EXHIBIT 10.01  
 [ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.  
 MANUFACTURING AGREEMENT  
 THIS MANUFACTURING AGREEMENT (“Agreement”) is entered into as of May 30, 2005 (the “Effective Date”) by and between Allos Therapeutics, Inc., a corporation duly organized and existing under the laws of the State of Delaware, having an address at 00000 Xxxxxx Xxxxx Xxxx, Xxxxx 000 Xxxxxxxxxxx, XX 00000-0000 (“Allos”), and Hovione Inter Limited, a Swiss Corporation, with its principal place of business in Luzern, Switzerland (“Hovione”). Allos and Hovione are sometimes hereinafter each referred to as a Party (collectively “Parties”) to this Agreement.  
 BACKGROUND  
 A. Hovione possesses the necessary facilities, equipment, manufacturing technology, professional expertise, personnel, and capacity to manufacture API and to furnish Allos with a continuing API supply, and desires to undertake API manufacturing for Allos and Allos desires to have Hovione manufacture the API for Allos.   
 B. The Parties executed a term sheet on March 25, 1999 providing the principal terms under which Hovione would manufacture and supply certain of Allos’s requirements of API (the “Term Sheet”). By a letter dated January 11, 2000 the Parties confirmed their understanding set forth in the Term Sheet and agreed that the Term Sheet would serve as an interim supply agreement. The Term Sheet was entered into by the Parties with the understanding that such principal terms would be subject to the negotiation and preparation of a final agreement of the complete and definitive terms.   
 C. The Parties have now negotiated such definitive terms under which Hovione will Manufacture API for Allos. The terms and conditions of this Agreement shall govern the supply of API from and after the Effective Date.  
 NOW, THEREFORE, the Parties hereto, intending to be legally bound, hereby agree as follows:  
 1. DEFINITIONS  
 All capitalized words and phrases used in this Agreement shall have the meaning provided in this Article 1.  
 1.1 “AAA” means the American Arbitration Association.  
 1.2 “Affiliate” means any person, organization, or entity that is, directly or indirectly, controlling, controlled by, or under common control with a Party. The term “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”), as used with respect to any person or entity, means the possession, directly or indirectly, of the power to direct, or cause the direction of, the management and policies of such person, organization, or entity, whether through the ownership or control of voting securities (or their voting power) or by contract, or court order, or otherwise. The ownership of voting securities of a person, organization, or entity shall not, in and of itself, constitute “control” for purposes of this  
   
 definition, unless said ownership is of a majority of the outstanding securities entitled to vote of such person, organization, or entity.  
 1.3 “Allos Indemnitees” has the meaning set forth in Section 13.1.  
 1.4 “API Improvements” means inventions, discoveries or improvements related to the API (including API Related Compounds) or API Manufacturing (including analytical methods, manufacturing processes, API formulations and packaging) that Hovione invents, develops or discovers, conceives, reduces to practice, in connection with or arising from its activities under this Agreement (including during the period since the effective date of the Term Sheet) or from its access to the Allos Confidential Information, whether patentable or not and whether alone or jointly with others.  
 1.5 “API Related Compound(s)” means the API and any other compound covered by patents owned or licensed to Allos, including their salts, acids, esters, and non-covalent derivative (e.g., complex, chelate, or clathrate of such compound).  
 1.6 “API” means the proprietary compound known as RSR-13 (efaproxiral), Chemical Name: 2-[-[[(3,5-Dimethylanilino)carbonyl]methyl]phenoxy]-2-methylpropionic acid] and its sodium salt.  
 1.7 “Applicable Laws and Regulations” means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders, policies and other requirements of each of the Regulatory Authorities applicable to the manufacture, sale, labeling, use, marketing, distribution, import, export, price or reimbursement of the Services or API. Applicable Laws and Regulations shall include, but are not limited to, the U.S. Federal Food, Drug & Cosmetic Act and regulations administered by the FDA (specifically including, but not limited to 21 C.F.R. Parts 11, 210 and 211) and the following to the extent not in conflict with any laws or regulations that are issued or enforced by the FDA and other Regulatory Authorities as in effect during the provision of and applicable to API Manufacturing and Services: (a) USP/NF/EP and other applicable compendia standards; (b) guidance documents (including Guidelines, Points to Consider, Inspection Technical Guides, International Conference on Harmonization “Step 4 and 5” documents), and (c) current good manufacturing practices as accepted without object in the pharmaceutical industry for the manufacture of a sterile API.  
 1.8 “Benchmark Rate” means [ \* ] Euro per 1.00 U.S. dollar.  
 1.9 “Campaign Plan” has the meaning set forth in Section 4.1.  
 1.10 “CIF” means “Cost, Insurance and Freight” as provided for under Incoterms 2000 promulgated by the International Chamber of Commerce.  
 1.11 “CMC” means the Chemistry, Manufacturing and Controls portion of an IND, NDA or Drug Master File.  
 1.12 “Commercial Supply Phase” means all activities and API lots manufactured after the Launch Phase.  
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 1.13 “Confidential Information” has the meaning set forth in the Nondisclosure Agreement.  
 1.14 “Corporate Partner” means any organization to whom Allos grants the right, whether by license or otherwise, to manufacture and sell the Product.  
 1.15 “Delivery Failure” has the meaning set forth in Section 6.1(e).  
 1.16 “Delivery Forecast” has the meaning set forth in Section 4.2.  
 1.17 “Drug Master File” means a confidential submission by one Party describing the Specifications (including composition and methods of manufacture) for a product or activity made or performed by one Party that is made available for confidential review by a Regulatory Authority in connection with its review or approval of a Regulatory Submission for the other Party where disclosure of such information in the Regulatory Submission of that Party is undesired.  
 1.18 “Effective Date” has the meaning assigned to such term in the preamble.  
 1.19 “Equivalent Third Party” means a third party contract manufacturer that: (a) is registered with the FDA as an Active Pharmaceutical Ingredient manufacturing facility; (b) has had experience in the manufacture of injectable grade Active Pharmaceutical Ingredients; and (c) has successfully completed a pre-approval inspection with the FDA for an injectable grade Active Pharmaceutical Ingredient.  
 1.20 “Exchange Rate” means the three (3) month average exchange rate of the Euro per U.S. dollar, as published in The Wall Street Journal on the last business day of each calendar quarter.  
 1.21 “Exclusivity Period” has the meaning set forth in Section 12.5.  
 1.22 “Facility” means the specific premises identified in Attachment B under “8. Facilities.”  
 1.23 “FDA” means the United States Food and Drug Administration, or any successor thereto.  
 1.24 “FD&C Act” means the United States Food, Drug and Cosmetic Act, as amended from time to time.  
 1.25 “Force Majeure” has the meaning set forth in Section 16.4.  
 1.26 “Forecast” means a written statement of Allos’s anticipated purchase requirements prepared and delivered to Hovione as provided in Sections 3.1, 4.1 or 4.2(a).  
 1.27 “Generic Methods” has the meaning set forth in Section 12.5.  
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 1.28 “Hovione Indemnitees” has the meaning set forth in Section 13.2.  
 1.29 “Hovione Quality System” means the procedures and controlled documentation that HOVIONE has in place at its Facility during the Term that are necessary to evidence compliance with FDA current good manufacturing Practices requirements and all ICH guidelines, as well as any other requirements necessary to Manufacture API.  
 1.30 “Hovione References” has the meaning set forth in Section 9.5.  
 1.31 “Hovione Regulatory Documents” has the meaning set forth in Section 9.5.  
 1.32 “IND” means an investigational new drug application filed with the FDA, in order to commence human clinical testing of a drug.   
 1.33 “In-Process API” means partially synthesized API, which includes compounds in the intermediate manufacturing steps subsequent to the first modification of the Raw Materials and before the final modification to the API.  
 1.34 “Intellectual Property Rights” means without limitation all proprietary rights under any and all patent, patent applications, trade secret, copyright, trademark trade dress, and other proprietary rights, in any discoveries, inventions, ideas, improvements, works, compilations and all interests and title in the materials, information, technology, methods, processes, specifications, data, records, results, and documentation.  
 1.35 “Launch Phase” means all activities and API lots manufactured after the Effective Date and prior to the [ \* ] of Allos’ receipt of Marketing Approval by the FDA or European Medicines Agency.  
 1.36 “Loss” and “Losses” means any and all claims, liabilities, losses, costs, damages and expenses (including, without limitation, reasonable attorneys’ fees and legal and court costs) together with any related interest, fines and penalties.  
 1.37 “Lot” means one (1) discrete quantity of API as that term is defined under 21 CFR §210(b)(10).  
 1.38 “Manufacturing” means any pharmaceutical procedures conducted to produce the API, including processing, packing, labeling, holding, testing, and quality control of the API, the Raw Materials and In-Process API, and actions taken to comply with Applicable Laws and Regulations and this Agreement (e.g., validation of process, facilities, equipment, methods and operations).  
 1.39 “Manufacturing Forecast” has the meaning set forth in Section 4.1.  
 1.40 “Marketing Approval” means an approval by the FDA to commence commercial marketing and distribution for the Product, and comparable foreign equivalents, including amendments and supplements to such Marketing Approvals.  
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 1.41 “Master Batch Record” means the then-current procedures to be followed by Hovione with respect to the manufacture of API, and the handling and storage of API, as separately set forth and agreed upon by the parties from time to time during the term of this Agreement.  
 1.42 “Material Safety Data Sheet” or “MSDS” means the written description of safety information on the API for use by persons engaged in API Manufacturing.  
 1.43 “Methods of Analysis” means the analytical methods to be used in testing API for compliance with the API Specifications as set forth in the Quality Agreement, as amended from time to time.  
 1.44 “NDA” means a New Drug Application for Marketing Approval filed in the United States.  
 1.45 “Nondisclosure Agreement” has the meaning set forth in Section 12.1.  
 1.46 “Out of Specification” or “OOS” means failure of the API to meet the Specifications.  
 1.47 “Planning Forecast” has the meaning set forth in Section 4.1.  
 1.48 “Product” means the human pharmaceutical product containing the API.  
 1.49 “Production Fee” means the fees charged by Hovione in connection with API Manufacturing and Services, including, without limitation, the disposal of Wastes.  
 1.50 “Production Materials” has the meaning set forth in Section 9.3.  
 1.51 “Project Manager” means the individuals identified in Attachment A as the Project Managers for Hovione and Allos.  
 1.52 “Purchase Order” means a written order for Hovione to manufacture and/or deliver and Allos to purchase a specific quantity of API.  
 1.53 “Quality Agreement” means the document mutually agreed upon by the Parties, pursuant to Section 9.2, as may be amended from time to time, containing the policies, procedures, and standards by which the Parties will coordinate and implement the operational and quality assurance activities needed to efficiently achieve regulatory compliance objectives.   
 1.54 “Quality Control Release Date” has the meaning set forth in Section 7.3.  
 1.55 “Raw Material” means the compounds, water, solvents, reagents and other materials and supplies, including disposable manufacturing equipment and labeling and packaging materials used in Manufacturing.  
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 1.56 “Record” means all documents, reports, data, data listings, charts, process control/monitoring commands and data summaries, logs, notes, standard operating procedures, Master Batch Records, lot batch records, analyses, correspondence, notes, memorandum, (including, without limitation, production and quality assurance and quality control documentation) and other items containing information or data related to API Manufacturing and Services, whether in paper or electronic form, including originals and copies, including without limitation all items that would be considered “records” under any Applicable Laws and Regulations.  
 1.57 “Regulatory Authority” means the multinational, federal, regional, state and local government authorities (including public, quasi-public and private bodies contracted, certified or authorized by such governmental bodies) in a country or other jurisdiction with authority to regulate, approve, license, inspect, review or otherwise control or supervise the manufacture, sale, labeling, use, marketing, distribution, import, export, price or reimbursement for the Services or API, including but not limited to the FDA and its counterparts in the European Union and Japan.  
 1.58 “Regulatory Submission” means any document, correspondence, data, article, certifications, physical samples that are, or that are required to be, delivered or made available for inspection or review by any Regulatory Authority in connection with any Service or otherwise in connection with the activities carried out by either Party relating to this Agreement, specifically including but not limited to applications, dossiers or reports supporting the manufacture or use of the Product for investigational or commercial use, including any INDs, NDAs, Drug Master Files, field reports, annual reports, adverse event and corrective action reports, and export approvals, change being effected reports, information packages for meetings with the Regulatory Authorities and any amendments, supplements, corrections, and updates.  
 1.59 “Services” mean, collectively unless context indicates otherwise, all formulation and process development, regulatory, manufacturing, testing and other services provided, and to be provided by Hovione under this Agreement.  
 1.60 “Specifications” mean the characteristics and qualities established by the Parties in writing and with which a API Lot or Service (including reference standards, In-Process API, and Raw Materials) must conform including but not limited to all conditions of and procedures to be used in its Manufacture, (e.g., Master Batch Records, production, sampling, testing, packaging, storage and shipment standard operating procedures, production environment standards, chemical names, formulas, and other instructions, approved vendors/SKUs/grades, release criteria and associated analytical methods). Where no Specification has been established by the Parties, the Specifications may be those that that are reasonably established in compliance with Applicable Laws and Regulations and the Quality Agreement.  
 1.61 “Technology Transfer Fee” means the fees to be paid to Hovione in connection with a technology transfer.  
 1.62 “Term” means the period commencing on the Effective Date and ending as provided in this Agreement (unless extended as otherwise provided in this Agreement).  
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 1.63 “Term Sheet” has the meaning assigned to such term in the preamble.  
 1.64 “Waste” means all waste, as defined by Applicable Laws and Regulations and all non-hazardous waste, to the extent arising out of API Manufacturing and Services, including without limitation, rejected or unusable Raw Materials, In-Process API or API, disposable manufacturing equipment and materials (including chromatography matrix, solvents, excess buffers or rinses, filters, gowns and other consumables).  
 2. PROJECT MANAGEMENT  
 2.1 Project Managers. Each Party shall designate a representative with authority as to technical matters to serve as the primary contact for the other Party about the API and the Parties’ relationship under this Agreement. Each Project Manager shall be responsible for obtaining cooperation and input from other individuals within such Project Manager’s organization whose expertise and ability may be required from time to time to maximize the potential for successful collaboration under this Agreement. The Project Managers shall develop procedures to optimize communication and collaboration between the Parties. The Project Managers will communicate regularly during the Term at mutually agreeable times, and, when necessary, hold meetings at mutually agreeable places, to review project management and status. The Project Manager shall be a member of the Steering Committee described in Section 2.2 below.  
 2.2 Steering Committee. A Steering Committee, consisting of the Project Managers and at least one (1) senior management representative from each Party, shall meet periodically during the Term, but on at least an annual basis. The Steering Committee shall: (a) oversee and provide management direction for the achievement of the objectives of this Agreement; (b) review the Services to be performed and API to be provided under this Agreement; (c) review requests by Regulatory Authorities, or a Party, to changes in or additions to the Services to be performed, to the extent not addressed by the Project Managers; (d) provide guidance regarding planned or anticipated events in each Party’s business or operations that might affect the work conducted under the contract changes; (e) review of any materially adverse regulatory matters affecting this Agreement, the Services or API; (f) review and resolve all matters not satisfactorily addressed by the Project Managers; and (g) review production reports periodically prepared by Hovione pursuant to Section 2.3, and recommend to the Parties corrective actions as necessary. Hovione shall implement in accordance with this Agreement such changes as may be recommended by the Steering Committee following its review of Hovione’s periodic production reports.  
 2.3 Monthly Progress & Budget Reports. Each month, Hovione shall provide Allos with a written production status report describing the following:  
 (a) Activity Progress. Progress on completion of outstanding obligations (e.g., production runs, process development, validation, stability data, Regulatory Submissions, and pending corrective actions). The status report shall indicate Hovione’s progress toward task or delivery milestones relative to planned completion schedules.  
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 (b) Inventories. Current inventory of API, In-Process API, Raw Materials, safety stock and reference standards.   
 (c) Computer Access. Notwithstanding Hovione’s written reporting obligations set forth in subsections (a) and (b) above, Hovione and Allos acknowledge the benefit of and will work towards Allos having on-going, on-line access to a secure part of Hovione’s computer systems that shall enable Allos to obtain the information described above under subsections (a) and/or (b). If computer access is made available to Allos, Hovione will provide reasonable assistance and training to Allos to ensure that: (i) on-line access is adequately established and maintained at Allos’s facilities; and (ii) the appropriate Allos personnel are able to access such information.  
 2.4 Adverse Issues & Corrective Actions. Hovione shall inform Allos promptly of any events that might materially affect the ability of Hovione to timely and fully perform and/or deliver any Services or API or otherwise affect the established schedule or budgets, including any unexpected adverse final or interim results or data from validation, stability or other studies. The status report also shall fully describe all Out of Specification (“OOS”) and out of trend events, failure investigations, process deviations, batch failures and similar matters, as well as the corrective or other actions to be taken by Hovione. Hovione shall conduct periodic review of production records, on at least an annual basis, including trend analysis of batch production records and other process data, and prepare a report for submission to the Steering Committee summarizing Hovione’s findings, conclusions and recommendations.   
 3. LAUNCH PHASE  
 3.1 Forecasts and Orders. During the Launch Phase, Allos shall provide Hovione with Forecasts of its expected requirements of API, on a regular basis, but in no event updated less frequently than once every [ \* ] months. Allos may submit Purchase Orders for such quantities of API indicated in such Forecasts no less than [ \* ] months prior to the requested delivery date or as may be agreed upon by the Parties. Within ten (10) days of receipt of a Purchase Order from Allos, Hovione shall notify Allos in writing of Hovione’s acceptance of such Purchase Order. The minimum campaign size requirement as set forth in Attachment B under “3. Minimum API Lot Sizes for Pricing,” for the Launch Phase Purchase Orders shall apply.  
 3.2 Order Fulfillment. Following payment by Allos of a non-refundable pre-payment amount equal to [ \* ] of the applicable Purchase Order value, Hovione shall be obligated to deliver the required quantity of API indicated in such Purchase Order within a [ \* ] month period thereafter; provided that the amount ordered does not exceed [ \* ]. If the amount of API ordered is greater than [ \* ], then Hovione shall only be obligated to deliver an initial [ \* ] within [ \* ] months and not less than [ \* ] thereafter until the total quantity of the Purchase Order has been fulfilled. Allos shall be free to cancel all or part of any outstanding Purchase Order prior to Allos’ payment of the [ \* ] pre-payment amount by providing written notice to Hovione of such cancellation. Hovione shall be free to Manufacture and deliver the API from any Facility that has been approved by Allos and validated. If Allos requests in writing that Hovione use its best efforts to deliver any ordered quantities of API earlier than the agreed [ \* ] delivery delay  
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 period, Hovione will be entitled to receive an additional amount equal to [ \* ] of the invoice value of such quantity for each [ \* ] that early delivery occurs prior to the original [ \* ] lead time delivery date.  
 3.3 Order Cancellation. Allos may cancel all or part of any outstanding Purchase Order submitted under Section 3.1 by providing Hovione written notice; provided, however, that if such cancellation occurs after Allos has paid the [ \* ] pre-payment amount, Hovione shall be entitled to retain the pre-payment amount.   
 4. COMMERCIAL PHASE FORECASTS AND PURCHASE ORDERS  
 4.1 Planning Forecasts. On or before July 31 of each year during the Commercial Supply Phase, Allos shall submit to Hovione (a) a forecast of Allos’s estimated requirements for API for each of the next [ \* ] (each, a “Planning Forecast”) and (b) [ \* ] forecast projecting estimated quantities that will be ordered by Allos during the following [ \* ] (each, a “Manufacturing Forecast”) split over [ \* ] calendar quarters. All estimates set forth in Planning Forecasts and Manufacturing Forecasts shall not constitute a contractual commitment by Allos for such quantities; however, such estimates shall constitute Allos’s anticipated maximum level of demand and utilization of capacity for API production, subject to Section 4.3(c), and Hovione may use such estimates for facilities, personnel, production and campaign scheduling and budget planning purposes. The Parties agree that each annual Manufacturing campaign undertaken by Hovione shall be no smaller than that stated in Attachment B under “3. Minimum API Lot Sizes for Pricing,” and that Hovione may produce a campaign of any amount that is supported by Allos’ Planning and Manufacturing Forecasts. No less than [ \* ] prior to the start of the annual campaign, Hovione shall inform Allos of its proposed format, quantity and calendar (“Campaign Plan”). Should Allos require that the campaign be any different than proposed, it shall notify Hovione in writing no less than [ \* ] prior to its planned conclusion and Hovione will use good faith efforts to adjust the campaign in accordance with Allos’ request. If requested by Hovione, Allos shall promptly issue Purchase Orders in amounts that justify the requested changes to the Campaign Plan.  
 4.2 Delivery Forecast. [ \* ] before each [ \* ] during the Commercial Supply Phase, Allos shall provide Hovione with an [ \* ] written rolling Forecast of the estimated total amount of API that Allos anticipates it will order from Hovione (“Delivery Forecast”).  
 (a) The first [ \* ] of each Delivery Forecast shall be firm commitments as to quantities and month for delivery. The [ \* ] of a Delivery Forecast shall be non-binding estimates for informational purposes only. Allos may revise the estimated portions of Delivery Forecast [ \* ] as and when it deems appropriate. Pricing shall be based on the first [ \* ] of the Delivery Forecast submitted for the beginning of each [ \* ], with corrections made upon the delivery of the Purchase Order for the [ \* ], unless annual pricing thresholds are exceeded by earlier Purchase Orders.  
 (b) Allos shall provide to Hovione the first Planning Forecast for the Commercial Supply Phase within [ \* ] after the date Allos first submits a Regulatory Submission to apply for Marketing Approval in any country.   
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 (c) No later than [ \* ] after receipt of either a Manufacturing Forecast or Planning Forecast from Allos, Hovione shall inform Allos in writing if it will be able to furnish the estimated quantities of API in the manner and schedule set forth in said Forecasts, and if unable to fulfill the Forecasts the reasons why the Forecasts cannot be fulfilled.  
 4.3 Purchase Orders.  
 (a) During the Term, Allos shall purchase and Hovione shall supply at least the percentage of Allos’s annual API requirements stated in Attachment B under “1. API Purchase/Supply Minimums.”  
 (b) During the Commercial Supply Phase, Allos shall provide Hovione with Purchase Orders on Allos’s forms for [ \* ] at least [ \* ] before the start of such [ \* ]. Each Purchase Order shall be formally accepted by Hovione within [ \* ] of its transmission, and shall not be rejected unless Allos has either not observed the [ \* ] of each Delivery Forecast (subject to Section 4.3(c)) or materially breached the Agreement and despite written notice from Hovione has failed to cure such breach. Any Purchase Order not rejected by Hovione within [ \* ] shall be deemed accepted. If there is a conflict between the terms contained in this Agreement and the terms contained in any of Allos’s standard form Purchase Orders, any delivery documents or in Hovione’s acceptance documents, the terms of this Agreement shall govern.  
 (c) Each Purchase Order submitted to Hovione by Allos shall state the specific quantities of API requested by Allos, which shall be based on API batch sizes, the expected minimum size of which is provided in Attachment B under “3. Minimum API Lot Sizes for Pricing,” and shall include the expected delivery date(s) for such quantity of API ordered. Subject to Hovione’s written consent, which shall not be unreasonably withheld, the aggregate Purchase Orders for a [ \* ] shall not be less than [ \* ] nor more than [ \* ] of the amount estimated for that [ \* ] in the most recent Delivery Forecast for that quarter; provided, that Hovione shall use its commercially reasonable efforts to timely supply Purchase Orders in excess of [ \* ] of the applicable Delivery Forecast. Deliveries against Purchase Orders shall be made on the dates specified in the Purchase Order.  
 (d) During the Commercial Supply Phase, Allos shall notify Hovione if Allos desires to cancel or reduce the quantities of API ordered in a Purchase Order that has been accepted by Hovione. If such notification is provided to Hovione less than [ \* ] prior to the requested delivery date for API contained in such Purchase Order, Allos shall be solely liable to Hovione for: (i) losses actually incurred (as evidenced by written documentation) because of the underutilization of the operational portion of the Facility that would have ordinarily been used in API Manufacturing but could not be rescheduled for other uses, and (ii) the costs of Raw Materials purchased by Hovione to Manufacture that Purchase Order (including Waste disposal costs) that could not be returned for credit or refund by Hovione or that could not be used by Hovione for other purposes, including subsequent API Manufacturing. Such losses for each cancelled kilogram of API shall not exceed the amount set forth in Attachment B for that quantity of API.  
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 (e) If, in Allos’ sole discretion, at the time of placing a Purchase Order, Allos pays to Hovione a non-refundable pre-payment equal to [ \* ] of the value of such Purchase Order, then Hovione will be deemed to have expressly waived the Commercial Phase minimum campaign size requirement set forth in Attachment B under “3. Minimum API Lot Sizes for Pricing,” in connection with such Purchase Order and Allos shall have the right to cancel all or part of such Purchase Order; provided, however, that in no event shall Hovione be required to produce any campaign smaller than the minimum Launch Phase campaign size requirement set forth in Attachment B under “3. Minimum API Lot Sizes for Pricing,” in connection with any other Purchase Order. If Allos cancels the quantities of API ordered in a Purchase Order, Hovione will retain the pre-payment amount and the payment obligations contained under Section 4.3(d) above will not apply. Notwithstanding the foregoing, Hovione retains the right to cancel the terms of this Section 4.3(e) upon [ \* ] prior written notice to Allos.  
 (f) Hovione, on at least a monthly basis, shall provide Allos with a written schedule of all then-outstanding accepted Purchase Orders for API, including the expected delivery date(s). If the Parties establish access to Hovione’s computer systems as provided in Section 2.3(c) above, Allos will also be able to obtain on-line information on the then-outstanding accepted Purchase Orders for API, including the expected delivery date(s). If such computer access is made available to Allos, Hovione will provide reasonable assistance and training to Allos to ensure that: (i) on-line access is adequately established and maintained at Allos’s facilities; and (ii) the appropriate Allos personnel are able to access such information.  
 5. FEES, INVOICING & PAYMENT  
 5.1 Pre-Commercial Projects. In satisfaction of Allos’s payment obligations under the Term Sheet for Services and API provided by Hovione to Allos prior to the Effective Date, Allos shall pay to Hovione a final amount equal to [ \* ]. Such payment shall be made by Allos within fifteen (15) days of the successful response by the Parties to any and all inquiries from the FDA regarding the CMC.   
 5.2 API Supply. During the Launch Phase and Commercial Supply Phase, Hovione shall be paid for the Services and API Manufacturing in accordance with the price schedule provided in Attachment B under “2. API Pricing.” All amounts specified in Attachment B are for supply of API by Hovione delivered pursuant to Section 6.1(b) below.   
 5.3 Invoicing. Hovione may invoice Allos for all released API Lots upon shipment as per the delivery dates indicated in the applicable Purchase Order. Any API Lots Manufactured but not shipped because such API Lots are to be maintained as safety stock pursuant to Section 7.3, shall be invoiced, at Hovione’s option, either on (a) one hundred and eighty (180) days of the Quality Control Release Date or (b) one hundred and eighty (180) days after the delivery date(s) set out in the applicable Purchase Order.  
 5.4 Payment. Subject to Section 5.1, payment of all Purchase Order pre-payments and undisputed invoices shall be delivered by wire transfer in U.S. dollars to the accounts provided in Attachment B under “7. Wire Instructions.” Payment of undisputed amounts shall be made within thirty (30) days of the invoice date. Payment shall be considered received once  
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 funds become available to Hovione, or Hovione’s agent, at its bank account in a USA located bank. Except for the fault of Allos, payment delivery shall be deemed to occur no later than 24-hours after the transmission of the Allos payment. In the case one invoice is in dispute, its payment shall not affect settlement of other outstanding and due invoices. Repeated delay in settlement of invoices will entitle Hovione to only ship against confirmed letter of credit terms.  
 5.5 No Liens. Hovione shall ensure that all API Lots are delivered free of any liens. Hovione has the option to arrange invoicing by any company of the Hovione group or by its agents if Allos first provides its written consent to such invoicing arrangement, which consent shall not be unreasonably withheld. Any person seeking payment from Allos shall be subject to all defenses, claims and rights that Allos might have against Hovione, and Hovione shall be responsible for the actions of such other person. Hovione shall have no set-off rights or remedy against Allos in the event that Hovione’s agent fails to remit payments received from Allos.  
 5.6 Change In Circumstance. The costs and fees provided in this Agreement are based on current experience and do not take into account items that are unforeseeable (such as unexpected issues in the API development, materials changes in the regulations, FDA’s views, toxicity of the API or the process, or legislation (e.g., health, safety or environment). The Parties shall negotiate in good faith any changes to the pricing set out in Attachment B should unforeseen dramatic changes occur that cause a substantial hardship to either Party.  
 5.7 Currency & Taxes. All shipments of API shall be invoiced in United States dollars and all payments therefore shall be made in United States dollars. Hovione shall be responsible for all Portuguese and Macau taxes (including, but not limited to, VAT, sales, income, export duties, income, social security and withholding taxes) and workers’ compensation and unemployment insurance with respect to the Manufacturing of API and performance of Services in Portugal or in Macau under this Agreement. Allos shall be responsible for all taxes applicable in the USA and in the other markets where the API is exported to (including, but not limited to, VAT, sales, income, import duties, income, social security and withholding taxes) with respect to this Agreement.  
 5.8 Exchange Rate Risk. To share the exchange rate risk, Allos and Hovione agree that the API prices set forth in Attachment B under “2. API Pricing” shall be subject to adjustment as follows:  
 (a) If the Exchange Rate determined at the end of any calendar quarter and the Benchmark Rate differ by more than [ \* ], the API prices set forth in Attachment B under “2. API Pricing” shall be increased or decreased, as appropriate, by an amount equal to [ \* ] of the percentage increase or decrease, as appropriate, in the Exchange Rate relative to the Benchmark Rate, and such API prices, as adjusted, shall apply to all invoices issued by Hovione pursuant to Section 5.3 during the immediately succeeding calendar quarter.  
 (b) If the Exchange Rate determined at the end of any calendar and the Benchmark Rate differ by [ \* ] or less, then no adjustment will be made to the API prices set forth in Attachment B under “2. API Pricing”, and such API prices, as set forth in Attachment B  
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 under “2. API Pricing”, shall apply to all invoices issued by Hovione pursuant to Section 5.3 during the immediately succeeding calendar quarter.  
 The following table sets forth representative examples of the impact of various Exchange Rates:  
 Exchange Rate  
 % Change from Benchmark Rate  
 API Price Adjustment  
 $1 =  
€ [ \* ]  
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 6. DELIVERY AND ACCEPTANCE  
 6.1 Delivery Instructions.  
 (a) Release Confirmation Testing. Hovione shall be responsible for conducting all testing required as set forth in the Quality Agreement prior to the release of any API for shipment as provided in this Section 6.1. Allos has the right to review all release testing data as provided in the Quality Agreement and to approve the release of any API for shipment.   
 (b) Shipment. Each API Lot shall be shipped by Hovione CIF to Allos’s designated Product manufacturer; provided, however, that (i) API Lots shall be shipped in the mode of transport provided in the delivery instructions included in each Purchase Order, which will be air for international and truck for inland shipment, and (ii) Hovione shall be responsible for all risks and additional normal transport costs that occur prior to arrival of any shipment at Allos’s designated Product manufacturer. API shall be shipped in accordance with the shipping conditions and procedures established under the Quality Agreement. Each API Lot shall be accompanied by certificates of analysis in a form specified in the Quality Agreement.  
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 (c) Acceptance. Allos, or its Product manufacturer, shall promptly initiate acceptance testing of API Lots upon physical receipt of API Lots. An API Lot shall be deemed accepted upon successful completion of acceptance testing, subject to revocation upon subsequent determination of any latent defects (e.g., subsequent testing, inspections or audits, stability data, or failure investigations). However, if the defect would have been detected by reasonable physical inspection and acceptance testing, and notice of the defect is not received within ninety (90) days of physical receipt (as indicated by the airway xxxx), Hovione will be under no obligation to replace the Lot. Allos (and the Product manufacturer) shall be entitled to rely on the accuracy and validity of Hovione certificates of analysis and compliance provided with each delivered API Lot. Allos shall notify Hovione in writing of any deficiencies of a received API Lot within five (5) business days of Allos’s receipt of final test reports for all testing performed on such Lot by either Allos or its Product manufacturer.  
 (d) Dispute. At the request of either Party, unresolved disputes regarding the conformance of an API Lot with its applicable Specifications will be referred to a mutually acceptable third party referee laboratory. The referee laboratory will conduct testing in accordance with the methods established for testing as set forth in the agreed Master Batch Record for the API as reflected in the applicable NDA, CMC or Drug Master File filing, if any. The costs of the referee testing will be charged to the Party in error. Hovione, if at fault, shall be solely responsible for the prompt replacement of each non-conforming API Lot, provided that a replacement lot which meets Allos specification requirements is available for prompt shipment. In the event conforming API is not then available, Allos may, at it election, require Hovione to refund the amounts paid or incurred by Allos on account of such rejected API Lot(s).  
 (e) Delivery Failure. Following a failure by Hovione to deliver the amounts of API specified in a Purchase Order, where such failure results in Allos incurring additional costs to obtain the undelivered amounts of API from an Equivalent Third Party to cover Allos’ requirements (“Delivery Failure”), then, in addition to any of Allos’s other rights and remedies, Hovione shall reimburse Allos in an amount equal to the increased cost incurred by Allos in purchasing such non-delivered API from other vendors. The quantity not delivered, and the amount that Allos would have paid Hovione if it had been delivered shall be included in determining the annual quantity of API purchased by Allos for purposes of pricing, requirements purchasing and other matters set forth in Attachment B.  
 6.2 Title to In-Process and Finished API. Title to all In-Process API shall at all times remain in Hovione, and title to all finished API shall remain in Hovione until its delivery to Allos’s designated Product manufacturer pursuant to Section 6.1(b), subject to Section 7.3. Hovione shall keep all In-Process API and finished API stored in accordance with the applicable Specifications, the Quality Agreement and Applicable Laws and Regulations. Hovione shall bear the risk of loss, contamination or damage to the API until it is delivered to Allos pursuant to Section 6.1(b).  
 7. SUPPLY ASSURANCE  
 7.1 Production Site & Commercial Capacity Assurance. All Manufacturing of API (including all testing, filing and packaging activities) shall occur at the Facility, except as  
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 approved by the Parties in writing. No work shall be subcontracted except with Allos’s written approval, which shall not be unreasonably withheld; provided, however, that in the event Allos approves of any subcontracted Services, Hovione shall be responsible for the work of the subcontractor as if it was performed by Hovione directly. Hovione shall maintain the ability to deliver at least thirty thousand kilograms (30,000 kg) per year during the Commercial Supply Phase, and shall provide assurances of secure primary and contingent supplies of Raw Materials.  
 7.2 Change Control. Without Allos’s prior written consent, Hovione shall make no change to: (a) the Specifications of the API (as the Specifications are defined in the applicable Regulatory Submission made by Allos for the Product); (b) any validated analytical methods used to test critical Raw Materials, In-Process API, and the API; (c) the Manufacturing of the API; (d) any Regulatory Submission made by Hovione for the API; or (e) Master Batch Record(s). In the event a change is requested and approved by Allos, Hovione will continue to Manufacture the Product in accordance to Allos’s original Regulatory Submission pending the completion of re-validation and receipt of approval from the FDA and other Regulatory Authorities. The implementation of changes shall be subject to Allos authorization in light of potential regulatory implications; however, Allos (and Allos licensees or other users of the API) recognize that change may be necessary to enable Hovione to remain efficient and cost-effective and thus shall be fully supportive of the implementation of such changes where justified. The procedures for revising Specifications are set forth below.  
 (a) Notice. A Party proposing a change to the Specifications shall provide written notice to the other Party. If the proposed change is required by a Regulatory Authority, then such notice shall include complete and full disclosure of the Regulatory Authority request and relevant correspondence, if any, and the other Party shall have the opportunity to participate in the dialogue with the Regulatory Authority regarding the proposed change. If the change is proposed by Allos or is required by a Regulatory Authority, then within thirty (30) days of such notice, Hovione shall notify Allos in writing whether and the extent to which Hovione’s Production Fees will increase or decrease if the proposed revision is implemented. Any proposed increase or decrease in Hovione’s Production Fees shall be supported by documentation, in a form and content satisfactory to, and subject to verification by, Allos. If Allos rejects the proposed price increase, the Parties agree to negotiate in good faith a mutually acceptable increase or decrease to such Production Fees. If Allos adopts the proposed Specifications revision, the Production Fees for API will be adjusted upon its implementation or as otherwise agreed.  
 (b) Feasibility Determination. If Allos, in consultation with Hovione, determines that Hovione cannot implement the revision in a cost-effective manner, it may withdraw the proposed Specification revision. If the revision is required by a Regulatory Authority, however, then upon reasonable written notice to Hovione, Allos may terminate this Agreement in whole or in part or may treat the circumstance as an “inadequate supply” event and take other actions as provided in Section 7.5.  
 (c) Implementation Plan. Before implementing the change, the Project Managers shall develop and agree on a written implementation plan, which includes the specific procedures to be used in preparing for and implementing such change to the Specifications.  
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 These shall include, but are not limited to the following: (i) required methods or process development and validation, including stability testing requirements and validation pass/fail criteria; (ii) Regulatory Submissions; (iii) Lots, Purchase Orders, or dates for change implementation; (iv) further change approval steps; and (v) technology transfer, if any.  
 (d) Regulatory Submissions. Allos will be responsible for any Regulatory Submission pertaining to the changes to the Specifications with the FDA and other Regulatory Authorities, except that Hovione will be responsible for updating its Drug Master Files, if any; provided that Hovione shall only make such amendment in consultation with Allos. The Parties shall advise each other of the FDA’s, or other Regulatory Authorities’, approval and the effective date of any such changes to such Specifications. Hovione’s responsibility shall be limited to the documents it prepares in connection with Regulatory Submissions.  
 7.3 Safety Stock. During the Commercial Supply Phase, Hovione shall, upon Allos’s request, maintain a [ \* ] safety stock inventory of all critical Raw Materials or, if requested by Allos through the issue of Purchase Orders, finished API based upon the rolling Forecasts (in both cases the safety stock shall be turned over as new Raw Materials are received or new API Lots are released to as to maximize the shelf life of the safety stock). Hovione may invoice Allos for unshipped, released and approved API Lots that Hovione is required to maintain in its inventory for more than [ \* ] beyond the date Hovione’s Quality Assurance group gives its written approval for the release of the applicable API Lot (the “Quality Control Release Date”). Allos shall assume title and risk of loss relating to all API inventoried as set forth in this Section 7.3 upon its release by Hovione into inventory. Hovione shall keep all API safety stock stored in accordance with the applicable Specifications, the Quality Agreement and Applicable Laws and Regulations. Hovione shall provide storage for quantities of critical Raw Materials and finished API that is designated as safety stock at no cost to Allos for as long as Hovione has warehousing storage space available for such purpose. If at any time during the Term, Hovione no longer has warehouse storage space available to store critical Raw Materials or API safety stock, Hovione shall so notify Allos, the Parties shall discuss reasonable alternatives.  
 7.4 Assured Supply. During the Term, Hovione shall assure that Allos has an uninterrupted API supply. In consideration of this obligation, Allos grants Hovione a “right of first supply” to supply up to [ \* ] of Allos’s requirements in excess of [ \* ]. Hovione may exercise this right in its entirety or in part, but must do so at a competitive price that is within [ \* ] of the written bids obtained by Allos from Equivalent Third Parties. In the event that Hovione does not exercise its right of first supply option, Hovione is obligated to find an alternative source of API, subject to the written approval of Allos. Hovione must also ensure that up-to-date technology is transferred to such approved alternative supplier(s) as efficiently as possible, and in accordance with a mutually acceptable technology transfer procedure, and in compliance with any necessary regulatory requirements. In the event that Hovione cannot find an alternative API supplier that is acceptable to Allos, Hovione, at its expense, shall invest in additional capacity to meet all Allos requirements and shall remain the primary supplier of [ \* ] of Allos’s API requirements for an additional [ \* ] period at prices to be negotiated in good faith.  
 7.5 Inadequate Supply. In the event that Hovione fails to supply at least [ \* ] (by weight) of the API specified in a Hovione-accepted Purchase Order for any reason, including  
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 Force Majeure, or conditions occur in which Hovione cannot give satisfactory assurances of supply as provided in Section 7.1 above (e.g., insolvency, adverse FDA actions, loss of supply), Allos shall (among other remedies such as termination of this Agreement or reduction in its purchase obligation, or both) have the right to require Hovione to initiate technology transfer for API Manufacturing to Allos or any manufacturer designated by Allos in accordance with a technology transfer procedure established by Allos. Hovione shall fully assist with such transfer, and no Technology Transfer Fees as provided under Section 12.6(a), or any royalties or other obligations shall be due in connection with such transfer or API Manufacturing by this contingent, secondary, or new supplier, as the case may be.   
 8. REPRESENTATION & WARRANTIES  
 8.1 Legal Authority. Each Party represents and warrants to the other Party that: (a) it has the legal power, authority and right to enter into this Agreement and to perform all of its respective obligations; (b) it is in good standing under the law of the jurisdiction it is incorporated in or in which it is engaged in business activities; (c) it has no knowledge of any legal or other restriction, limitation, adverse financial or other conditions affecting its ability to fully perform under this Agreement; (d) that it shall not commit any act or fail to take any action that, in any significant way, would be in conflict with its material obligations under this Agreement; and (e) that it shall comply in all material respects with Applicable Laws and Regulations, and in particular those related to API Manufacturing, and with all requirements under this Agreement.  
 8.2 Non-Infringement. Each Party represents and warrants to the other Party that to its knowledge the Manufacture of the API and performance of the Services, shall not infringe upon or result from the misappropriation of any pending or issued patent, trade secret, or other Intellectual Property Right, or from the breach of any obligation to any third party.  
 8.3 Ability & Capacity. Hovione represents and warrants that: (a) it has all permits, approvals, personnel, professional experience, equipment, facilities, funds, and capacity to fully perform it obligations under this Agreement; and (b) that it will not use in any manner, employ, engage or utilize the services of any person who has been or is threatened with debarment under the Generic Drug Enforcement Act or subject to any other comparable administrative, institutional or other sanction for misconduct.  
 8.4 API Warranty. Hovione represents and warrants that API, when delivered to Allos hereunder, (i) will be manufactured, tested, and packaged in accordance with Applicable Laws and Regulations; (ii) will meet the Specifications; and (iii) will not be adulterated or misbranded within the meaning of the FD&C Act or any similar laws or regulations of applicable Regulatory Authorities. Hovione’s sole obligation and Allos’ exclusive remedy for breach of the foregoing warranty will be limited to prompt replacement of the API at no additional cost to Allos, subject to Hovione’s recall obligations under Section 10.2 and indemnification obligation under Section 13.1.  
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 9. PROCESS QUALITY & REGULATORY MANAGEMENT  
 9.1 Compliance with Specifications and Other Requirements. Hovione shall Manufacture all API Lots, and carry out all other Services, in compliance with the applicable Specifications, Applicable Laws and Regulations, and the other requirements under this Agreement, in each case as in effect with respect to that API Lot or Service. For clarity, the parties agree that the API is an injectable grade Active Pharmaceutical Ingredient that shall be manufactured in accordance with 21 CFR Part 211. In February 2003, Allos audited the Facility located in Loures, Portugal, and as of that date found such Facility to be adequate to comply with, and to evidence compliance with, such requirements.  
 9.2 Quality Agreement. Within ninety (90) days following the Effective Date, the Parties shall mutually agreed upon an initial Quality Agreement, which may be amended by mutual agreement from time to time by the Parties. To the extent that the terms or conditions of the Quality Agreement, or any procedure, specification or requirement referenced by it, conflicts or is materially inconsistent with the terms of this Agreement (excluding the Quality Agreement), the terms of this Agreement shall prevail.  
 9.3 Raw Materials and Other Components. Hovione shall purchase, for its own account, all Raw Materials and other components and equipment required for API Manufacturing (“Production Materials”). Hovione shall procure all Production Materials, including acceptance testing of each lot or batch of the Production Materials in accordance with the Specifications, Applicable Laws and Regulations, and the Quality Agreement.  
 9.4 Regulatory Submissions. All Regulatory Submissions related to the API shall be made, owned, and controlled by Allos in its sole discretion. Hovione, in consultation with Allos, shall prepare at its expense the description of the API Manufacturing operations and related information (e.g., methods validation package, stability, representative data and batch records) as required for inclusion in the Allos Regulatory Submissions to the FDA and other Regulatory Authorities, which will contain all of the Manufacturing information. Hovione will assist Allos in the preparation of annual updates and other required or requested Regulatory Submissions, and in promptly responding to any questions from Regulatory Authorities. Hovione shall provide qualified technical representatives to attend meetings and/or teleconferences with the FDA and other Regulatory Authorities as needed.   
 9.5 Hovione Pre-Review of Regulatory Submission. Hovione accepts responsibility for the accuracy, integrity and completeness of all documentation prepared by Hovione that is filed with Regulatory Authorities (“Hovione Regulatory Documents”). Allos will provide Hovione with a certified true copy of the portions of each Allos Regulatory Submission that contains or directly addresses the information in Hovione Regulatory Documents (other than incidental abstracts or cross-references, or copies of previously submitted information) (“Hovione References”). The certified copy will be provided to Hovione for its review at least [ \* ] before the filing by Allos of the relevant Regulatory Submission; provided, that if [ \* ] pre-review by Hovione of the Hovione References is not reasonably feasible, then the Allos shall provide the Hovione References as soon as possible, Hovione shall immediately review and provide Allos with any objections and/or comments to the Hovione References no  
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 later than [ \* ] of its receipt and the Allos Project Manager and Hovione’s Regulatory Affairs Unit shall discuss and resolve any differences prior to submitting the Regulatory Submission.  
 9.6 OOS and Other Events and Rework. Hovione shall immediately inform Allos in writing of all OOS and out-of-trend events (provided such trend constitutes a deviation), failure investigations, process deviations, batch failures and similar matters (including any unexpected adverse final or interim results or data from validation, stability or other studies) and provide Allos with the applicable investigation report and corrective action plans prior to release of the in-process or finished Lots that are subject to the OOS event. All OOS and other investigations, and all corrective actions, shall be performed in accordance with a written procedure acceptable to the Parties. Except as specifically provided in the NDA or other Marketing Approval and in the manner specifically described in the approved Master Batch Record, Hovione shall not carry out any reworking, in-process or batch blending (including recrystallization or recycling of mother liquors or solvents) without prior written authorization from Allos.  
 9.7 Pre-Approval Inspections and Other Inspections. Hovione shall use its best efforts to successfully pass the FDA pre-approval inspection and all other regulatory inspections by the Regulatory Authorities, and Allos audits, without material objection. Should Hovione fail FDA or EU pre-approval inspection or review of Regulatory Submissions results in materially adverse actions (e.g., delay of Marketing Approval or requirement for corrective actions), in any event due to Hovione’s negligence, inadequate planning or implementation or failure to comply with Applicable Laws and Regulation or other requirements under this Agreement, it shall refund [ \* ] of amount paid for validation batches and amounts charged to Allos in preparing the Regulatory Submissions related to API Manufacturing and other Services of Hovione. Except as specifically provided otherwise in this Agreement, Hovione shall bear the expense of establishing and maintaining its compliance with Applicable Laws and Regulations and other requirements in their Agreement, including implementation of any corrective or other actions needed to bring about such compliance.  
 9.8 Records. Hovione shall prepare and maintain all Records relating to this Agreement. Records shall be prepared and maintained in compliance with Applicable Laws and Regulations and other requirements under this Agreement. All Records shall be complete, accurate, legible, valid, verifiable and contemporaneous with the events or activities described. All Records shall be available for Allos’s inspection upon advance notice during business hours, and Allos shall have the right to make copies thereof, during the Term and for up to four (4) years following the later of: (a) the expiration date of the last batch of API or Product; or (b) the expiration or termination of this Agreement. Notwithstanding the foregoing, Allos and its representative may at any time have access to the Records during business hours, and the right to make copies thereof, in connection with investigation of any complaint or injury related to the API or the Product or any dispute between the Parties. Hovione shall not destroy, alter (except for corrections as and in the manner permitted by Applicable Laws and Regulations), remove or dispose of any Records without Allos’s prior written consent and in which case Allos may take possession and custody of such Records.  
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 9.9 Retention Samples, Analytical Verification & Qualification. Hovione shall collect and retain samples as required by the Specifications and Applicable Laws and Regulations. In addition, as directed by Allos, Hovione also shall retain sufficient quantities of samples of API (including production samples taken during the Manufacturing process) to twice replicate the quality control and release testing applicable to the sample. These additional samples shall be maintained by Hovione for the longer of two (2) years from expiration date or four (4) years after the Manufacture of each API Lot and, upon request, furnished to Allos CIF its designated testing facility. There shall be no charge for preparing these additional samples, other than any costs incurred with special packing requirements or courier services.  
 9.10 Notice of Adverse Discovery. During the Term and for a period of four (4) years following the Manufacture of a API Lot, Hovione shall notify Allos immediately in writing in the event Hovione discovers or has reason to believe that there may be defects or deviations of any kind whatsoever in such API Lot, including any non-conformance with Specifications or any requirements applicable to its Manufacture.  
 9.11 Inspections of Hovione’s Facility.  
 (a) Observation & Audits. Upon reasonable notice, Hovione shall permit Allos’s authorized representatives (who shall be either full-time employees or appointed experts) to enter its Facility and other premises during any or all parts of Manufacturing activities. During the audits, the Allos representatives may observe and audit all Manufacturing, including all equipment, facilities, operations, procedures, materials and Records relating to the activities performed under this Agreement. Allos representatives also may audit Hovione’s laboratory where quality control testing of Raw Materials and API is conducted. During the Commercial Supply Phase, at no cost to Allos, Allos may conduct [ \* ] of each manufacturing location per year during the performance of Manufacturing operations upon [ \* ] prior notice, and additional audits (with no fewer than [ \* ] notice) upon the occurrences of any product problems, or changes in Manufacturing. Allos will provide a clear identification of the individuals it wishes to have present at Hovione facilities. For good cause, Hovione may reasonably refuse entry to individuals, other than the Allos Directors of Manufacturing, Operations or Quality Assurance, and to limit Allos to two (2) representatives present at any single part of the Manufacturing where more persons might reasonably disrupt such Manufacturing. Allos shall be responsible for any expenses it incurs in connection with the audits it is permitted to conduct pursuant to this Section 9.11(a). Upon Allos’s reasonable request and upon reasonable notice, Hovione shall permit Allos licensees or partners to conduct a quality assurance audit of the Facility for due diligence purposes. In connection with any such audit conducted by an Allos licensee or partner, Hovione shall be entitled to charge the fees set forth in Attachment B under 9. Fees for Due Diligence Audits.  
 (b) Regulatory Inspections. Hovione, at its own expense, shall allow representatives of the FDA and other Regulatory Authorities to inspect its Facility. Hovione shall notify Allos immediately of an inspection by the FDA or other Regulatory Authorities that may pertain to API Manufacturing or other Services, and Allos may have its representatives present at such inspections. If representatives of Allos are not present at an inspection or audit, Hovione shall notify Allos in writing of the results of such inspection, immediately after such  
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 inspection or audit has occurred (but in no event later than two (2) days after such inspection or audit has occurred). Hovione shall provide Allos with copies of any documents or other communications provided to or received from the Regulatory Authorities in connection with the inspection or resulting actions, including FDA Form 483 reports, EIRs, Warning Letters, or equivalents. In addition, Hovione shall furnish Allos promptly any Warning Letter or FDA-483 from the FDA (or similar documents from other Regulatory Authorities) that pertains to products and activities unrelated to this Agreement; however, Hovione may redact the customer identity and other confidential information disclosed in such correspondence.  
 (c) Other Conditions of Audits & Inspections. There shall be no charge for any inspections or audits as described in Section 9.11(a) above, and Hovione shall cooperate with both, including providing of reasonable space for review and copying of Records and assistance of key personnel. Allos representatives, when on Hovione’s premises, shall at all times comply with Hovione’s internal policies. It is agreed that the audits and observation by Allos representatives or access to the computer system as set forth in Section 2.3(c) shall not in any way serve as a limitation on any of Hovione’s obligations or liabilities under this Agreement; although Allos has a duty of care to annually audit the Facility and will provide Hovione with the results of any quality audit performed by Allos. All other audits, inspections or technical visits by Allos, which are not necessary for the normal course of Hovione’s production of the API shall be charged at Hovione’s standard unit rates in Attachment B under 9. Fees for Due Diligence Audits.  
 9.12 Hovione’s Right to Audit. Upon thirty (30) days written notice, Hovione shall have the right to audit, or to have audited by a mutually acceptable and reputable auditor, the good manufacturing practices and materials management related documentation of Allos in order to verify the quantities of API purchased from third party suppliers. Any such audit will be performed during Allos’ normal business hours. The auditor shall be instructed to provide to Hovione a report on the findings during the audited period, but shall not disclose to Hovione any Confidential Information of Allos not necessary therefore. The costs of the audit will be paid by Hovione and may be conducted no more than once in any period of twelve (12) consecutive months.  
 10. RECALLS & RECALL COSTS  
 10.1 Recall Procedures. If the API or Product are recalled (including product in inventory that must be destroyed or reprocessed), for any reason whether voluntarily or governmentally imposed, Allos shall be responsible for effecting such recall. Any voluntary decision to recall the Product shall be made by Allos in its sole discretion, but in consultation with Hovione. Notwithstanding the foregoing, Hovione shall cooperate with Allos in carrying out any recall, including identifying the locations to which API was shipped, providing access to applicable Records and retention samples, conducting testing, and the like and, if applicable, in identifying and correcting any deficiency in API Manufacturing. All recalls shall be carried out in the procedure set forth in the Quality Agreement, or as later agreed by the Parties. Hovione will provide assistance in responding to API and Product complaints and similar events, including Records review and retained sample testing.  
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 10.2 Responsibility for Recall Costs. In the event that it is ruled by arbitration or in a court of Law, or as otherwise agreed by the Parties, that a recall resulted from, arose out of, or is connected with any inaccuracy in, breach of, or non-fulfillment of, any representation, warranty, covenant or other obligation of Hovione, or any negligent, reckless or willful misconduct or omissions of Hovione, its directors, officers, employees, vendors or agents, Hovione shall reimburse Allos for: (a) any costs expended by Allos to effect the recall, including, but not limited to, all notification letters, all direct shipping expenses, and the costs of disposal and/or destruction of the recalled items; (b) any Production Fees for API involved in such recall and for any other API that cannot be shipped due to the recall; (c) shipping fees paid for the Product and/or API involved in such recall. Hovione’s obligation to reimburse Allos shall be subject to the arbitration and other dispute procedures set forth in Article 15. Hovione’s total aggregate liability for recalls costs associated with a recall shall not exceed a value equal to [ \* ].  
 10.3 Traceability. If during any calendar year Allos incorporates into Product API obtained from another third party manufacturer, then Allos shall provide Hovione, within thirty (30) days of the end of such calendar year, with written documents tracing Hovione batch numbers to the Product batch numbers that have been released to the market.  
 11. TERM AND TERMINATION  
 11.1 Term. Unless sooner terminated as provided for herein, this Agreement shall remain in full force and effect for an initial Term commencing on the Effective Date and ending upon the seventh (7th) anniversary of the date Allos obtains a Marketing Approval from the FDA for a Product. This Agreement shall be automatically extended for successive two (2) year terms unless a Party provides written notice of non-extension at least twenty-four (24) months before the date when the new extension period is to begin.  
 11.2 Termination.   
 (a) Mutual Consent. The Parties may at any time terminate this Agreement, in part or in its entirety, by mutual written agreement.  
 (b) Material Breaches.  
 (i) Either Party shall have the right to terminate this Agreement on ninety (90) days written notice in the event the other commits a material breach of its obligations hereunder and fails to remedy it within ninety (90) days after notice of such breach. After the end of the applicable cure period, if the breach has not been cured, the Party having the right to termination may terminate in whole or in part immediately upon notifying the breaching Party in writing. Any termination of this Agreement shall not release the breaching Party from its obligations or otherwise affect or limit the Parties’ rights and remedies.  
 (ii) This Agreement may be terminated immediately on account of a material breach upon written notice if such breach cannot be reasonably remedied within a ninety (90) day period following notice, or if continuing would subject the non-breaching Party to a substantial risk of material Loss, civil or criminal liability (including the imposition of a Warning  
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 Letter, Import Detention or other official sanction by a Regulatory Authority on the manufacture or import of the API or operations of a Party).  
 (c) Insolvency. Each Party shall have the right to terminate this Agreement effective upon written notice to the other Party in the event that: (i) the other Party becomes insolvent; (ii) a receiver is appointed for the other Party; or (iii) bankruptcy proceedings are instituted by or against the other Party or on the other Party’s behalf.  
 (d) Product Failure. This Agreement may be terminated immediately by Allos on written notice if no Product will be marketed or further developed, or if in Allos’s opinion the supply or use of the API might result in liability for infringement of patents or other Intellectual Property Right. If terminated by Allos for such causes, then unless agreed otherwise, all Purchase Orders accepted by Hovione by the date the termination notice is provided and not subject to cancellation shall be fulfilled; provided that Allos may “buy-out” the purchase of those Lots by paying Hovione an amount determined by the manner provided under Section 11.3(a)(i) below, plus the amount of gross profit Hovione would have realized on the those Lots of API if they had been purchased by Allos.  
 (e) Failure to Meet Minimum. Hovione may terminate this Agreement on three (3) months written notice if Allos does not buy at least the applicable amount of API set forth in Attachment B under “4. Annual API Purchase Base” in the applicable year, unless such failure is due to Hovione’s fault. Notwithstanding the foregoing, Allos shall have the right to obtain three extensions to the dates set forth in Attachment B; provided that Allos shall pay Hovione the amount set forth in Attachment B under “5. Extension Fees” for each extension on or before December 31st of the year in which the minimum purchase obligation was not met. Each extension moves the Annual API Purchase Base by one year. In each case termination shall not occur if Allos has cured such fault within three (3) months of Hovione’s notice.  
 11.3 Effect of Termination.  
 (a) Purchase of Inventories. In the event of the Agreement’s termination, Hovione shall ship in the manner provided for under the Quality Agreement, all inventory of API purchased by Allos and held by Hovione as safety stock pursuant to Section 7.3. Allos may at its election purchase all remaining API in Hovione’s inventory that it would not otherwise be obligated to purchase under this Agreement at the lowest price indicated in Attachment B. In addition, at Allos’s election, it may either: (i) purchase, at Hovione’s documented purchase cost, its Raw Materials or In-Process API (valued on a pro-rata basis to manufacturing cycle-time) reasonably purchased or produced for API Manufacturing that cannot be returned for credit or used for producing products for its other customers, plus shipping costs; or (ii) pay for such Raw Materials or In-Process API to be Manufactured into API in accordance with the Agreement. In no event shall Allos be charged for Raw Materials or In-Process API with an amount that exceeds the value of the corresponding amounts of API specified by Allos’ relevant Purchase Orders in effect at the termination date.  
 (b) Return of Materials. Hovione shall immediately return to Allos copies of all documentation and information and materials relating to API Manufacturing (including  
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 copies of development reports and Master Batch Records), the Product, and the Specifications, and Hovione shall make no further use of such documentation, information and materials unless required by a Regulatory Authority. Any original documents provided by Allos to Hovione during the Term shall be returned to Allos, along with any copies thereof, provided that Hovione may keep one archival copy if required by a Regulatory Authority. Documents and materials shall be packaged and shipped in the manner reasonably requested by Allos as needed to preserve their integrity and acceptability to Regulatory Authorities.   
 (c) Survival. Termination of this Agreement shall not operate to release any Party from any obligation or liability incurred under the terms of this Agreement before or upon termination hereof, nor shall it relieve the Parties of their obligations with respect to API supplied by Hovione hereunder. In addition Sections 9.8, 9.9, 9.10, 10.2 (with respect to claims relating to activities occurring during the Term) and 11.3 and Articles 1, 12 (excluding Section 12.6), 13 (with respect to claims relating to activities occurring during the Term), 14 and 16 shall survive the expiration or termination of this Agreement on account of any cause.  
 12. CONFIDENTIALITY & INTELLECTUAL PROPERTY  
 12.1 Non-Disclosure Agreement. The Parties each agree that the obligations of confidentiality, non-use and non-disclosure set forth in the Mutual Non-disclosure Agreement executed by them concurrently with this Agreement (the “Nondisclosure Agreement”) are incorporated into this Agreement for purposes of determining the Parties rights and obligations with respect to Confidential Information disclosed by each Party under this Agreement.  
 12.2 Disclosure of Agreement. Neither Allos nor Hovione shall release any information to any other person regarding the terms of this Agreement without the prior written consent of the other, which consent shall not be withheld unreasonably. The foregoing consent requirement includes, but is not limited to, press releases, educational and scientific conferences, promotional materials and discussions with the media. If a Party determines that it is required by law to release information regarding this Agreement to any another person, it shall notify the other Party of this fact before releasing the information. The notice to the other Party shall include the text of the information proposed for release. The other Party shall have the right to confer with the notifying Party regarding the necessity for the disclosure and the text of the information proposed for release. Hovione acknowledges that as a public company Allos is required to disclose its material business relationships and principal terms, subject to certain rights to redact Confidential Information. Allos shall confer with Hovione before making such disclosures; however, Allos shall have sole discretion in the contents of the disclosure. Hovione and Allos shall each have the right to disclose the terms of this Agreement to persons engaged or proposing engagement in fiduciary relationships, such as banks extending credit with the Party and bona fide investors and legal counsel, if such persons are subject to reasonable confidentiality and non-use obligations.   
 12.3 No Implied Licenses. Only the licenses granted pursuant to the express terms of this Agreement shall be of any legal force and effect. No license or any other proprietary rights shall be created by implication or estoppel, in the patents, know-how, trade-secrets, copyrights,  
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 trade and other marks, or other Intellectual Property Rights, owned or licensed to the respective Parties  
 12.4 Ownership of Improvement to the API or API Manufacturing Process. Hovione shall disclose to Allos promptly and in writing all API Improvements, and hereby assigns all API Improvements to Allos and shall execute and provide, and to cause its employees, officers and agents to execute and provide all documents, affidavits, evidence and testimony, and take such other actions as are reasonably requested by Allos to perfect its ownership of the API Improvements and to seek, defend and enforce patents and other Intellectual Property Rights related to the API Improvements. Allos shall have sole discretion over the management of Intellectual Property Rights issues, but shall reimburse Hovione for the reasonable costs incurred by its employees for their assistance in connection with Allos’s efforts to seek, defend and enforce patents and other Intellectual Property Rights related to the API Improvements. Allos makes no claim to any of Hovione’s proprietary technology existing before the Effective Date.  
 12.5 Hovione License. Allos shall grant Hovione a non-exclusive, non-transferable license under Allos’s Intellectual Property Rights to use (but not sublicense or disclose to or authorize others to use on Hovione’s behalf) generically applicable process improvements and analytical methods within the API Improvements (“Generic Methods”). Such license shall fully exclude any right to use, and Hovione hereby covenants that it shall not use, the Generic Methods to manufacture or test the API or any API Related Compound for any third party until the end of later of the following three periods (“Exclusivity Period”):  
 (a) The expiration of all United States and European patents covering the API Related Compounds or Products containing any API Related Compounds (including any term extensions and non-patent market exclusivity periods);  
 (b) [ \* ] from the approval by the FDA of the NDA for the Product; and  
 (c) [ \* ] following the last full calendar year during which Hovione supplied Allos with at least [ \* ] of any of its API requirements.  
 In order to protect the confidentiality and other Intellectual Property Rights of Allos, except as directed by Allos, neither Hovione nor any of its Affiliates shall manufacture the API or any API Related Compound during the Term and the Exclusivity Period.  
 12.6 Hovione Compensation. In order to provide Hovione with an incentive to explore API Improvements; and in order to assure that Hovione acts in the best interests of Allos and its other manufacturers, Hovione shall be entitled to the good consideration set forth below for as long as it is not in breach of the Agreement:  
 (a) Technology Transfer Fee. For every new API manufacturer that practices any API Improvement, Allos shall pay Hovione a Technology Transfer Fee for the successful, complete and prompt transfer of the API Manufacturing process and API Improvements to that API manufacturer, in the amount set forth in Attachment B under “6. Technology Transfer Fee–  
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 Transfer Fee,” fifty percent (50%) of which shall be paid when Allos directs Hovione to initiate technology transfer, and the balance upon completion of technology transfer as demonstrated by successful manufacture of three (3) API “Process Validation Batches” meeting all Specifications.  
 (b) Production Fee. For every new API manufacturer that practices any API Improvement, Allos shall pay Hovione a Technology Transfer Fee for its successful, complete and prompt transfer of the API Manufacturing process and API Improvements, in the amount set forth in Attachment B under “6. Technology Transfer Fee–Production Fee” on [ \* ] manufactured by each such new API manufacturer.  
 (c) Divided Manufacturing. For purposes of this Section 12.6, “Manufacturing” by a new API producer shall only include the API synthesis and purification and not the performance of incidental services such as testing and processing, and in the case that synthesis and or purification are divided between manufacturers, then multiple Technology Transfer Fees shall not be due, but they shall be treated as a single new manufacturer.  
 12.7 Trade Names and Trademarks. Allos hereby acknowledges that except as otherwise set forth in this Agreement, it does not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark or trade name of Hovione, nor in any of Hovione’s trademark or trade names appearing on the label or packaging materials of API. Hovione hereby acknowledges that it does not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark or trade name of Allos, nor in any of Allos’s trademarks or trade names appearing on the label or packaging materials of API or Product. Neither Party shall use the trademarks or trade names owned by the other under which API is manufactured on any other goods or products, except as provided hereunder. Each Party further agrees not to contest, deny or dispute the validity of any trademarks or trade names owned by the other Party appearing on the labels or packaging materials of API or the title of such other Party, and not to assist others in doing so, and not to take any action of any kind inconsistent with the holding of all such rights by such other Party.  
 13. INDEMNIFICATION  
 13.1 Hovione’s Obligation to Indemnify. Hovione shall indemnify, defend and hold Allos and its directors, officers, employees and agents (“Allos Indemnitees”) harmless against any and all Losses incurred by any of them as a result of any third party claim, demand, suit, action or proceeding resulting from, arising out of, or connected with: (a) liability claims arising directly and exclusively from the manufacture of the API to the extent caused by Hovione’s breach of any obligation under the Agreement; (b) infringement claims arising from a breach of any of Hovione’s warranties or a breach of its other obligations; and (c) the clean-up, remediation and restoration arising out of or related to Hovione’s storage, handling, transportation, incineration or disposal of any Waste that may be generated by API Manufacturing. Hovione’s obligations set forth in this Section 13.1 shall not include Losses on such claims to the extent that they are caused by the (y) breach by any Allos Indemnitee of its obligations under the Agreement, or (z) any negligent or otherwise wrongful act or omission of any Allos Indemnitee or Affiliate.   
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 13.2 Allos’s Obligation to Indemnify. Allos shall indemnify, defend and hold harmless Hovione and its directors, officers, employees and agents (“Hovione Indemnitees”) against any and all Losses incurred by any of them as a result of any third party claim, demand, suit, action or proceeding resulting from, arising out of, or connected with: (a) product liability claims arising from the testing, sale or use of the API or the Product, including the effects of the intrinsic properties of the API and (b) infringement claims arising from a breach of any of Allos’s warranties or a breach of its other obligations. Allos obligations set forth in this Section 13.2 shall not include Losses on such claims to the extent that they arise from the (y) breach by any Hovione Indemnitee of its obligations under the Agreement, or (z) any negligent or otherwise wrongful act or omission by any Hovione Indemnitee or Affiliate.  
 13.3 Obligations of the Party Seeking to be Indemnified. Each Party’s indemnification obligations shall be conditioned on compliance with the procedure outlined below by that person and other persons associated with the same Party. The Party providing the indemnification is the “Indemnifying Party,” and the Party or other person seeking or receiving such indemnification is the “Indemnified Party.”  
 (a) Notice. Upon receipt or occurrence of any written claim, demand or other event that the Indemnified Party believes might give rise to the indemnification obligations, the Indemnified Party shall, as soon as reasonably practicable after forming such belief, give written notice to the Indemnifying Party; provided, that the failure to give timely notice to the Indemnifying Party shall not relieve the Indemnifying Party from any liability to the Indemnified Party unless the Indemnifying Party demonstrates that the investigation, defense, settlement or mitigation of such claim is prejudiced by such failure.  
 (b) Control. The Indemnifying Party shall have the right, by prompt notice to the Indemnified Party, to assume, at its cost, the investigation, defense and settlement of such claim. If the Indemnifying Party does not so assume the defense of such claim or, having done so, does not diligently pursue such defense, the Indemnified Party may, but will not be obligated to, assume such defense, with counsel of its choice, but at the cost of the Indemnifying Party. If the Indemnifying Party assumes such defense, it shall have absolute control of the conduct of the litigation, including settlement and investigation, unless the Indemnified Party has relieved the Indemnifying Party from indemnification liability with respect to the particular claim; the Indemnified Party may, nevertheless, participate therein through counsel of its choice and at its cost.  
 (c) Assistance. The Party not assuming the defense of any claim shall cooperate and render all reasonable assistance to the Party assuming the defense, and all out-of-pocket costs of such assistance shall paid by the Indemnifying Party. No such claim shall be settled other than by the Party defending such claim, and then only with the prior written consent of the other Party, which shall not be unreasonably withheld.  
 13.4 Limitation on Liability. Hovione’s total aggregate liability (whether for breach of contract, negligence, breach of statutory duty and/or other tort, or otherwise) in connection with or as a result of the work carried out or materials provided under this Agreement shall not  
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 exceed a value equal to [ \* ]. Notwithstanding the foregoing, the limitation on liability shall not apply in respect of Hovione’s indemnification obligation under Section 13.1.  
 14. INSURANCE  
 14.1 Coverage. During the Term of the Agreement and for [ \* ] years thereafter, if issued on a claims made basis, Hovione shall maintain Commercial General Liability insurance providing not less than [ \* ] per occurrence, excluding product liability insurance on a worldwide basis and contractual liability coverage. All coverage shall be underwritten by reputable underwriters. Promptly after the Effective Date, Hovione shall add Allos as an additional insured under Hovione’s policy. Hovione shall provide Allos with a certificate of insurance upon request. Hovione shall provide Allos with at least thirty (30) days prior written notice of any material change, cancellation or expiration of the above-required insurance.  
 14.2 Review. On an annual basis, Hovione shall provide Allos with a current certificate of coverage demonstrating that the coverage specified in Section 14.1 is in force and shall immediately notify Allos of any actual or threatened reduction, termination, non-renewal or materially adverse change in terms of coverage. Hovione shall provide Allos with thirty (30) days’ written notice of any cancellation or material change in the coverage specified in Section 14.1. Hovione represents and warrants that it has obtained and shall maintain all coverage, including its preparation of any applications and endorsements in compliance with its obligations under the terms of coverage of such polices and shall otherwise comply with all requirements under such policies. Failure to maintain the insurance coverage as set forth in this Article 14 shall be deemed a material breach of the Agreement.   
 15. DISPUTE RESOLUTION  
 15.1 Internal Mediation of Dispute. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or otherwise between the Parties or their Affiliates, the Parties shall try to settle the differences amicably through the Project Managers, and if necessary the Steering Committee. If the Steering Committee is unable to resolve the matter, the issue shall be addressed by the Chief Executive Officers of each Party or their respective designees. The designees shall be individuals who possess the authority to settle the dispute but who do not have direct responsibility for administration of this Agreement. ANY DISPUTES NOT RESOLVED BY THE DESIGNEES SHALL BE FINALLY AND EXCLUSIVELY RESOLVED BY CONFIDENTIAL BINDING ARBITRATION AS PROVIDED IN SECTION 15.2.  
 15.2 Arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Party giving such notice shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. The arbitration shall be held in New York, New York according to the rules of the American Arbitration Association (“AAA”). A single arbitrator mutually chosen by the Parties shall conduct the arbitration. If the Parties cannot agree upon a single arbitrator within fifteen (15) days after the institution of the arbitration proceeding, then the arbitration shall be conducted by a panel of three (3) arbitrators appointed in accordance with AAA rules; provided, however, that each Party shall, within thirty (30) days after the institution of the arbitration  
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 proceedings, appoint one arbitrator with the third arbitrator being chosen by the other two arbitrators. If only one Party appoints an arbitrator, then such arbitrator shall be entitled to act as the sole arbitrator to resolve the controversy. All arbitrators eligible to conduct the arbitration must agree to render their opinion(s) within thirty (30) days of the final arbitration hearing. The arbitrator(s) shall have the authority to grant injunctive relief and specific performance and to allocate between the Parties the costs of arbitration in such equitable manner as he determines; provided, however, that each Party shall bear its own costs and attorneys’ and witness’ fees. The arbitrator(s) shall, upon the request of either Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Decisions of the arbitrator(s) shall be final and binding on all of the Parties. Judgment on the award so rendered may be entered in any court having jurisdiction thereof.  
 15.3 Injunctions. Notwithstanding anything to the contrary, a Party also shall have the right to obtain provisional remedies, including preliminary and temporary injunctive relief or/and specific performance, from a court having jurisdiction, as well as such equitable remedies as needed to enforce an arbitration decision. A Party seeking and/or obtaining injunctions shall not be required to prove the amount, irreparability, immediacy or likelihood of damages, nor shall it be required to post any bond (the posting of which is irrevocably waived).  
 15.4 Choice of Law & Venue. This Agreement shall be construed and the rights of the Parties shall be determined in accordance with the laws of the State of New York, USA, without regard to its conflict of law provisions; provided, however, that patents and other intellectual property rights shall be construed and determined in accordance with the laws of the country under which such rights are granted. In no event shall the provisions of this Agreement be governed by the United Nations Convention on Contracts for the International Sale of Goods. THE PARTIES ALSO HEREBY AGREE AND FOREVER WAIVE ANY OBJECTION TO THE PERSONAL JURISDICTION AND VENUE OF THE ARBITRAL AND JUDICIAL BODIES PROVIDED IN THIS ARTICLE 15, AND TO SERVICE OF PROCESS BY NOTICE AS PROVIDED BY SECTION 16.5 BELOW.  
 16. GENERAL PROVISIONS  
 16.1 Integration & Severability. This Agreement, together with its Attachments, the Quality Agreement and the Nondisclosure Agreement, is the full and final negotiated contract between the Parties and all prior and contemporaneous written and oral understandings, contracts, purchase orders, and agreements (including the Term Sheet) are merged into, and shall be deemed as if performed under this Agreement. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute a single agreement. In the event that any provision of this Agreement is judicially determined to be unenforceable, in part or in whole, the remaining provisions or portions of this Agreement shall be valid and binding to the fullest extent possible, and the Parties shall endeavor to negotiate modified or additional terms, as feasible, in a timely manner so as to fully effectuate the original intent of the Parties to the extent possible, and in the event they are unable to reach an agreement then the arbitrator or court may establish such modified provision.  
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 16.2 Waivers & Amendment. Any failure by a Party to enforce any right which it may have hereunder in any instance shall not be deemed to waive any right which it or the other Party may have with respect to any provision of this Agreement, including the provision which such Party has failed to enforce. A waiver of a breach shall not act as a waiver or release of any other breach, regardless if prior, contemporaneous or subsequent, known or unknown or of the same or different nature, cause, effect or provision of this Agreement. No provision of this Agreement shall be waived, amended, supplemented or otherwise modified except in a in writing signed by a duly authorized officer of each Party.  
 16.3 Legal Relationship. The Parties acknowledge, agree, and declare that the relationship hereby established between them is solely that of provider and recipient of manufacturing services and that each Party hereto is an independent contractor with respect to the other, and not as a joint venturer, partner, distributor or any other type of relationship, and shall not be construed as an authorization of either Party to act as an agent of the other. Nothing in this Agreement shall be construed as to create an exclusive relationship between the Parties hereto. Each may enter into similar or dissimilar arrangements with others and engage in activities for its own account, subject to their compliance with confidentiality and other provisions of this Agreement. The Parties agree that they have and shall at all times perform this Agreement in good faith.  
 16.4 Force Majeure.   
 (a) Occurrences. Neither Party shall be responsible to the other Party for any failure, delay or interruption in the performance of any of its obligations under this Agreement if such failure, delay or interruption is caused, directly or indirectly, by accident, casualty, fire, flood, weather, typhoon, act of God, earthquake, epidemic, riot, terrorist act, insurrection, war, failure or delay of normal sources of supply of materials, failure or delay of public utilities or carriers, act, exercise, assertion or requirement of a governmental authority, or other cause beyond the reasonable control of the Party affected (“Force Majeure”) if the Party affected has used its best efforts to avoid such occurrence and such occurrence is not due to any fault or neglect of such Party. If either Party believes that the performance of any of its obligations under this Agreement will be delayed or interrupted as a result of any of the reasons stated in this Section 16.4(a) and provided it is able to do so, then it shall promptly notify the other Party of the delay or interruption and the cause, and also provide the other Party with a good faith estimate of when performance of its obligations will resume.  
 (b) Production Assurance. When the Party affected is able to recommence the performance of obligations delayed or interrupted as a result of any of the reasons stated in Section 16.4(a), it shall notify the other Party and, except as otherwise provided in this Agreement, it shall promptly resume performing its obligations. Hovione shall not be entitled to invoke the provisions of this Section 16.4 as an excuse for default or delay in performance based upon its need to do work for others or on its own behalf resulting in constraints upon the availability of its manufacturing and packaging capacity, unless such constraints resulted from an event of Force Majeure as defined herein. In such an event, Hovione shall equitably allocate its resources among its various customers, including Allos. Additionally, in the event Hovione cannot provide Allos with API for more than [ \* ], Hovione will notify Allos and Allos may, at  
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 its option, terminate or suspend this Agreement in whole or in part upon written notice to Hovione. Should this Agreement be suspended or terminated pursuant to this Section 16.4(b), Hovione agrees to give Allos, or a third party designated by Allos, such technical assistance as Allos or its designee may reasonably require to enable Allos or its designee to Manufacture API, including, without limitation, the transfer of know-how, technical data, documentation and the provision of material support and training at the manufacturing site or sites designated by Allos. No Technology Transfer Fees as set forth under Section 12.6 above shall be due in connection with the technology transfer to and API manufacture by such third parties, and Allos’s purchase obligations shall be suspended.  
 16.5 Notice. Any notice required or permitted to be given under this Agreement shall be in writing and shall be given in person, delivered by recognized overnight delivery service, sent by mail (certified or registered or air mail for addresses outside of the continental United States), or by telefax (or other similar means of electronic communication), the receipt of which is confirmed by confirming telefax, and addressed as indicated in Attachment A (Notices, Project Managers and Other Key Personnel), or such other person and/or address as may have been furnished in writing to the notifying Party of the change to such Attachment. Except as otherwise provided herein, any notice shall be deemed delivered upon the earlier of: (a) actual receipt; (b) three (3) business days after delivery to such recognized overnight delivery service; (c) five (5) business days after deposit in the mail (ten (10) days for international mail); or (d) the date of receipt of the confirming telefax.  
 16.6 Assignment. This Agreement shall not be assigned by either Party, except to an Affiliate, without the prior written consent of the other Party, and any such assignment without such prior written consent shall be void. If this Agreement is assigned to an Affiliate of a Party, the assigning Party shall remain responsible for all of its obligations specified in this Agreement. Notwithstanding the preceding, in the event of: (a) a sale or transfer of all or substantially all of a Party’s assets related to API Manufacturing or developing and/or marketing Products; or (b) the merger or consolidation of a Party with another company, this Agreement shall be assignable to the transferee or successor company of the assigning Party, without the need of the prior written consent of the other Party. This Agreement shall be binding upon all permitted successors in interest, assigns, trustees and other legal representatives of the Parties.  
 16.7 Further Assurances Regarding Corporate Partnerships. During the Term, Allos shall not enter into any agreement with a Corporate Partner that would conflict with Allos’ obligations under this Agreement or result in a material adverse change in Hovione’s economic rights under this Agreement. Allos will provide a copy of this Agreement to any Corporate Partner to whom Allos may supply API manufactured by Hovione pursuant to this Agreement. At Hovione’s request, Allos shall obtain from such Corporate Partner a letter signed by an officer of the Corporate Partner acknowledging receipt of a copy of this Agreement. Allos further assures that Hovione’s interests will be taken into consideration and defended when Allos negotiates the Corporate Partnership.  
 16.8 Interpretation. All references to Articles shall refer to the Articles contained in this Agreement. All references to Attachments shall, except as otherwise explicitly provided, refer to the Attachments appended to this Agreement, all of which are incorporated herein by  
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 reference. The captions of the Articles of this Agreement are for general information and reference only and shall not affect the interpretation of this Agreement. Where applicable in this Agreement, the singular includes the plural and vice versa. English shall be the official language of this Agreement and all communications between the Parties hereto shall be conducted in that language. Both Parties acknowledge that they were represented by competent legal counsel and advisors, and fully negotiated the contract and each of its terms, and that ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.  
 «Signatures on Next Page»  
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 IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date.  
 Hovione Inter Limited  
Allos Therapeutics, Inc.  
 By:  
/s/Xxx Xxxxxx  
 By:  
/s/Xxxxxxx X. Xxxx  
 Name:  
Xxx Xxxxxx  
 Name:  
Xxxxxxx X. Xxxx  
 Title:  
Chief Executive  
 Title:  
President and CEO  
 Date:  
 Date:  
June 16, 2005  
 CONFIDENTIAL  
 MANUFACTURING AGREEMENT  
SIGNATURE PAGE  
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 ATTACHMENT A  
 Notices, Project Managers and Other Key Personnel  
 To Allos.:  
 To Hovione  
 Vice President of Manufacturing  
Attn: Xxxxxxx Xxxxxxx  
Allos Therapeutics, Inc.  
00000 Xxxxxx Xxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxxx, XX 00000  
(phone) 000-000-0000  
(fax) 000-000-0000  
(email) xxxxxxxx@xxxxx.xxx  
 Attn: Xxxxx Xxxxxx  
Hovione Inter Limited  
X/X Xxxxxxx XxxxxXxxxxxx XX  
Xxxx Xxxxx 0000-000 Xxxxxx, Xxxxxxxx  
(phone) 000-000-00-000-0000  
(fax) 000-000-00-000-0000  
(email) pvillax@hovione..com  
 And copied to:  
 And copied to:  
 Attn: General Counsel  
Allos Therapeutics, Inc.  
00000 Xxxxxx Xxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxxx, XX 00000  
(phone) 000-000-0000  
(fax) 000-000-0000  
 Managing Director  
Xxxxx Xxx  
11 Xxxxx House  
000 Xxxxxxxxxx Xxxx  
Xxxx Xxxx  
(phone) x000 0000000  
(fax) x000 0000000  
(email) xxxx@xxxxxxx.xxx  
 Project Managers:  
 For Allos:  
 For Hovione:  
 Vice President of Manufacturing  
Attn: Xxxxxxx Xxxxxxx  
Allos Therapeutics, Inc.  
00000 Xxxxxx Xxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxxx, XX 00000  
(phone) 000-000-0000  
(fax) 000-000-0000   
(email) xxxxxxxx@xxxxx.xxx  
 Industrial Director   
Attention: Xxxx Xxxxx  
Hovione PharmaScience Limited  
Xxxxxxx Xxxxxxx Xxxxxxxx  
Ilha da Taipa  
Macau  
(phone) x000 00 00 00  
(fax) x000 00 00 00  
(email) xxxxxx@xxxxxxx.xxx  
 For Hovione Inter Limited:  
 For Hovione FarmaCiencia S.A.:  
 Xxxx Xxxxxxx  
President, US Operations  
Hovione LLC, as agent  
00 Xxxx Xxxxx  
Xxxx Xxxxxxx, XX 00000  
(phone) 000-000-0000  
(fax) 000-000-0000  
(e-mail) xxxxxxxx@xxxxxxx.xxx  
 Xxxxxxx Xxxxx  
Production Engineer - B15  
Sete Xxxxx  
0000-000 Loures  
(phone) x000 00 0000000  
(fax)x000 00 0000000  
(email) xxxxxx@xxxxxxx.xxx  
 CONFIDENTIAL  
 Attachment A-1  
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 Other Key Personnel:  
 For Hovione:  
Hovione FarmaCiencia X.X.  
Xxxxx Xxxx  
Head of Regulatory Affairs Department  
Sete Xxxxx  
0000-000 Loures  
(phone) x000 00 0000000  
(fax)x000 00 0000000  
(email) xxxxx@xxxxxxx.xxx  
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 Attachment A-2  
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 ATTACHMENT B  
 Pricing and Other Terms for Commercial Supply  
 1. API Purchase/Supply Minimums  
 Allos Annual  
 Purchase/Supply  
 Volume Requirements  
 Obligations  
 [ \* ] Metric Tons  
 [ \* ] of Requirements  
 [ \* ] Metric Tons  
 [ \* ] of Requirements  
 [ \* ] Metric Tons  
 [ \* ] of Requirements  
 [ \* ] Metric Tons  
 [ \* ] of Requirements\*  
 (\*provided that Hovione exercises its right of first refusal set forth in Section 7.4 of the Agreement)  
 Note: Requirements/supply obligations are subject to exceptions as provided in the Agreement  
 2. API Pricing  
 Annual Purchase  
 API Price  
 [ \* ]  
 $  
[ \* ]  
 [ \* ]  
 $  
[ \* ]  
 [ \* ]  
 $  
[ \* ]  
 All prices are CIF Allos’s designated Product manufacturer location.  
 Note: Although CIF is used, API shall be shipped in the mode of transport provided in the delivery instructions, which will be air for international and truck for inland shipment.  
 3. Minimum API Lot Sizes,  
 Campaign Size and Frequency for Pricing:  
 [ \* ]/Lot  
 Launch Phase: Hovione is not required to run more than [ \* ] production campaign of the API per every [ \* ] and to produce less than [ \* ] of API per campaign.  
 Commercial Phase: Hovione is not required to produce less than [ \* ] metric tons of API per campaign.  
 4. Annual API Purchase Base:  
 2006  
 $  
2,000,000  
 2007  
 $  
3,500,000  
 To End of Term  
 $  
5,000,000  
 5. Extension Fees:  
 First  
 $  
100,00  
 Second  
 $  
150,000  
 Third  
 $  
200,000  
 6. Technology Transfer Fees:  
 Transfer Fee  
 $  
[ \* ]  
 Production Fee  
 $  
[ \* ]  
 7. Wire Instructions  
 [ \* ].  
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 Attachment B-1  
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 8. Facilities  
 Hovione’s campus at Loures, Portugal and/or Taipa, Macau.  
 9. Fees for Due Diligence Audits  
 Audits conducted by Allos licensees or partners for due diligence purposes shall be charged at a rate of [ \* ] per day for each member of the licensee or partner team participating in such audit.  
 10. Reimbursement for Sundry Costs  
 During the Term of this Agreement it may become necessary for Hovione to carry out tasks, technical, scientific or otherwise, that may give rise to the incurring by Hovione of the use of its resources and for out-of-pocket expenses. Allos will accept debit notes for pre-approved, documented, reasonable in-house and out-of-pocket expenses and will reimburse Hovione promptly for these.  
 CONFIDENTIAL  
 Attachment B-2  
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