreement.   
(d)Termination for Material Breach. In the event a Party materially breaches this Agreement, and such breach shall have continued for [\*\*\*] after notice thereof was provided to the breaching Party, the non-breaching Party will have the right to terminate this Agreement [\*\*\*]written notice to the breaching Party referencing this Section 10.2(d).   
(e)Termination for Insolvency. Either Party shall have the right to terminate this Agreement in the event the other Party becomes insolvent. “Insolvent” means that a Party (i) is declared insolvent or bankrupt by a court of competent jurisdiction, (ii) files a voluntary petition in bankruptcy in any court of competent jurisdiction, (iii) has an involuntary petition filed against it and such petition is not dismissed within [\*\*\*] after filing, (iv) makes or executes an assignment of substantially all of its assets for the benefit of creditors, or (v) has a receiver or trustee appointed for substantially all of its assets or business, unless such appointment is dismissed or set aside within [\*\*\*] from the date of such appointment.  
10.3Effects of Termination  
.   
(a)Reversion of Rights. Upon termination of the Agreement for any reason, subject to Sections 10.3(c) and 10.4(c), all rights, licenses and assignments granted by DURECT to INNOCOLL under this Agreement shall revert back to DURECT without any charge.   
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 (b)Return of Transferred Know-How. Upon termination of the Agreement by INNOCOLL pursuant to Section 10.2(a) or 10.2(b), or by DURECT pursuant to Section 10.2, INNOCOLL shall promptly return to DURECT copies of the Data and Licensed Know-How that were transferred by DURECT to INNOCOLL under this Agreement. In addition, INNOCOLL shall or shall cause its Affiliates and sublicensees to assign or transfer back to DURECT, at INNOCOLL’s expense, (1) the IND, NDA and any other Regulatory Materials that were transferred by DURECT to INNOCOLL hereunder and (2) the Product Supply Agreement as such agreement exists at the effective date of termination.  
(c)Clinical Trials. In the event of termination of the Agreement for any reason, if applicable, INNOCOLL shall be permitted to continue in its sole discretion any ongoing clinical trial for a Licensed Product for which INNOCOLL has responsibility and in which patient dosing has commenced. In the event the agreement is terminated by INNOCOLL pursuant to Section 10.2(a) or 10.2(b), or (a) by DURECT pursuant to Section 10.2(c) or (b), if INNOCOLL elects not to continue such trial, DURECT, at its sole election, shall have the right but not the obligation to take over the cost and responsibility for such trial, in which case INNOCOLL shall use [\*\*\*] to effect a smooth transition of such trial to DURECT or its designee.  
10.4General Effects of Expiration or Termination  
.  
(a)Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.  
(b)Non-Exclusive Remedy. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.  
(c)Inventory. In the event of a termination of this Agreement, INNOCOLL will have the right, but not the obligation, for [\*\*\*] following the effective date of such termination to sell any remaining inventory of Licensed Product controlled by INNOCOLL or its Affiliates, as long as INNOCOLL continues to make milestone payments and pay Royalties under Article 6 in respect of the Net Sales resulting from sales of such inventory.   
(d)General Survival. Articles 1, 11 and 12 and Sections 6.4, 6.5, 7.1, 7.2, 8.1, 8.2, 8.3, 9.3, 9.4, 9.5 (for the period specified therein), 9.6, 10.3, 10.4 and Exhibit 1.16 (Paragraphs II(e), (f), and (g) (with respect to periods during the Term and under Section 10.4)) shall survive expiration or termination of this Agreement for any reason. Except as otherwise provided in this Article 10, all rights and obligations of the Parties under this Agreement shall terminate upon expiration or termination of this Agreement for any reason.   
10.5Termination Press Releases  
. In the event of termination of this Agreement for any reason, the Parties shall cooperate in good faith to coordinate public disclosure of such termination, and shall not, except to the extent required by Applicable Law, including securities laws and  
-30-  
 regulations, disclose such information without the prior approval of the other Party, such approval not to be unreasonably withheld, conditioned or delayed. To the extent possible under the situation, each Party shall provide the other Party with a draft of any such public disclosure it intends to issue, if any, [\*\*\*] in advance and with the opportunity to review and comment on such statement, it being understood that if the Party receiving such draft does not notify the other Party in writing within such [\*\*\*] period (or such shorter period if required by Applicable Law) of any reasonable objections, such disclosure shall be deemed approved, and in any event the Parties shall work diligently and reasonably to agree on the text of any such proposed disclosure in an expeditious manner.   
ARTICLE 11  
DISPUTE RESOLUTION  
11.1Dispute Resolution  
. The Parties agree that any dispute, controversy or claim arising out of or in connection with this Agreement (each, a “Dispute”), shall be resolved through the procedures set forth in this Article 11.  
11.2Excluded Claims  
. Any Dispute relating to the inventorship, scope, validity, enforceability or infringement of a patent, trademark or copyright, or any antitrust, anti-monopoly or competition law or regulation (an “Excluded Claim”) shall not be subject to binding arbitration under Section 11.4, but instead shall be submitted to a court of competent jurisdiction.  
11.3Initial Escalation  
. With respect to all Disputes, if the Parties are unable to resolve any such Dispute within [\*\*\*] after such Dispute is first identified by either Party in writing to the other, either Party shall have the right to refer such Dispute to the Chief Executive Officer of each Party (“CEOs”) for attempted resolution by written notice to the other Party referencing the particular Dispute and this Section 11.3. In such case, the CEOs shall conduct good faith negotiations and seek to resolve the Dispute within [\*\*\*] after such notice is received. If the CEOs resolve such Dispute, a memorandum setting forth their agreement to resolve the Dispute will be prepared and signed by both Parties if requested by either Party. In all events, the Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute.  
11.4Binding Arbitration  
. If a Dispute other than an Excluded Claim is not resolved by negotiation pursuant to Section 11.3, such Dispute shall be finally settled under the Rules of JAMS (f/k/a Judicial Arbitration & Mediation Services) by one (1) arbitrator appointed in accordance with the rules. The arbitrator shall be a neutral and independent individual. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages, except as allowed under Section 9.6. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrator’s and any administrative fees of arbitration, unless the arbitrator determines that a Party has incurred unreasonable expenses due to vexatious or bad faith position taken by the other Party, in which event, the arbitrator may make an award of all or any portion of such expense so incurred. Except to the extent necessary to confirm an award or in seeking interim relief under Section 11.5, or as may be required by Applicable Law, and subject to Article 8, neither Party nor the arbitrator may disclose the existence, content, or results of an arbitration without  
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 the prior written consent of both Parties. The legal place of arbitration shall be San Francisco, California.  
11.5Interim Relief  
. Either Party may seek in a court of competent jurisdiction or as part of the arbitration proceedings, immediate injunctive or other provisional relief as necessary to enforce the terms of this Agreement. The Parties hereto acknowledge and agree that any breach of the terms of this Agreement could give rise to irreparable harm for which money damages would not be an adequate remedy and accordingly the Parties agree that, in addition to any other remedies, each Party shall be entitled to obtain preliminary or injunctive relief and to enforce the terms of this Agreement by a decree of specific performance without payment of a bond or surety. Any request to a court of competent jurisdiction for relief as set forth in this paragraph shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.   
ARTICLE 12  
MISCELLANEOUS  
12.1Governing Law  
. This Agreement and any Dispute shall be governed by and construed and enforced in accordance with the substantive laws of the State of Delaware, without reference to conflicts of laws principles.  
12.2Assignment  
. This Agreement may not be assigned or transferred by either Party without the prior written consent of the other Party, except as follows: (a) a Party may, subject to the terms of this Agreement, assign its rights and delegate its obligations under this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions, as long as such successor-in-interest agrees in writing to be bound by the terms and conditions of this Agreement; and (b) a Party may assign its rights and delegate its obligations under this Agreement to any of its Affiliates, as long as, in each case ((a) and (b)), such assigning Party remains liable for all of its rights and obligations under this Agreement. No assignment or transfer of this Agreement shall be valid and effective unless and until the assignee/transferee agrees in writing to be bound by the provisions of this Agreement. Any attempted assignment or transfer in violation of this Section 12.2 shall be null and void. Subject to the foregoing, this Agreement shall be binding on and inure to the benefit of the Parties’ respective successors and permitted assigns.   
12.3Consequences of Bankruptcy  
. The Parties acknowledge and agree that all rights and licenses now or hereafter granted under or pursuant to any Section of this Agreement are rights to “intellectual property” as defined in Section 101(35A) of Title 11 of the United States Code. Each Party may elect to retain and may fully exercise all of its rights and elections under Section 365(n) of Title 11 of the United States Code. In the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code (the “Insolvent Party”), the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any Intellectual Property licensed to it under this Agreement and all embodiments of such Intellectual Property (including all information related to such Intellectual Property and rights of reference with respect to Regulatory Materials), and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless the Insolvent  
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 Party continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of the Insolvent Party upon written request therefor by the other Party. For clarity, the foregoing shall not expand any license granted herein.  
12.4Notices  
. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) or [\*\*\*] after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within [\*\*\*] after such mailing, to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party will have last given by notice to the other Party.  
If to DURECT, addressed to:  
Durect Corporation  
00000 Xxxx Xxxx  
Xxxxxxxxx, XX 00000  
Xxxxxx Xxxxxx  
Attention: Legal Department  
Telephone: [\*\*\*]  
Facsimile: [\*\*\*]  
 With a copy to:  
Xxxxxx Xxxxxxx Xxxxxxxx & Xxxxxx, P.C.  
000 Xxxx Xxxx Xxxx  
Xxxx Xxxx, XX 00000-0000  
Xxxxxx Xxxxxx  
Attention: Xxx X. Xxxxxxxx, Esq.  
Telephone: [\*\*\*]  
Facsimile: [\*\*\*]  
If to INNOCOLL, addressed to:  
Innocoll Pharmaceuticals Limited  
Xxxx 0, Xxxxx X  
Xxxxxxxxx Xxxxxxxx Xxxx  
Xxxxxxxxx  
Athlone  
Co. Roscommon  
Ireland  
Attention: Chief Executive Officer  
-33-  
 With a copy to:Xxxxxx & Xxxxxxx, LLP  
000 Xxxxx Xxxxx  
Xxxxx Xxxx, XX 00000  
Attention: Xxxxxx X. Xxxxx, Esq.  
Phone: [\*\*\*]  
Fax: [\*\*\*]  
12.5Waiver  
. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.  
12.6Severability  
. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, 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 all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.  
12.7Entire Agreement/Modification  
. This Agreement, including its Exhibits, and the other Transaction Agreements (once executed) sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersedes and terminates all prior agreements and understandings between the Parties including the Prior CDA and the non-binding term sheet between the Parties dated [\*\*\*]. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.  
12.8Relationship of the Parties  
. The Parties agree that the relationship of DURECT and INNOCOLL established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.  
12.9Force Majeure  
. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, strike, flood, or other cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use [\*\*\*] to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable.  
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 12.10Compliance with Applicable Law  
. Notwithstanding anything to the contrary herein, all rights and obligations of DURECT and INNOCOLL are subject to prior compliance with, and each Party shall comply with, Applicable Law, including obtaining all necessary approvals required by the applicable agencies of the United States government.  
12.11Counterparts  
. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and all of which together, shall constitute one and the same instrument.  
[Intentionally left blank; signature page follows]  
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 IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement as of the Effective Date.  
 DURECT CORPORATION  
INNOCOLL PHARMACEUTICALS LTD.  
By: /s/ Xxx Xxxxx  
By: /s/ Xxxxx Xxxxxxxxxx  
Name: Xxx Xxxxx  
Name: Xxxxx Xxxxxxxxxx  
Title: CEO  
Title: CEO  
 US-DOCS\127839505.14  
 List of Exhibits:  
Exhibit 1.5:Assigned Trademark  
Exhibit 1.16: Financial Exhibit  
Exhibit 1.23: Licensed Patents  
Exhibit 1.24:Initial Product  
Exhibit 5.1:Materials Purchase And Reimbursed Expenses  
Exhibit 5.2:Key Terms For Excipient Supply Agreement  
Exhibit 9.2: Exceptions To Representations & Warranties  
Exhibit 9.5:Insurance Requirements  
  
 EXHIBIT 1.5  
ASSIGNED TRADEMARK  
 Xxxx  
Registration No.  
Jurisdiction  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
   
 EXHIBIT 1.16  
FINANCIAL EXHIBIT  
I.  
Milestone Payments.  
INNOCOLL shall pay DURECT the corresponding amount following the occurrence of each milestone event set forth on subsections a), b) and c) below (each, a “Milestone Event”).  
a)  
Regulatory Milestones: INNOCOLL shall pay to DURECT [\*\*\*]set forth in the following table [\*\*\*] upon the [\*\*\*]:  
 Regulatory Milestone Event  
Regulatory Milestone Payment (U.S. Dollars)  
[\*\*\*] of the [\*\*\*] for any [\*\*\*] after [\*\*\*]  
[\*\*\*][\*\*\*] of the [\*\*\*] for any [\*\*\*] after [\*\*\*]  
[\*\*\*]  
Commercial Milestones: INNOCOLL shall pay to DURECT [\*\*\*]set forth in the following table [\*\*\*] upon the [\*\*\*]:  
Commercialization Milestone Event  
Commercialization Milestone Payment  
(U.S. Dollars)  
1.First Commercial Sale of Licensed Product in the Licensed Territory  
Two Million Dollars ($2,000,000)  
2.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
3.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
4.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
5.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
6.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
7.[\*\*\*] of [\*\*\*] in the [\*\*\*] equal to or greater than [\*\*\*]  
[\*\*\*]  
For clarity, if [\*\*\*] occurs in a particular calendar year all corresponding [\*\*\*] for such [\*\*\*] so occurring in such calendar year shall [\*\*\*] as described in this Financial Exhibit; however,  
 it is understood that [\*\*\*] shall be [\*\*\*] of the applicable [\*\*\*] even if such [\*\*\*] is achieved [\*\*\*].   
b)  
Patent Milestones. Subject to the terms and conditions of this Agreement, INNOCOLL shall pay to DURECT [\*\*\*] set forth in the following table .   
 Patent Milestone Event  
Patent Milestone Payment  
(U.S. Dollars)  
The issuance of an [\*\*\*] with a [\*\*\*] of such [\*\*\*], with such [\*\*\*]having an [\*\*\*]  
 The issuance of an [\*\*\*] with a [\*\*\*] of such [\*\*\*], with such [\*\*\*]having an [\*\*\*]  
 c)  
Payment Terms. INNOCOLL shall notify DURECT [\*\*\*] of the occurrence of [\*\*\*] of the occurrence thereof and pay the [\*\*\*] of receiving an [\*\*\*]. DURECT shall notify INNOCOLL [\*\*\*] of occurrence of [\*\*\*] and INNOCOLL shall [\*\*\*] within [\*\*\*] such notice and invoice therefor. For clarity, [\*\*\*] under this Paragraph I shall be [\*\*\*].  
II.Royalties  
Royalty Payments. Subject to Section II(b) (Royalty Term) and Section II(c) (Royalty Reduction), INNOCOLL shall pay to DURECT [\*\*\*] at the [\*\*\*]t in the [\*\*\*] as set forth below:  
Portion of [\*\*\*] of [\*\*\*]  
[\*\*\*]Rate ([\*\*\*])  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
For example, in the event the applicable Annual Net Sales of Licensed Product is [\*\*\*], then the royalty owed for such period would be [\*\*\*].  
d)  
Royalty Term. Royalties payable under Section II(a) (Royalty Payments) shall be paid by INNOCOLL on a [\*\*\*] from the [\*\*\*] in the [\*\*\*] until the [\*\*\*]: (i) [\*\*\*]of the last [\*\*\*] of a [\*\*\*] the [\*\*\*] of such [\*\*\*] in the [\*\*\*], (ii) the [\*\*\*] for such [\*\*\*] in the [\*\*\*], and (iii) [\*\*\*] from the [\*\*\*] of the [\*\*\*].  
 e)  
Generic Products. If a [\*\*\*]of a [\*\*\*] is [\*\*\*] by a [\*\*\*] during the [\*\*\*], and for so long as any such [\*\*\*] is on the [\*\*\*] in the [\*\*\*] and the [\*\*\*] of such [\*\*\*] in the [\*\*\*] is [\*\*\*] of the [\*\*\*] of the corresponding [\*\*\*] and all such [\*\*\*] in the [\*\*\*] in any given [\*\*\*], then the [\*\*\*] pursuant to Paragraph II(a) on account of [\*\*\*] in the [\*\*\*] in such [\*\*\*] and each [\*\*\*] thereafter shall be [\*\*\*]. If the [\*\*\*] of such [\*\*\*] of the amount [\*\*\*] of the corresponding [\*\*\*] in the [\*\*\*] in any given [\*\*\*], then the [\*\*\*] pursuant to Paragraph II(a) on account of [\*\*\*] such corresponding [\*\*\*] in the [\*\*\*] in such [\*\*\*] and each [\*\*\*] for so long as the [\*\*\*] shall be [\*\*\*] by the [\*\*\*] of all [\*\*\*] in the [\*\*\*] in the corresponding [\*\*\*]. Should [\*\*\*] on a [\*\*\*] be [\*\*\*], INNOCOLL shall have [\*\*\*], subject to [\*\*\*].  
f)  
Royalty Reduction.   
 i.  
Third Party Payments. On a Licensed Product-by- Licensed Product basis, subject to Section II(d)(ii) (Anti-Stacking), INNOCOLL may deduct from the [\*\*\*] otherwise [\*\*\*] pursuant to Section II(a) (Royalty Payments) with respect to such [\*\*\*] with respect to such [\*\*\*].  
 ii.  
Anti-Stacking. [\*\*\*].  
g)  
Payment/Reports. All payments under this Section II shall be due and payable [\*\*\*] after the [\*\*\*] during which the corresponding [\*\*\*]. Together with any such payment, [\*\*\*] specifying: (i) [\*\*\*] during the [\*\*\*]; (ii) [\*\*\*]; and (iii) amounts [\*\*\*] from [\*\*\*] to calculate [\*\*\*].  
h)  
Inspection of Records. INNOCOLL shall, and shall cause its Affiliates to, [\*\*\*] setting forth [\*\*\*] taken to [\*\*\*] and other amounts [\*\*\*] under this Section II. INNOCOLL shall permit [\*\*\*], to examine such books and records [\*\*\*]. In no event will such examinations be conducted [\*\*\*] than [\*\*\*]. Such accountants may be required [\*\*\*]to enter into [\*\*\*] which will include provisions [\*\*\*] to only whether the [\*\*\*] and the amount of [\*\*\*]. [\*\*\*]of any such [\*\*\*]provided that if the [\*\*\*]shows an [\*\*\*] of the [\*\*\*]in connection with such examination and review. INNOCOLL shall [\*\*\*]. Any overpayment [\*\*\*] under this Section II.  
i)  
Late Payment. Subject to Section II(g) (Disputed Payments), any undisputed payments or portions thereof due hereunder which are [\*\*\*] shall [\*\*\*] equal to [\*\*\*] of (i) the [\*\*\*] to the [\*\*\*] for the [\*\*\*], as published by [\*\*\*], on the [\*\*\*], plus an [\*\*\*], or (ii) the [\*\*\*] permitted by [\*\*\*], calculated on [\*\*\*].   
j)  
Disputed Payments. If a dispute arises between the Parties, each acting in good faith, in respect of any part of an invoice, the disputing Party shall [\*\*\*]. Each Party shall use [\*\*\*] to promptly and in good faith resolve the dispute in accordance with Article 11 (Dispute Resolution). Payment of any resolved amounts shall be made within [\*\*\*] following the resolution of such dispute, and, unless [\*\*\*], the payee Party may not use such withholding as a basis for terminating this Agreement pursuant to Section 10.2(d) (Termination for Material Breach).  
 EXHIBIT 1.23  
LICENSED PATENTS  
[\*\*\*]: [\*\*\*]  
Country  
Sub Case  
Case Type  
Status  
App. No.  
Filing Date  
Patent No.  
Issue Date  
[\*\*\*]  
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 [\*\*\*]: [\*\*\*]  
Country  
Sub Case  
Case Type  
Status  
App. No.  
Filing Date  
Patent No.  
Issue Date  
[\*\*\*]  
[\*\*\*]  
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[\*\*\*]  
 [\*\*\*]: [\*\*\*]  
Country  
Sub Case  
Case Type  
Status  
App. No.  
Filing Date  
Patent No.  
Issue Date  
[\*\*\*]  
[\*\*\*]  
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[\*\*\*]  
[\*\*\*]  
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[\*\*\*]  
 [\*\*\*]: [\*\*\*]  
Country  
Sub Case  
Case Type  
Status  
App. No.  
Filing Date  
Patent No.  
Issue Date  
[\*\*\*]  
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[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 EXHIBIT 1.24  
INITIAL PRODUCT  
DURECT’s formulated product known, as of the Effective Date, as POSIMIR® and described NDA No. 204803.  
 EXHIBIT 5.1  
MATERIALS PURCHASE AND REIMBURSED EXPENSES  
 Descriptions  
Amount  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
Total amount [\*\*\*]:  
[\*\*\*] (see details below)  
   
 EXHIBIT 5.2  
KEY TERMS FOR EXCIPIENT SUPPLY AGREEMENT  
 Agreement Term  
Description  
Term  
Term of the License Agreement  
Termination  
In accordance with the License Agreement  
Forecasting  
INNOCOLL to provide DURECT with [\*\*\*]of needs at [\*\*\*]prior to the [\*\*\*]  
Purchase and Supply Commitment  
Orders must be [\*\*\*] of the forecasted amounts. [\*\*\*] to accept and [\*\*\*] for up to [\*\*\*] of the [\*\*\*]  
Purchase Order Form  
To be agreed by the parties within [\*\*\*]  
Order Acceptance  
[\*\*\*] of its [\*\*\*] an order [\*\*\*], subject to [\*\*\*] Orders will be [\*\*\*].  
Shipment Terms  
[\*\*\*]  
Shipment Expenses  
All [\*\*\*] and [\*\*\*] shall be [\*\*\*]  
Title Transfer  
Transferred to [\*\*\*] to the [\*\*\*] for transport [\*\*\*]  
Risk of Loss  
[\*\*\*] upon delivery to the [\*\*\*] for transport to [\*\*\*]`  
Product Inspection Period  
[\*\*\*] from [\*\*\*] to [\*\*\*]  
Non-Conformance & Testing  
If [\*\*\*] is found by [\*\*\*] to be non-conforming, [\*\*\*]shall [\*\*\*]; otherwise [\*\*\*] shall [\*\*\*]  
Manufacturing Standards  
[\*\*\*]  
Stock Pile  
[\*\*\*] commits to having [\*\*\*] of excipient [\*\*\*] within [\*\*\*] from [\*\*\*]  
Backup Manufacturing License  
Upon Release Condition, [\*\*\*] shall grant to [\*\*\*] a [\*\*\*] to manufacture (through [\*\*\*], such [\*\*\*]) the excipient  
Release Condition  
Release Condition occurs if (A) [\*\*\*] to [\*\*\*] with the properly-ordered excipient quantities for [\*\*\*] or [\*\*\*], or (B) [\*\*\*]elects to transfer the [\*\*\*] to [\*\*\*]  
SAIB Supply & Technology Transfer  
In the event of the occurrence of a [\*\*\*], [\*\*\*]will [\*\*\*] the process for the additional processing [\*\*\*] for use in a [\*\*\*], as to be set forth in the [\*\*\*].  
Pricing  
[\*\*\*]. [\*\*\*]shall have the [\*\*\*] [\*\*\*] upon [\*\*\*] by an [\*\*\*] not exceed the total aggregate percentage [\*\*\*] (as reported [\*\*\*]) since the [\*\*\*]  
Invoicing  
Upon [\*\*\*]  
Payments  
Due and payable [\*\*\*]  
 Agreement Term  
Description  
DMF  
[\*\*\*] shall maintain [\*\*\*], or shall transfer the [\*\*\*] of the [\*\*\*] in accordance with Section 5.3 (Drug Master File) of the License Agreement  
   
 EXHIBIT 9.2  
EXCEPTION TO REPRESENTATIONS & WARRANTIES  
 [\*\*\*] regarding [\*\*\*]  
 EXHIBIT 9.5  
INSURANCE REQUIREMENTS  
(a)Worker’s Compensation and Employer’s Liability. Workers’ Compensation coverage with statutory limits and Employers’ Liability coverage with a limit of [\*\*\*].  
(b)Products Liability. Products Liability policy with a limit of [\*\*\*].  
(c)Commercial General Liability. A Commercial General Liability policy with a limit of [\*\*\*].  
(d)Automobile Liability. An Automobile Liability policy with a [\*\*\*].  
(e)Professional Liability. A Professional Liability policy with a limit [\*\*\*].  
(f)Umbrella/Excess Coverage. Umbrella liability coverage of [\*\*\*].