ACTIVE PHARMACEUTICAL INGREDIENT  
MANUFACTURING AND CLINICAL SUPPLY AGREEMENT  
  
(RECOMBINANT HUMAN INSULIN)  
  
THIS MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) is entered into as of July 5, 2010 (the “Effective Date”) ORAMED LTD., a company organized under the laws of the State of Israel with principal offices at Hi-Tech Park 2/5 Givat-Ram, XX Xxx 00000, Xxxxxxxxx 00000, Israel (“Buyer”) and SANOFI-AVENTIS DEUTSCHLAND GMBH, a company existing under the laws of Germany, located at Xxxxxxxxxxxxx Xxxxxxx, 00000 Xxxxxxxxx xx Xxxx, Xxxxxxx (“SAD”).  
  
Buyer and SAD are individually referred to herein as a “Party” and are collectively referred to herein as the “Parties”.  
  
Background  
  
A. Buyer wishes to engage SAD to perform services for Buyer, as more specifically set forth herein, in connection with the manufacturing and supply of Active Ingredient (as defined below) for use in clinical trials of the Product (as defined below).  
  
B. SAD wishes to perform such services, all on the terms and conditions set forth in this Agreement.  
  
Covenants  
  
In consideration of the mutual covenants and promises set forth herein, and intending to be legally bound hereby, the Parties agree as follows:  
  
ARTICLE 1  
DEFINITIONS  
  
The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement  
  
“Acquisition Cost” shall mean the actual invoiced price actually paid by SAD to any Third Party for materials, components and packaging materials required to manufacture and package the Active Ingredient hereunder, including, but not limited to, shipping and handling costs, taxes and customs duties incurred and paid by SAD to any Third Party in connection with the acquisition of such materials and components, as the case may be.  
  
“Active Ingredient” shall mean Recombinant Human Insulin as manufactured by SAD in accordance with the Active Ingredient Specifications, for use in the Product.  
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“Active Ingredient Price(s)” shall have the meaning set forth in Section 8.1(a) hereof.  
  
“Active Ingredient Specifications” shall mean the specifications for the Active Ingredient attached hereto as Exhibit 2 and made a part hereof, as determined in accordance with this Agreement, the analytical methodology set forth and in accordance with the terms and conditions of the Quality Agreement.  
  
“Affiliate” shall mean any corporation or non-corporate entity which controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or if it directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation or (a) in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.  
  
“Agreement” shall mean this Manufacturing and Supply Agreement, as it may hereafter be amended or supplemented from time to time.  
  
“cGMPs” shall mean applicable standards for current good manufacturing practices of active ingredients specified in (i) the ICH Guidelines,(ii) the FDA’s “Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients”, and (iii) the EU GMP Guidelines. For clarity, such definition of cGMPs shall not include other country-specific regulatory requirements.  
  
“Certificate of Analysis” shall mean a document, signed by an authorized representative of SAD, certifying the Specifications for, and testing methods applied to, the Active Ingredient, and the results thereof, and which includes the Active Ingredient date of manufacture, date for re-testing or expiration date as appropriate.  
  
“Certificate of cGMP Compliance” shall mean a document, signed by an authorized representative of SAD, certifying that the Active Ingredient being delivered to Buyer has been manufactured in conformity with cGMPs.  
  
“Confidential Information” shall mean, as the case may be, any and all information relating to the Active Ingredient, of a confidential nature not known to the public or to the recipient of the information before its disclosure belonging to either Party in written, electronic or any other form. This includes, but is not limited to, Know-How, operational methods, formulae, samples, Specifications, analytical methods as well as any details of commercial, technical, pharmaceutical, scientific and industrial nature. The terms of this Agreement shall also be deemed Confidential Information. Confidential Information shall not include information, materials, technical data or Know-How which: (i) is in a receiving Party’s possession at the time of disclosure as evidenced by the receiving Party’s written records immediately prior to the time of disclosure; (ii) is in the public domain at the time of disclosure; (iii) becomes part of the public domain by publication or otherwise after disclosure hereunder other than by breach of this Agreement by a receiving Party; (iv) is disclosed to a receiving Party by a third party having the right to disclose such information without any violation of any rights of or obligations to the disclosing Party; or (v) is independently developed by an employee or agent of a receiving Party without knowledge of the disclosing Party’s Confidential Information as evidenced by the receiving Party’s written records.  
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“FDA” shall mean the United States Food and Drug Administration or any successor entity thereto.  
  
“FDCA” shall mean the Federal Food, Drug and Cosmetic Act (21 U.S.C. § et seq.), as the same may be amended from time to time, together with any rules and regulations promulgated thereunder, and any foreign counterpart.  
  
“Force Majeure Event” shall have the meaning set forth in Section 18.1 hereof.  
  
“ICH Guidelines” shall mean the document titled “Q7A - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” endorsed by the International Conference on Harmonisation of Technical Requirements for Registrations of Pharmaceuticals for  
  
“Invention” shall mean information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, Know-How, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.  
  
“Know-How” shall mean all confidential and identified technical and scientific information and data, irrespective of its subject-matter and form, including, but not limited to, processes, formulae, designs and data as well as Inventions and improvements whether patentable or not.  
  
 “Packaging Specifications” shall mean the packaging and labeling specifications for the Active Ingredient attached hereto as Exhibit 1 and made a part hereof, as such specifications may be amended from time to time by mutual agreement of the Parties in accordance with the terms and conditions of the Quality Agreement.  
  
“PO” shall have the meaning set forth in Article 6 hereof.  
  
“Product” shall mean Buyer’s finished oral insulin product  
  
“Production Site” shall mean [the SAD site in which it manufactures the Active Ingredient i) the active pharmaceutical ingredient facility owned by SAD or an Affiliate of SAD (both directly or indirectly under the control of Sanofi-Aventis, SA, the French parent company) located at Xxxxxxxxxxxxx Xxxxxxx, 00000, Xxxxxxxxx xx Xxxx, Xxxxxxx, and (ii) such other facilities owned by SAD or an Affiliate of SAD, if any, as the Parties may mutually agree to in writing from time to time].  
  
 “Quality Agreement” shall mean the Quality Agreement which the parties shall in good faith negotiate and execute within thirty (30) days after the execution of this Agreement, and which shall be made part hereof.  
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“Recall” shall have the meaning set forth in Section 12.2(a) hereof.  
  
“Recalled Product” shall mean any Product subject to a Recall.  
  
“Regulatory Change” shall have the meaning set forth in Section 18.2 hereof.  
  
“Specifications” shall mean the Active Ingredient Specifications and the Packaging Specifications.  
  
“Term” shall have the meaning set forth in Section 11.1 hereof.  
  
“Territory” shall mean those territories set forth in Exhibit 4 as may be modified from time to time only in accordance with the terms of the Agreement.  
  
 “Third Party” shall mean any person or entity other than Buyer, SAD and their respective Affiliates.  
  
“Third Party Claims” shall have the meaning set forth in Section 13.1 hereof.  
  
ARTICLE 2  
MANUFACTURE, SALE AND PURCHASE OF ACTIVE INGREDIENT  
  
2.1 Generally. Subject to the terms and conditions of this Agreement, SAD shall manufacture and supply to Buyer and Buyer shall exclusively purchase from SAD, all of its Active Ingredient required to conduct clinical trials used to register the Product for sale in the Territory. For clarification, Buyer shall not use any clinical trial or data related thereto to register Product in the Territory unless the active ingredient for such clinical trial is supplied by SAD.  
  
2.2 Additional Territories. Should Buyer seek to conduct clinical trials outside the Territory in order to register the Product outside the Territory, then Buyer will discuss with SAD a proposal for SAD to supply Active Ingredient for those trials, and SAD will make its best commercial efforts in order accommodate Buyer’s commercially reasonable requirements.  
  
ARTICLE 3  
PACKAGING  
  
SAD shall procure all packaging materials and components for, and shall package, the Active Ingredient in accordance with the Production Site receipt procedures and the Packaging Specifications as set forth in Exhibit 1 attached hereto. Typical packaging materials and components are described in the Drug Master File in respect of the Active Ingredient and the use thereof is supported by extant stability data.  
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ARTICLE 4  
  
COOPERATION WITH GOVERNMENTAL REQUIREMENTS  
  
The Parties shall cooperate with one another as may be reasonably necessary or appropriate to satisfy all governmental requirements and obtain all needed permits, approvals and licenses with respect to the manufacture and supply of the Active Ingredient. Such cooperation shall include, without limitation but strictly in regards to United States territories, communicating with regulatory authorities and making available as promptly as practicable all information, documents and other materials which result from the performance by SAD of its services hereunder which Buyer is required to submit or which Buyer may otherwise reasonably request in connection with governmental filings relating to the Active Ingredient. The costs and expenses of such cooperation, if applicable, shall be subject to the Parties’ mutual agreement. Notwithstanding the foregoing, it shall be the responsibility of (i) Buyer to obtain and maintain all such permits, approvals and licenses which are specific to the Active Ingredient or the Product, and (ii) SAD to obtain and maintain all such permits, approvals and licenses which are generally required for the Production Site and to maintain the Drug Master File in respect of the Active Ingredient.  
  
ARTICLE 5  
SPECIFICATION CHANGES  
  
Upon any change in the Active Ingredient Specifications or Packaging Specifications requested by Buyer (“Buyer Specification Changes”), including the addition of new packaging configurations, Buyer shall promptly advise SAD in writing of any requested Buyer Specification Changes, and SAD shall promptly advise Buyer as to the feasibility of the Buyer Specification Changes, and if in SAD’s reasonably exercised discretion, the Buyer Specification Changes are found to be commercially reasonable and feasible, SAD will inform Buyer of any scheduling and/or price adjustments which may result from the Buyer Specification Changes. Prior to implementation of Buyer Specification Changes, the Parties shall negotiate in good faith in an attempt to reach agreement on (a) the new Active Ingredient Price for any Active Ingredient which embodies the Buyer Specification Changes, (b) any amounts to be reimbursed by Buyer to SAD as described in the next sentence of this paragraph, and (c) any other amendments to this Agreement which may be necessitated by the Buyer Specification Changes (i.e., an adjustment to the lead time for POs). Buyer shall reimburse SAD for the mutually agreed upon reasonable expenses incurred by SAD as a result of the Buyer Specification Changes, including, but not limited to, reimbursing SAD for its mutually agreed validation and development costs, capital expenditure costs and costs for any reasonable inventory of packaging components or other materials maintained by SAD for purposes of this Agreement and consistent with the PO, and rendered unusable as a result of the Buyer Specification Changes. If during the Term, Buyer, in accordance with this Article 5, causes the amendment of the Active Ingredient Specifications or Packaging Specifications so as to render obsolete reasonable quantities of the Active Ingredient and/or materials and components used to manufacture and package the Active Ingredient pursuant to this Agreement on hand at SAD, Buyer shall purchase from SAD (i) all such obsolete Active Ingredient at the Active Ingredient Prices then in effect, (ii) all work-in-progress of the Active Ingredient at SAD’s actual cost thereof, and (iii) at SAD’s Acquisition Cost, all such obsolete materials and components obtained by SAD pursuant to its normal procurement policies to manufacture quantities of the Active Ingredient pursuant to the PO. SAD’s normal procurement policies for purposes of the preceding sentence of this Article 5 shall be considered to be quantities of materials and components corresponding to the PO. For greater certainty, the foregoing provisions of this Article 5 shall not apply in respect of any change in the Active Ingredient Specifications or Packaging Specifications made by SAD other than pursuant to a Buyer request. SAD shall provide Buyer with not less than three (3) months’ prior written notice of SAD’s implementation of any intended significant change(s) to its manufacturing processes for the Active Ingredient, which might affect the quality of the Active Ingredient (“Change Notice”) (e.g. any change in the Active Ingredient Specifications or Packaging Specifications made by SAD other than pursuant to a Buyer request). If a significant change is implemented by SAD and Buyer provides SAD with demonstrable evidence that the utility (i.e. the conditions of being useful as a pharmaceutical product in connection with the manufacture and performance of the Product) of the Active Ingredient is significantly altered in that there is no similar bioequivalence (to Active Ingredient before the significant change) or similar Product specifications when formulated in the final Product formulation (together, “Utility Loss”), the parties shall exert their best commercial efforts to resolve issues related to the Utility Loss in order to continue operating under this Agreement. If the parties cannot reach agreement and resolution regarding Utility Loss, Buyer shall have the option to provide sixty (60) days written notice of termination of this Agreement to SAD.  
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ARTICLE 6  
FORECASTS AND ORDERS  
  
6.1 Communication of Forecasts and Purchase Orders by Buyer. Subject to and upon [REDACTED], and subsequent finalization of Buyer’s continuing trial(s) design(s), Buyer shall submit in writing to SAD a binding purchase order (“the PO”) of all clinical quantities of Active Ingredient which are required to conduct such clinical trials of Product.  
  
SAD will supply the Active Ingredient in packaging in accordance with the Packaging Specifications set forth in Exhibit 1.  
  
6.2 Confirmation by SAD. No later than fifteen (15) business days after receipt of Buyer’s POs, SAD shall confirm that it can fulfill the monthly quantities specified in such orders.  
  
6.3 Intentionally omitted.  
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6.4 Purchase Orders. Buyer shall issue the PO for all known total clinical quantities of Active Ingredient from SAD which are required to conduct [REDACTED] of Product at the Active Ingredient Price. The quantities of the Active Ingredient and the PO dates will be dependent upon the relevant regulatory authorities’ responses to the Product’s clinical trials, whether during review of the clinical program or after completion of clinical trial which may necessitate further trials, regarding trial participant number, dosage, length, and other relevant factors. Buyer estimates that it will require a quantity of Active Ingredient greater or equal to [REDACTED]for the anticipated clinical trials, and that the PO related thereto shall occur within the year 2011. The only quantities that Buyer is bound to purchase shall be those as determined in accordance with section 6.1. PO(s) for quantities up to 10KG shall be issued by Buyer at least three (3) months in advance of the expected date of delivery of Active Ingredient from SAD to Buyer. PO(s) for quantities from 10KG to 50KG shall be issued by Buyer at least six (6) months in advance of the expected date of delivery of Active Ingredient from SAD to Buyer. In the event that Buyer submits PO(s) for quantities above 50KG, the parties shall discuss and negotiate in good faith the lead time and advance notice required for delivery of Active Ingredient to Buyer. SAD shall deliver to Buyer those quantities ordered on a PO issued in accordance with this section 6.4 within the respective timeframe set out in immediately above. For clarification, regardless of expiration or termination of this Agreement, Buyer is obligated to pay any amounts due in accordance with issued POs.  
  
ARTICLE 7  
DELIVERIES  
  
7.1 Purchase Quantities. SAD will use commercially reasonably efforts to ship the quantities specified in the PO. Variations in shipments as outlined herein shall be deemed to be in compliance with such PO; provided, however, that Buyer shall only be invoiced and required to pay for the quantities of Active Ingredient which SAD actually ships to Buyer. Quantities shipped are subject to the Packaging Specifications set out in Exhibit 1 hereto.  
  
7.2 Active Ingredient Release. No Active Ingredient shall be released to Buyer without a Certificate of Analysis and Certificate of cGMP Compliance, both of which shall be supplied to Buyer by SAD. SAD shall conduct such quality assurance testing for the Active Ingredient as is required by the Specifications[,] [and ]cGMPs[ and the Quality Agreement. SAD shall conduct in parallel on-going stability studies of the Active Ingredients].  
  
7.3 Delivery Terms. Shipment of the Active Ingredient will be to one location as designated by Buyer. Buyer will select and pay the carrier to be used. The Active Ingredient will be shipped with the requisite Certificates of Analysis and Certificate of cGMP Compliance, FCA Production Site (Incoterms 2000), freight class, Class 70 (Class of Commodity for Food and Pharmaceutical Compound). Loading of the Active Ingredient shall be performed at no cost by SAD, but under the responsibility and liability of Buyer. All shipments of the Active Ingredient to Buyer shall be made via such carrier(s) as Buyer may direct. Title and risk of loss shall pass to Buyer upon delivery to the carrier. Freight charges shall be billed ship collect.  
  
7.4 Shipping; Dating and Customs Costs. SAD shall make commercially reasonable efforts to cause Active Ingredient delivered hereunder to have [REDACTED]months until expiration, but in any event, SAD shall deliver Active Ingredient hereunder with at least twelve (12) months until expiration. For clarity, costs for the shipment of Active Ingredient from the Production Site and all customs tariffs and duties shall be for the account of Oramed.  
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7.5 Inconsistencies. In the event of any inconsistencies between the terms of this Agreement and the PO issued by Buyer hereunder or any acceptance thereof by SAD, the terms of this Agreement shall govern.  
  
7.6 Inspections by Buyer. With reasonable written notice and upon a mutually agreed upon date, Buyer or its designated agents shall have the right to inspect those portions of the manufacturing, storage and warehouse facilities of a Production Site where Active Ingredient is being manufactured or stored, during regular business hours, to verify compliance with the terms and provisions of this Agreement or for insurance inspection purposes. Unless for reasonable cause, Buyer agrees to not inspect a Production Site more often than one (1) time in a three-calendar year period or any other frequency mutually agreed upon.  
  
7.7 Governmental Inspections. If SAD is notified that the Active Ingredient or the Production Site will be subject to an inspection related to the Active Ingredient, by any governmental authority of the Territory, SAD shall promptly inform Buyer of such inspection and shall cooperate with and allow such inspection to the extent required by applicable laws. Buyer shall not have the right to be present at any meetings or events related to such inspection. Subject to being excluded due to restrictions under confidentiality obligations of SAD to Third Parties, and to SAD’s determination that particular information and/or documentation is confidential in nature, SAD shall provide information related to inspection outcomes to Buyer resulting from such inspection to the extent relevant to the Active Ingredient. SAD will promptly inform Buyer whether any Form FDA 483 or warning letters or citations are issued to SAD (by the FDA or any other governmental authority) which are related to or impact the supply of the Active Ingredient to Buyer.  
  
ARTICLE 8  
PRICE; PRICE ADJUSTMENTS; PAYMENT TERMS  
  
8.1 Price.  
  
(a) General. The per- gram price(s) payable by Buyer for all quantities of the Active Ingredient ordered hereunder (the “Active Ingredient Price(s)”) shall be [REDACTED]Euros[REDACTED].  
  
8.2 Payment Terms. SAD shall invoice Buyer for all quantities of the Active Ingredient purchased hereunder concurrently with SAD’s shipment thereof to Buyer. Subject to Section 7.3 and Section 13.1, all amounts properly invoiced by SAD hereunder shall be due and payable [REDACTED]from the date of such invoice. SAD shall deliver invoices to Buyer on the date the invoice is issued. Payment may be made by Buyer’s corporate check or by wire transfer of funds to such account as SAD may designate. Orders, invoices and payments under this Agreement shall be made in Euros. Invoices shall reflect the actual quantities shipped and Buyer shall be responsible for payment for such actual quantities shipped in accordance with this Agreement.  
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ARTICLE 9  
SAD’S REPRESENTATIONS, WARRANTIES AND COVENANTS  
  
SAD represents, warrants and covenants to Buyer as follows:  
  
9.1 Active Ingredient. The Active Ingredient, at the time of sale and shipment to Buyer by SAD, (a) will conform to the Specifications, as then in effect, (b) will have dating until re-evaluation of not less than that which is set forth in Section 7.4 above, (c) will have been manufactured in all material respects in accordance with cGMP in effect at the time of manufacture, (d) will not be adulterated or mis-branded within the meaning of the FDCA, (e) will not have been manufactured, sold or shipped in violation of any applicable laws in any material respect, (f) will be conveyed with good title, free and clear of all security interests, liens or encumbrances, and (g) as may be appropriate or applicable, will have been approved by any and all requisite governmental and regulatory authorities.  
  
9.2 Manufacturing Standards. SAD shall manufacture the Active Ingredient in accordance with (i) the Specifications, (ii) then-current cGMPs, and (iii) ICH Guidelines.  
  
9.3 Compliance with Applicable Laws. SAD shall fully comply with all applicable federal, state and local laws in performing the services contemplated hereunder.  
  
9.4 Qualified Personnel. SAD shall engage and employ only professionally qualified personnel to perform the services contemplated hereunder, and will not knowingly utilize any individual, in any material capacity, who has been debarred under FDCA 21 USC 335a or who is subject to a conviction described in FDCA 21 USC 331.  
  
9.5 SAD represents and warrants to Buyer that the Production Site is wholly-owned by an Affiliate of SAD and that such Affiliate and SAD are wholly owned, directly or indirectly, by Sanofi-Aventis SA.  
  
ARTICLE 10  
GENERAL REPRESENTATIONS AND WARRANTIES  
  
Each Party represents and warrants to the other as follows:  
  
10.1 Power and Authorization. It has all requisite power and authority (corporate and otherwise) to enter into this Agreement and has duly authorized by all necessary action the execution and delivery hereof by the officer or individual whose name is signed on its behalf below.  
  
10.2 No Conflict. Its execution and delivery of this Agreement and the performance of its obligations hereunder do not and will not conflict with or result in a breach of or a default under its organizational instruments or any other agreement, instrument, order, law or regulation applicable to it or by which it may be bound.  
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10.3 Enforceability. This Agreement has been duly and validly executed and delivered by it and constitutes its valid and legally binding obligation, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors’ rights and except as enforcement is subject to general equitable principles.  
  
10.4 Debarment. As of the Effective Date, both parties have not been debarred under 21 USC 335a, and to the best of their knowledge, is not subject to pending debarment under 21 USC 335a.  
  
ARTICLE 11  
TERM; TERMINATION  
  
11.1 Term. Unless sooner terminated pursuant to the terms hereof, the term of this Agreement shall commence on the Effective Date and shall expire with the acceptance by Buyer of the total quantities of Active Ingredient as set forth in Article 6 above.  
  
11.2 Termination by Buyer for Utility Loss. Buyer shall be entitled to terminate this Agreement pursuant to and in accordance with Article 5 in the event of a Utility Loss. In the event of a termination by Buyer in accordance with this Section 11.2 and Article 5, Buyer’s then-current payment obligations under this Agreement which are not related to Utility Loss shall remain until fully satisfied, including the payment of amounts due to SAD for Active Ingredient or otherwise, which are not related to Utility Loss.  
  
11.3 Termination by Mutual Agreement. The Parties may terminate this Agreement at any time by mutual written agreement.  
  
11.4 Termination Upon Breach. Either Party may terminate this Agreement upon not less than thirty (30) days prior written notice to the other Party upon the material breach or default by the other Party of any of its representations, warranties, covenants or agreements (provided, however, that such notice period shall be extended by such additional period as the breaching Party may request upon the breaching Party’s written certification that (i) such breach is reasonably capable of being cured within the period of the proposed extension, but not within such thirty (30) day period and (ii) it has commenced and is diligently pursuing efforts to cure such breach). Upon the expiration of such notice period, this Agreement shall terminate without the need for further action by either Party; provided, however, that if the breach upon which such notice of termination is based shall have been fully cured to the reasonable satisfaction of the non-breaching Party within such notice period, then such notice of termination shall be deemed rescinded, and this Agreement shall be deemed reinstated and in full force and effect. Such right of termination shall be in addition to such other rights and remedies specified in this Agreement and as provided by law. For greater certainty, any breach or default (material or otherwise) by a Party under any other agreement between the Parties (other than the Quality Agreement) shall not entitle the other Party to terminate this Agreement.  
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 11.5 Other Termination. Either of the Parties may terminate this Agreement at anytime, upon written notice, during the clinical development of Product should Buyer execute and enter into binding agreements with [REDACTED]as a marketing partner related to the Product. Upon termination in accordance with this section 11.5, Buyer will compensate SAD for [REDACTED]of Active Ingredient shipped from SAD in accordance with a Letter of Intent between the parties, effective November 1, 2009, at a rate of [REDACTED], totaling [REDACTED]. Should Buyer enter into marketing partnerships for the Product with partners other than [REDACTED], Buyer shall remain obligated to the terms of this Agreement with SAD.  
  
11.6 Rights and Duties Upon Termination.  
  
(a) Unless otherwise mutually agreed by the Parties, SAD shall manufacture and ship, and Buyer shall purchase in accordance with the provisions hereof, all quantities of Active Ingredient ordered by Buyer hereunder prior to the date of expiration or termination.  
  
(b) Upon the expiration or termination of this Agreement (other than termination by Buyer pursuant to Section 11.2 or Section 11.4 hereof), Buyer shall, if so requested by SAD, purchase (i) all materials and components acquired by SAD hereunder to manufacture the Active Ingredient in accordance with the then-current Forecast, at SAD’s Acquisition Cost thereof, (ii) all work-in-progress of the Active Ingredient in respect of the then-current Forecast at SAD’ actual cost thereof, and (iii) all finished Active Ingredient inventory in respect of the then-current Forecast then in SAD’s possession at the then-current Active Ingredient Price hereunder. In addition, in such case Buyer shall pay SAD for any uncancellable commitments made by SAD for materials and components hereunder in respect of the then-current Forecast. Notwithstanding anything to the contrary in this Section 11.6 (b), the foregoing purchase and payment obligations of Buyer shall be limited solely to materials and components obtained as to the time periods for the types of materials and components provided in Article 5, and Active Ingredient quantities manufactured as to which Buyer’ Forecasts under Section 6.1 hereof constitute a firm commitment.  
 ARTICLE 12  
CLAIMS; RECALLS  
12.1 Claims. Buyer may reject any quantity of the Active Ingredient which fails to conform to any applicable PO, warranty, Specifications or laws upon written notice to SAD describing such nonconformity given within thirty (30) days after Buyer’s receipt thereof (or, in the case of any defects not reasonably susceptible of discovery upon receipt of such goods, within thirty (30) days after discovery thereof by Buyer). SAD shall have no liability to Buyer with respect to any such nonconformity which the Parties agree (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) (i) was caused by information supplied by Buyer or due to a fault in materials supplied by Buyer, (ii) was otherwise caused by Buyer or its agents, or (iii) was caused after delivery thereof to the carrier at the point of origin. In all other cases, SAD shall promptly credit Buyer’s account for SAD’s invoice price to Buyer of such nonconforming Active Ingredient. Additionally, if Buyer shall have previously paid for such nonconforming Active Ingredient, SAD shall promptly, at Buyer’s election, either (a) refund the invoice price thereof (b) offset the amount thereof against other amounts then due SAD hereunder or (c) replace such nonconforming Active Ingredient with conforming Active Ingredient at no additional cost to Buyer (including replacement shipping costs). THE FOREGOING REMEDY CONSTITUTES THE EXCLUSIVE REMEDY AGAINST SAD AND THE ENTIRE LIABILITY OF SAD IN CONNECTION WITH THE REJECTED SHIPMENT. The fees and expenses of any independent laboratory or consultant engaged by the Parties for purposes of this section shall be paid by the Party which is determined to bear responsibility for the nonconformity in question  
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 12.2 Recalls.  
  
(a) Notices. Each Party shall notify the other of any information, whether received directly or indirectly, which might affect the marketability, safety or effectiveness of Product which was manufactured using Active Ingredient supplied by SAD hereunder and/or which might result in the Recall or seizure of the Product which was manufactured using Active Ingredient supplied by SAD hereunder. For purposes of this Agreement, a “Recall” shall mean any action: (i) by either Party to recover title to or possession of quantities of the Product which was manufactured using Active Ingredient supplied by SAD hereunder sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of such Product which was manufactured using Active Ingredient supplied by SAD hereunder from the market) or (ii) by any regulatory authority to detain or destroy any of such Product which was manufactured using Active Ingredient supplied by SAD hereunder. “Recall” shall also include the election by either Party to refrain from selling or shipping quantities of such Product which was manufactured using Active Ingredient supplied by SAD hereunder to Third Parties that would have been subject to a Recall if sold or shipped.  
  
(b) Discretion. Buyer shall institute a Recall of the Product as a consequence of any defect that Buyer deems sufficiently serious. Buyer shall consult with SAD regarding any Recall of Product which was manufactured using Active Ingredient supplied by SAD hereunder; provided, however, that Buyer shall retain sole discretion whether to institute a Recall. SAD shall provide a rapid initial response and a full report with respect thereto within thirty (30) calendar days of such notification.  
  
(c) Responsibilities. SAD shall have no liability to Buyer with respect to any Recall which the Parties agree (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) (i) was caused by information or materials supplied by Buyer, (ii) was otherwise caused by Buyer or its agents, (iii) was caused by factors occurring after delivery of the Active Ingredient to the carrier at the point of origin, or (iv) did not result from a breach of SAD’s warranties provided under Article 10 hereof. In addition, Buyer shall reimburse SAD for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by SAD directly resulting from such Recall (subject to the limitations set forth in Section 15.2 hereof).  
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 (d) SAD Liability. For all Recalls which result from a breach of SAD’s warranties provided under Article 10 hereof, unless SAD does not have liability pursuant to Section 12.2(c), SAD shall: (x) promptly credit Buyer’s account for SAD’s invoice price to Buyer of the Active Ingredient used in such Recalled Product; if Buyer shall have previously paid for such Active Ingredient, SAD shall promptly, at Buyer’ election, either (A) refund the invoice price thereof, or (B) offset the amount thereof against other amounts then due SAD hereunder, or (C) replace such Active Ingredient at no additional cost to Buyer (including shipping costs); and (y) reimburse Buyer for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by Buyer directly resulting from such Recall (subject to the limitations set forth in Section 15.2 hereof).  
  
(e) Independent Laboratory Costs. The fees and expenses of any independent laboratory or consultant engaged by the Parties for purposes of this Section 12.2 shall be paid by the Party which is determined to bear responsibility for the Recall in question.  
  
(f) Limitation. Notwithstanding any other provision of this Agreement, the liability of SAD to reimburse Buyer for Third Party costs and expenses pursuant to Section 12.2(d)(y) hereof related to any Recall shall not exceed [REDACTED]in respect of each such Recall. The Parties shall, to the extent possible, meet to review, in advance, actions and budgets for any Recall for which SAD shall have financial responsibility to Buyer pursuant to this Section 12.2.  
  
12.3 Disposition of Nonconforming or Recalled Product. Buyer shall not dispose of any damaged, nonconforming or Recalled Product as to which it intends to assert a claim against SAD without SAD’s written authorization to do so. Alternatively, SAD may instruct Buyer to return such Product to SAD. SAD shall bear the cost of disposition (as well as all applicable shipping costs) with respect to any damaged, nonconforming or Recalled Product as to which it bears responsibility under Section 12.1 or 12.2 hereof.  
  
ARTICLE 13  
INDEMNIFICATION  
  
13.1 By Buyer. Buyer shall defend, indemnify and hold harmless SAD, its Affiliates and their respective officers, directors, shareholders, employees, licensees, agents, successors and assigns from and against any and all claims, demands, damages, judgments, settlements and awards made by or asserted by Third Parties (collectively, “Third Party Claims”) (including, without limitation, those associated with a Recall) which any of them may incur or become subject to arising out of or resulting from (a) Buyer’s use, handling, distribution, marketing or sale of the Active Ingredient or the Product (subject to Section 13.2 hereof), (b) the breach by Buyer of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement or (c) any claim that the manufacture, use or sale of the Product infringes a patent or any other proprietary rights; provided, however, that such obligation to indemnify shall not extend to any Third Party Claim to the extent they arise out of or resulting from any negligence, recklessness or wrongful conduct by SAD or the breach by SAD of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement.  
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 13.2 By SAD. SAD shall defend, indemnify and hold harmless Buyer, its Affiliates and their respective officers, directors, shareholders, employees, licensees, agents, successors and assigns from and against any and all Third Party Claims which any of them may incur or become subject to arising out of or resulting from (a) SAD’s negligent acts or omissions or willful misconduct in connection with the performance of the services contemplated by this Agreement, (b) the breach by SAD of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement, or (c) any claim that SAD’s manufacture, use or sale of the Active Ingredient alone infringes a patent or any other proprietary rights; provided, however, that such obligation to indemnify shall not extend to any Third Party Claim to the extent they arise out of or resulting from any negligence, recklessness or wrongful conduct by Buyer or the breach by Buyer of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement.  
 13.3 Procedure. Promptly after learning of the occurrence of any event which may give rise to its rights under the provisions of this Article 13, each indemnitee hereunder shall give written notice of such matter to the indemnitor. The indemnitee shall cooperate with the indemnitor in the negotiation, compromise and defense of any such matter. The indemnitor shall have the right to be in charge of and control such negotiations, compromise and defense and to select and manage counsel with respect thereto, provided that the indemnitor shall promptly notify the indemnitee of all developments in the matter. In no event shall the indemnitee compromise or settle any such matter without the prior written consent of the indemnitor, who shall not be bound by any such compromise or settlement absent its prior written consent, which consent shall not be unreasonably withheld or delayed  
  
ARTICLE 14  
INSURANCE  
  
Each Party represents that it has and shall maintain during the Term hereof, as well as after the expiration or termination of this Agreement, sufficient insurance or an appropriate program of self insurance, and in particular products liability insurance, with appropriate policy limits to cover all risks associated with the performance of its obligations under this Agreement. Each Party agrees to provide upon request copies of the relevant certificate(s) of insurance.  
  
ARTICLE 15  
LIMITATION OF LIABILITY  
  
15.1 DISCLAIMER OF WARRANTIES. THE WARRANTIES GIVEN BY SAD HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY SAD.  
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 15.2 DAMAGES. NO PARTY SHALL BE LIABLE FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS AND LOSS OF GOODWILL) ARISING FROM ANY BREACH OR ALLEGED BREACH OF THIS AGREEMENT (EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES).  
  
15.3 Remedies. SAD’s sole obligations, and Buyer’s sole and exclusive remedies, for any breach by SAD of this Agreement related to nonconforming Active Ingredient or Recalled Product shall be as set forth in Sections 12.1 and 12.2 hereof, respectively.  
  
15.4 LIMITATION. EXCEPT FOR SAD’S INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS, IN NO EVENT SHALL SAD’S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS OR LOSSES ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED THE AMOUNTS PAID TO SAD HEREUNDER DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO LIABILITY.  
  
ARTICLE 16  
CONFIDENTIALITY  
  
16.1 Treatment of Confidential Information. Except as otherwise provided in this Article 16, during the Term and for a period of ten (10) years thereafter:  
  
 (i)  
SAD will retain in confidence and use only for the purposes contemplated hereby any Confidential Information disclosed to it by or on behalf of Buyer in connection with the performance of this Agreement; and  
  
 (ii)  
Buyer will retain in confidence and use only for the purposes contemplated hereby any Confidential Information disclosed to it by or on behalf of SAD in connection with the performance of this Agreement.  
  
16.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, each Party may disclose Confidential Information to its Affiliates, sublicensees, consultants, outside contractors, clinical investigators or other Third Parties on condition that such entities or persons agree (a) to keep the Confidential Information confidential for the same time periods and to the same extent as each Party is required to keep the Confidential Information confidential and (b) to use the Confidential Information only for such purposes as such Party is entitled to use the Confidential Information. Each Party or its Affiliates or sublicensees may disclose such Confidential Information to government or other regulatory authorities to the extent that such disclosure (i) is reasonably necessary to obtain patents or authorizations to conduct clinical trials with and to market commercially the Product, provided such Party is otherwise entitled to engage in such activities under this Agreement or (ii) is otherwise legally required.  
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 16.3 Confidentiality Agreement. This Agreement contains the entire understanding of the Parties with respect to the Confidential Information and supersedes the Confidentiality Agreement entered into on September 26, 2008.  
  
16.4 Material Transfer Agreement. The Material Transfer Agreement executed by the parties shall remain in effect.  
  
ARTICLE 17  
OWNERSHIP OF PROPERTY  
  
17.1 Ownership of Rights. Each Party shall exclusively own and retain all right, title and interest in and to (i) all intellectual property rights, information, documents and tangible and intangible materials owned by it as of the Effective Date, and (ii) all Inventions which are conceived, reduced to practice, or created by such Party and/or its Affiliates or agents (including without limitation Inventions based upon any background or preexisting technology of such Party) and which do not include any intellectual property rights of the other Party from and after the Effective Date. Each Party shall be solely responsible for the conduct and costs of filing, prosecution and maintenance of patents and patent applications on its own intellectual property rights, including without limitation its Inventions.  
  
17.2 Trademarks. Buyer shall retain all right, title and interest arising under the laws of the United States and Israel and all other applicable laws in the trademarks of Buyer that may be adopted with respect to the Product.  
  
ARTICLE 18  
FORCE MAJEURE  
  
18.1 Effects of Force Majeure. Neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement (other than the payment of money owed hereunder) to the extent that such failure or delay results from any cause beyond its reasonable control, including, without limitation, fire, flood, natural disaster, explosion, war, strike, labor unrest, riot, embargo, acts or omissions of carriers, or act of God (each, a “Force Majeure Event”). Such excuse shall continue as long as the Force Majeure Event continues, following which such Party shall promptly resume performance hereunder.  
  
18.2 Effects of Regulatory Changes. Neither Party shall be held responsible or liable for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent that such failure or delay results from good faith efforts to comply with the enactment or revision of any law, rule, regulation or regulatory advisory opinion or order applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of the Product (a “Regulatory Change”). Such excuse shall continue as long as performance is prevented by the affected Party’s good faith efforts to comply with such Regulatory Change, following which such Party shall promptly resume performance hereunder.  
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 18.3 Notice. The Party affected by a Force Majeure Event or a Regulatory Change shall notify the other Party thereof as promptly as practicable after its occurrence. Such notice shall describe the nature of such Force Majeure Event or Regulatory Change and the extent and expected duration of the affected Party’s inability to fully perform its obligations hereunder. The affected Party shall use due diligence, where practicable, to minimize the effects of or end any such event so as to facilitate the resumption of full performance hereunder and shall notify the other Party when it is again fully able to perform such obligations.  
  
ARTICLE 19  
INDEPENDENT CONTRACTORS  
  
The relationship between Buyer and SAD is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between Buyer and SAD. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.  
  
ARTICLE 20  
MISCELLANEOUS  
  
20.1 General Notices. Except as otherwise provided in Section 20.2 hereof, all notices, requests, instructions, consents and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed received (i) on the same day if delivered in person, by same-day courier or by facsimile transmission, (ii) on the next day if delivered by overnight mail or courier, or (iii) on the date indicated on the return receipt, or if there is no such receipt, on the third calendar day (excluding Sundays) if delivered by certified or registered mail, postage prepaid, to the Party for whom intended to the following addresses:  
  
If to Buyer:  
 ORAMED Ltd.  
 HI-TECH PARK 2/5 GIVAT-RAM  
 XX Xxx 00000, Xxxxxxxxx 00000, Israel  
 Attention: CFO: Xxxxx Xxxxxx  
 Email: xxxxx@xxxxxx.xxx  
 Facsimile: + 972 2 566 0004  
 If to SAD:  
 SANOFI-AVENTIS DEUTSCHLAND GMBH  
 Xxxxxxxxxxxxx Xxxxxxx, 00000  
 Xxxxxxxxx xx Xxxx, Xxxxxxx  
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 With a copy to:  
 sanofi-aventis XX  
 00 Xxxxxxxxx Xxxxx  
 Xxxxxxxxxxx, XX 00000  
 General Counsel  
 Facsimile: 000-000-0000  
 Each Party may by written notice given to the other in accordance with this Agreement change the address to which notices to such Party are to be delivered.  
  
20.2 Special Notices. Each Party shall notify the other by telephone as soon as practicable (with written confirmation within three business days) upon its receipt of any technical complaint or notice of adverse reaction; provided, however, that notification of serious, new or unexpected experiences reported with increased frequency shall be made immediately (but in any event not more than thirty-six (36) hours after the notifying Party learns of such experiences). All such notices shall be directed to the Parties at the addresses set forth in Section 20.1 to the attention of the following personnel:  
  
If to Buyer:  
 Technical complaints:   
Quality Assurance Specialist  
 Adverse reactions:  
Director of Product Surveillance  
 If to SAD:  
 Technical complaints:   
Site Quality Manager  
 Adverse reactions:  
Site Quality Manager  
  
20.3 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, whether written or oral, between them with respect to the subject matter hereof. Each Party has executed this Agreement without reliance upon any promise, representation or warranty other than those expressly set forth herein.  
  
20.4 Amendment. No amendment of this Agreement shall be effective unless embodied in a written instrument executed by both of the Parties.  
  
20.5 Waiver of Breach. The failure of either Party at any time to enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any provisions hereof or the right of any Party to thereafter enforce each and every provision of this Agreement. No waiver of any breach of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the Party against whom or which enforcement of such waiver is sought; and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.  
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 20.6 Neither Party shall subcontract any of its obligations under this Agreement; provided, however, that (i) either party may subcontract to a Third Party any of its obligations under this Agreement with the prior written approval of the other Party, such approval not to be unreasonably withheld, and (ii) SAD may subcontract any services to an Affiliate, or otherwise if permitted in the Specifications or Packaging Specifications, including without limitation the supply of materials and components, or pursuant to Section 20.7 hereof.  
  
20.7 Assignment; Requirement to Assign to Successor to Business. Neither Party may assign its rights under this Agreement in whole or in part without the prior written approval of the other Party (such approval not to be unreasonably withheld or delayed). Any such attempted assignment without such prior written consent shall be void and ineffective. Notwithstanding the foregoing: SAD may, without the other Party’s consent, assign its rights and delegate its duties under this Agreement in whole or in part to any entity with which it merges or consolidates, which acquires all or substantially all of its business and assets, or which otherwise is or becomes an Affiliate of the assigning Party;  
  
20.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of New York, USA, without regard to any choice-of-law principle that would dictate the application of the laws of another jurisdiction. Failing amicable agreement, all disputes arising in connection with this Agreement shall be settled by the courts of New York, New York, USA.  
  
20.9 Severability. All of the provisions of this Agreement are intended to be distinct and severable. If any provision of this Agreement is or is declared to be invalid or unenforceable in any jurisdiction, it shall be ineffective in such jurisdiction only to the extent of such invalidity or unenforceability. Such invalidity or unenforceability shall not affect either the balance of such provision, to the extent it is not invalid or unenforceable, or the remaining provisions hereof, nor render invalid or unenforceable such provision in any other jurisdiction.  
 20.10 Publicity. Nothing in this Agreement shall be deemed to give either Party any rights to use the other Party’s trademarks or trade names without the other Party's prior specific, written consent. The parties agree that except for what has been provided for herein, neither party will issue any press release or otherwise make any public statement, advertisement or disclosure with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, which shall not be unreasonably withheld. The Parties agree that Exhibit 3 attached hereto represents a mutually approved announcement and Form 8-K to be released and filed by Buyer or its Affiliate with the Securities and Exchange Commission upon the full execution of this Agreement. In addition, if, in the opinion of the disclosing Party’s legal counsel, any other announcement is necessary to comply with applicable law, either Party shall be entitled to make a further public announcement of this Agreement and/or file forms with the Securities and Exchange Commission or other regulatory agencies, subject to the prior review and approval of such press release and/or forms by the other Party or its Affiliate, which approval will not be unreasonably withheld or delayed. In addition, if, in the opinion of Buyer's legal counsel this Agreement must be filed with the Securities and Exchange Commission, mutually agreed upon redacted versions of this Agreement may be exhibits to the Form 8-K Current Report or a periodic report. In addition, Buyer will be entitled to make reference to this Agreement in reports filed with the Securities and Exchange Commission, after providing SAD reasonable advance notice and a reasonable opportunity to review and comment thereon. Finally, Buyer shall be allowed to insert the statement "The recombinant human insulin was sourced from Sanofi-Aventis Deutschland GmbH" without any authorization from SAD in order to specify the SAD as the supplier of the Active Ingredient only in peer-review papers and posters published at scientific seminars when the Active Ingredient which was provided by SAD is used for the studies that are the subjects of the publication.  
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 20.11 Survival. The provisions of Article 4 (Cooperation with Governmental Requirements), Section 11.5 (Rights and Duties Upon Termination), Article 12 (Claims; Recalls), Article 13 (Indemnification), Article 14 (Insurance), Article 15 (Limitation of Liability), Article 16 (Confidentiality), Article 17 (Ownership of Property), , Section 20.8 (Governing Law), Section 20.10 (Publicity) and Section 24.11 (Survival) shall survive the expiration or termination of this Agreement.  
  
20.12 Headings. The headings of articles and sections have been included for convenience only and shall not be considered in interpreting this Agreement.  
  
20.13 Counterparts; Facsimile Signatures. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via facsimile or other electronic means with the same force and effect as if it were executed and delivered by the Parties simultaneously in the presence of one another.  
  
20.14 Execution. At the time of execution of this Agreement, the Parties shall cause their authorized officers to execute two original copies of this Agreement, one copy of which shall be maintained by each Party at that Party’s offices. Each Party represents that the person who executes this Agreement is authorized and empowered to obligate and bind his or her Party under this Agreement.  
  
20.15 Further Actions. The Parties agree to execute such additional documents and / or agreements as may be reasonably necessary to perfect the intentions of the provisions contained herein.  
  
[Remainder of this page intentionally left blank.]  
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 IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the date first written above.  
  
ORAMED LTD.  
  
By:  
 Name:  
 Title:  
   
SANOFI-AVENTIS DEUTSCHLAND GMBH  
  
By:  
 Name:  
 Title:  
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 Exhibit 1  
 PACKAGING SPECIFICATIONS  
 SAD will supply the Active Ingredient in packaging units of [REDACTED] kilograms for a purchased quantity below [REDACTED]kg and in packaging units of [REDACTED]kilograms (standard preferred packaging unit) for a purchased quantity higher than [REDACTED]kilograms.  
  
The following sizes\* of stainless steel drums are utilized for packaging and delivery:  
  
 1[REDACTED][REDACTED]\* not factoring in the lid  
  
SAD shall have the right, at its option, to deliver ordered quantities in one drum where feasible.  
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 Exhibit 2  
 ACTIVE INGREDIENT SPECIFICATIONS  
 [REDACTED]  
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 Exhibit 3  
 Press Release to be issued by Buyer  
 [REDACTED]  
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 Exhibit 4  
  
Territory  
  
[REDACTED]  
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