# EX-10.15 5 dex1015.htm SUPPLY AGREEMENT

# **Exhibit 10.15**

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#### **SUPPLY AGREEMENT**

This SUPPLY AGREEMENT (the "<u>Agreement</u>"), effective as of the seventh day of March, 2011 (the "<u>Effective Date</u>"), is made and entered into by and between Insys Therapeutics, Inc., a Delaware corporation having its principal place of business at 10220 South 51st St., Suite 2, Phoenix, AZ 85044-5231 (hereinafter called "<u>PURCHASER</u>") and Aptargroup, Inc., a Delaware corporation having its principal place of business at 475 West Terra Cotta, Suite E, Crystal Lake, IL, 60014-9695 (hereinafter called "<u>SELLER</u>"). PURCHASER and SELLER being hereinafter called individually the "<u>Party</u>" and collectively the "<u>Parties</u>".

WHEREAS SELLER is engaged in the development and manufacture of dispensing systems for medical use, with particular reference to nasal and oral devices:

WHEREAS PURCHASER desires to purchase the Device (defined below) for Purchaser's own use with Drug Product (defined below), subject to the terms and conditions herein; and

WHEREAS SELLER desires to sell the Device to PURCHASER subject to the terms and conditions herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

#### 1. **DEFINITIONS**

As used herein, the following terms and expressions shall have the meanings set forth below:

- 1.1 "<u>Affiliate</u>" means any person or entity that directly or indirectly through one or more intermediaries' Controls, is Controlled by, or is under common Control with a Party, where "<u>Control</u>" means the direct or indirect, legal or beneficial ownership of more than fifty percent (50%) of the outstanding voting rights in a company.
- 1.2 "<u>cGMP</u>" means the current good manufacturing practices stipulated or promulgated from time to time by the Regulatory Authorities that are applicable to the manufacture of the Device.
- 1.3 "<u>Cumulative Yearly Quantity</u>" means the cumulative total Minimum Yearly Quantity amount of the Device PURCHASER must procure from the SELLER to maintain pricing levels as defined in **Exhibit C.**
- 1.4 "<u>Development Activities</u>" means all research and development activities related to the development of a drug (including alternative delivery systems) through preclinical and clinical stages.
- 1.5 "<u>Device</u>" means the device described in the Device Specifications.

- 1.6 "<u>Device Equipment</u>" means the moulds and assembly machines required at SELLER's premises to manufacture the Device in commercial quantities.
- 1.7 "<u>Device Equipment Contribution</u>" means the PURCHASER's [...\*\*\*...] reimbursement of research and development costs of SELLER related to, but not limited to, the Device Equipment as described in **Exhibit C.**
- 1.8 "<u>Design</u>" means any combination of outer shape and color of the Device.
- 1.9 "Device Specifications" means the Device's specifications as described in Exhibit A.
- 1.10 "Drug Product" means the sublingual formulation of Fentanyl owned by PURCHASER and currently known as "Fentanyl SL".
- 1.11 "Effective Date" means the day inserted on the introductory clause of this Agreement.
- 1.12 "<u>FDA Approval</u>" means the approval of the new drug application (NDA) for the Finished Product by the Food and Drug Administration in the United States of America (FDA).
- 1.13 "Fentanyl" means the compound with molecular formula C<sub>22</sub>H<sub>28</sub> N<sub>2</sub>O and IUPAC name N-(1-2-phenlyethyl)-4-piperidinyl)-N-phenylpropanamide .
- 1.14 "Fentanyl Market" means the total unit sales of all non-extended release pharmaceutical products containing Fentanyl as an active pharmaceutical ingredient.
- 1.15 "Finished Product" means the Drug Product in conjunction with the Device.
- 1.16 "Intellectual Property" means all present and future intellectual property rights and information, material and trade secrets that relate to the Device or the Drug Product, as the case may be, whether or not patentable, including any know-how.
- 1.17 "Marketing Approval" means, with respect to any country, the approval of any marketing application for the Finished Product by the appropriate Regulatory Authority in such country, including (a) FDA Approval, (b) approval of a marketing authorization application by the EU Medicines Agency and (c) approval of other product registration application with respect to any other territory.
- 1.18 "Minimum Yearly Quantity" means the minimum amount of the Device PURCHASER must procure from the SELLER per year as defined in **Exhibit C.**
- 1.19 "Purchase Price" shall have the meaning set forth in **Exhibit C.**
- 1.20 "Regulatory Authority" or "Regulatory Authorities" means the United States Food and Drug Administration and any divisions thereof, any equivalent agency of any other country and any division thereof, and any other applicable regulatory body.

Supply Agreement

1.21 "Success Fee" means the fee to be paid by PURCHASER to SELLER as specified in **Exhibit D** upon successful FDA Approval.

# 2. MANUFACTURE AND SALE

- 2.1 <u>Supply and Purchase Obligations</u>. SELLER agrees to manufacture and sell to PURCHASER, and PURCHASER agrees to purchase from SELLER, such quantities of the Device as PURCHASER may order from SELLER in accordance with the terms and conditions of this Agreement.
- 2.2 <u>Device Equipment.</u> Seller will utilize Device Equipment for the manufacture of the Device. Ownership of Device Equipment shall remain with SELLER. In case PURCHASER wants to obtain ownership of Device Equipment, it shall purchase from SELLER Device Equipment at a price to be agreed between Parties and pay the applicable German VAT at the time of transfer of ownership. No such purchase shall occur without SELLER's prior written consent. In no case shall Device Equipment leave SELLER's premises.
- 2.3 <u>cGMP Compliance.</u> SELLER shall assemble and package the Device in accordance with the Device Specifications and applicable cGMP as of the Effective Date.
- 2.4 Intellectual Property. Any Intellectual Property owned or controlled as of the Effective Date by PURCHASER, SELLER, or their Affiliates shall remain the absolute unencumbered property of SELLER and PURCHASER respectively. SELLER shall own all arising Intellectual Property rights related to the Device. SELLER reserves the right to prosecute, maintain and defend SELLER's Intellectual Property, at SELLER's discretion and expense. SELLER's IP is broadly drafted and includes trade secrets and patents related to the Device. SELLER may have strategic reasons to defend or not such IP and will need flexibility to exercise in its own discretion, particularly any IP that has applications to other SELLER's products.

# 3. EXCLUSIVITY

- 3.1 SELLER is willing to supply the Device to PURCHASER on an exclusive basis per the conditions and limitations set forth in **Exhibit D**. For the avoidance of doubt, such Exclusivity does not contain any license for patents or technologies. Neither Party grants any licenses to the other party.
- 3.2 The SELLER agrees to that the PURCHASER has Design exclusivity to the Device.
- 3.3 The exclusivity rights granted to PURCHASER hereunder shall be valid for the duration of the Exclusivity Term (as defined in **Exhibit D**); *provided*, that, if the exclusivity provisions in this Agreement are challenged by a third party or any governmental authority, PURCHASER shall, at SELLER's option, either (i) defend, indemnify and hold harmless the SELLER, its Affiliates and their directors, officers,

employees and agents from and against any losses suffered or resulting from such challenge, or (ii) convert the exclusive rights herein to non-exclusive rights.

# 4. RIGHT OF FIRST REFUSAL

- 4.1 Grant of Right of First Refusal. PURCHASER hereby grants SELLER the exclusive option (but not the obligation) to supply to PURCHASER all of its requirements of a Drug Delivery System (as defined below) for any Alternate Route of Administration (as defined below) in accordance with the terms of this Article 4. For the avoidance of doubt, PURCHASER may not purchase from a Third Party, or develop and manufacture internally, a Drug Delivery System for any Alternate Route of Administration, unless (a) SELLER does not exercise its right of first refusal in accordance with Section 4.4 or (b) the feasibility study referred to in Section 4.5 below is not successful unless (c) PURCHASER is engaged in active development of such Drug Delivery System prior to the Effective Date.
- 4.2 <u>Alternate Route of Administration Drug Development.</u> PURCHASER agrees to notify SELLER in accordance with Section 4.4 about all Development Activities of any "Alternate Route of Administration" for a new drug that occur after the Effective Date. "<u>Alternate Route of Administration</u>" means any route of administration for a drug including, but not limited to the current sublingual route of administration, intranasal, pulmonary, buccal, topical, ophthalmic, and otic drug delivery but excluding oral solid dosing.
- 4.3 <u>Alternate Route of Administration Drug Delivery Systems.</u> PURCHASER agrees to notify SELLER about all Development Activities that would utilize any "Drug Delivery System" for any Alternate Route of Administration. "<u>Drug Delivery Systems</u>" used for Alternate Route of Administration includes but are not limited to all forms of spray devices, metered pumps, metered valves, continuous valves, dry powder inhalers, unit and bi dose devices, and dispensing closures.
- 4.4 Exercise of Right of First Refusal. PURCHASER shall deliver a written notice informing the SELLER of any Development Activities for a new drug involving an Alternate Route of Administration within [...\*\*\*...] of starting any such activities, which notice shall include information describing such Development Activities and specify whether any Drug Delivery System is preferred or is then being researched or assessed. Within [...\*\*\*...] following SELLER's receipt of such notice, SELLER shall notify PURCHASER of its intention to exercise the right of first refusal set forth in Section 4.1. If SELLER decides to exercise such right, then (a) PURCHASER shall provide to SELLER all information related to the applicable Development Activities relevant for the design or manufacture of the Drug Delivery System and (b) SELLER shall have [...\*\*\*...] from the date all necessary information and materials are provided by PURCHASER to present a Drug Delivery

- System for such Alternate Route of Administration to the PURCHASER, but in no event later than [...\*\*\*...] from the date of SELLER's notice unless PURCHASER is responsible for any delays.
- 4.5 <u>Feasibility Studies.</u> If SELLER provides to PURCHASER within the allotted time a Drug Delivery System for use with any such Alternate Route of Administration Development Activities, PURCHASER shall perform a feasibility study with SELLER's Drug Delivery System in accordance with the terms of a feasibility agreement to be negotiated by the Parties in good faith. If such feasibility study is successful (as defined in the feasibility agreement), PURCHASER will be required to move forward with SELLER's Drug Delivery System and the Parties shall then negotiate a supply agreement under terms similar to this Agreement. If the feasibility study is unsuccessful, PURCHASER is free to seek alternate partners for such Drug Delivery System.

# 5. FORECASTS, ORDERS AND DELIVERY

- 5.1 <u>Estimates and Forecasts</u>. Prior to FDA Approval and upon SELLER's request, beginning on the first day of each calendar quarter, PURCHASER shall provide SELLER a non-binding written rolling estimate of purchases of the Device for the [... \*\*\*...] following the calendar quarter in which such estimate is submitted (the "<u>Estimate</u>"). The Estimate shall specify the desired delivery dates for each month submitted. PURCHASER shall use its best efforts to assure that each Estimate is accurate, provided however, that the Parties agree that such Estimate shall not constitute an obligation of PURCHASER to purchase the estimated quantities contained in the Estimate.
  - Following FDA Approval, on the first day of each calendar quarter, PURCHASER shall provide SELLER a written rolling forecast of purchases of the Device for the [...\*\*\*...] following the calendar quarter in which such forecast is submitted (the "Forecast"). The Forecast shall specify the desired delivery dates for each month submitted. PURCHASER shall use its best efforts to assure that each Forecast is accurate, provided however, that the Parties agree that such Forecast (other than the quantities set forth in the Purchase Order) shall not constitute an obligation of PURCHASER to purchase the estimated quantities contained in the Forecast and that SELLER may charge PURCHASER for otherwise un-reimbursed charges incurred due to reasonable commitments made by SELLER to suppliers based on such Forecast. PURCHASER agrees that the first [... \*\*\*...] of each Forecast shall be a firm purchase order of the Device by PURCHASER for which SELLER is authorized to commence production, and which PURCHASER shall purchase (the "Purchase Order").
- 5.2 <u>Delivery.</u> SELLER shall manufacture, package and deliver ordered quantities of the Device as long as such orders are within the scope of confirmed Purchase Orders. SELLER shall promptly notify PURCHASER if it will be unable to deliver any part of an order exceeding the quantities set forth on the confirmation of the Purchase Order. SELLER shall not be obligated to supply in any month any quantity of the

- Device exceeding [...\*\*\*...] of the Purchase Order, and PURCHASER shall purchase at least [...\*\*\*...] of the quantities set forth in the Purchase Order. SELLER will use its reasonable commercial efforts to deliver the Device within the time schedule set forth in the confirmation of the Purchase Order.
- 5.3 Terms of Delivery. Unless otherwise specified in the Purchase Order, SELLER of the Device to PURCHASER shall be via truck, and shall be delivered EXW Congers, NY manufacturing site (INCOTERMS 2010) to the place of destination in the United States of America named in the Purchase Order. In the event PURCHASER requests SELLER to transport the Device to PURCHASER via air, PURCHASER shall bear all additional costs of such air transportation. SELLER shall arrange for transportation of the Device by insured common carrier, or SELLER's truck to PURCHASER's specified plant or other designated destination in the United States of America. In the event PURCHASER requires delivery to destination outside the United States of America, new delivery terms shall be negotiated. The Purchase Price for the Device is based on EXW Congers, NY manufacturing site (INCOTERMS 2010). If the Device is manufactured outside the United States, SELLER and PURCHASER shall negotiate in good faith to agree on appropriate terms.
- 5.4 <u>Shipment</u>. SELLER shall ship the Device in multiples of full production lots, as defined in **Exhibit C**. SELLER shall deliver with each lot a Certificate of Analysis substantially in the form attached hereto as **Exhibit B**.

# 6. PRICES AND PAYMENT

- 6.1 Purchase Price. The Purchase Price for the Device is set forth in **Exhibit C.**
- 6.2 <u>Payment for the Device</u>. Payment related to the Device shall be made in full within [...\*\*\*...] of the date of SELLER's invoice. SELLER shall date and send invoices for the Device upon shipment of the Device.
- 6.3 <u>Taxes.</u> The Purchase Price for the Device does not include any property, license, privilege, sales, service, use, excise, value added, gross receipts, or other like taxes. PURCHASER agrees to pay or reimburse SELLER for any such taxes that SELLER is required to pay or collect or that are required to be withheld.
- 6.4 <u>Payment of Success Fee.</u> PURCHASER shall pay the Success Fee within [...\*\*\*...] of the date of the SELLER's invoice. SELLER shall date and send invoices for the Success Fee upon the terms defined in **Exhibit D.**
- 6.5 <u>Device Equipment Contribution.</u> PURCHASER shall pay the Device Equipment Contribution within [...\*\*\*...] of the date of the SELLER's invoice. SELLER shall date and send invoices upon the milestones defined in **Exhibit C.**
- 6.6 <u>Currency.</u> All payments hereunder shall be made in United States Dollars (USD).

- 6.8 Interest. If PURCHASER fails to pay the full invoiced amount for the Device, or any part thereof, within [...\*\*\*...] after the due date, SELLER shall be entitled (without prejudice to any other right or remedy it may have whether under the terms of this Agreement or otherwise) to charge, in addition to any monies due hereunder, interest on the outstanding amount at the rate of [...\*\*\*...] or the highest applicable rate allowed by law, whichever is less, calculated on a daily basis from such date until the date actual payment is made.
- 6.8 Price Revision Due to Changes in Device Specifications.
  - 6.8.1 By PURCHASER.

PURCHASER may request a change, in writing, to the Device Specifications, the manufacturing procedures or control procedures. SELLER will use commercially reasonable efforts to implement the change subject to pricing adjustments, which will be negotiated in good faith by SELLER and PURCHASER.

6.8.2 By SELLER.

SELLER will notify PURCHASER in writing prior to implementing any change affecting the chemical, biological or physical aspects of the Device. SELLER will not make any changes to the Device Specifications without PURCHASER's prior written consent shall not be unreasonably withheld or delayed. SELLER will implement the change subject to pricing adjustments, which will be negotiated in good faith by SELLER and PURCHASER.

6.8.3 By Regulatory Authorities.

In the event of changes required by cGMP's or other applicable laws or regulations, or in the requirements for the Device, whether written or un-written, by the Regulatory Authorities, SELLER shall have the right to adjust the Purchase Price, such adjustment being negotiated in good faith by SELLER and PURCHASER.

# 7. REGULATORY RESPONSIBILITY

7.1 Regulatory Responsibility. SELLER shall be responsible, at its sole expense, for complying with applicable regulatory requirements relating to the manufacture of the Device as applicable in SELLER's facilities where the Device is manufactured and, shall use commercially reasonable efforts to perform all of its responsibilities and obligations, including applicable design, development, manufacture, testing, quality control and documentation activities relating to the Device under or contemplated by this Agreement substantially in accordance with all relevant quality standards that must be met to secure regulatory approval worldwide.

PURCHASER shall be responsible, at its sole expense, for complying with all other applicable regulatory requirements relating to the use and sale or resale of the Finished Product.

7.2 Import and Export Laws. PURCHASER shall comply, at its sole expense, with all export and import regulations and laws necessary to export and import components of the Device to and from PURCHASER's premises, including without limitation, procuring and maintaining all import and export licenses necessary to ship from the point of manufacture to PURCHASER's premises in accordance herewith and the payment of all duties, tariffs, surcharges and other customs and other governmental fees levied in connection with the exportation and importation of components of the Device from SELLER to PURCHASER's premises, or such other location as designated by PURCHASER.

# 8. QUALITY CONTROL REQUIREMENTS

# 8.1 Quality

- 8.1.1 The Parties shall agree upon reasonable release tests to be performed by SELLER prior to shipment of the Device in accordance with applicable regulatory requirements and subject to pricing conditions. Results of such testing will be supplied in the Certificate of Analysis with each shipment as seen in **Exhibit B**.
- 8.1.2 PURCHASER shall send prior written notice of any change requested to be made to Drug Product being delivered by the Device that PURCHASER suspects may affect the Device Specifications.
- 8.1.3 Notwithstanding any provision to the contrary in this Agreement, SELLER shall not assign or otherwise delegate any of its obligations to ensure the Device's quality or compliance with Device Specifications to any third party other than an Affiliate without consent from the PURCHASER.

# 8.2 PURCHASER's Inspections.

- 8.2.1 The Device shall be subjected to a quality control inspection by PURCHASER in accordance with the Device Specifications set forth in **Exhibit A**, within [...\*\*\*...] as from delivery of the Device to the location designated by PURCHASER in the applicable Purchase Order.
- 8.2.2 Upon reasonable prior notice, SELLER shall permit PURCHASER to review SELLER's quality control procedures and records related to the Device for the purpose of assuring satisfactory compliance with the Device Specifications and compliance with the provisions of the Quality Agreement. That review shall be conducted in a reasonable manner, during SELLER's business hours, in the presence of a SELLER representative and at PURCHASER's own expense.
- 8.2.3 Upon reasonable prior notice, SELLER may permit PURCHASER's quality assurance personnel to visit SELLER's production facility, to the extent that such visit is reasonably required to assure compliance with regulatory requirements or to the extent a review of records alone is not adequate to

- assure satisfaction with such quality control requirements. Such visit shall be conducted in a reasonable manner, during SELLER's business hours, in the presence of a SELLER representative, at PURCHASER's own expense and shall be limited to the equipment, records or production actually used in the manufacture of the Device.
- 8.2.4 SELLER shall (i) participate and cooperate with PURCHASER's personnel who may visit SELLER's production facility as provided in this Section 8, (ii) take corrective action in a timely manner as may be reasonably required by PURCHASER to comply with the provisions of this Agreement and with cGMP requirements when applicable, subject to pricing conditions in Sections 4 and Exhibit C, and (iii) when requested by PURCHASER, describe in writing, any appropriate corrective action planned or taken.

# 8.3 Regulatory Inspections.

- 8.3.1 In the event that any of SELLER's products, facilities and/or processes that are used for the manufacture of the Device are the subject of an inspection related to PURCHASER by any Regulatory Authority or any other duly authorized agency of any national, state, or local government, SELLER shall promptly notify PURCHASER of such inspection and shall supply PURCHASER with copies of any correspondence or portions of correspondence that relate to the Device, as well as SELLER's proposed response, if any.
- 8.3.2 In the event that any of PURCHASER's facilities that are used for the storage of the Device or the manufacturing of the Finished Product are the subject of an inspection by any Regulatory Authority or any other duly authorized agency of any national, state, or local government, PURCHASER shall promptly notify SELLER of such inspection and shall supply SELLER with copies of any correspondence or portions of correspondence that relate to the Device, as well as PURCHASER's proposed response, if any.
- 8.3.3 In the event that either Party receives any written communications from any Regulatory Authority in connection with the manufacture, use, or sale of the Device for PURCHASER, it shall provide the other Party with a copy of each such communication and the proposed response, if any.
- 8.3.4 <u>Records.</u> SELLER shall retain samples of the Device, batch and other manufacturing and analytical records, records of shipments of the Device and validation data relating to the Device for a minimum of [...\*\*\*...] and shall make such data available to PURCHASER and Regulatory Authorities upon PURCHASER's reasonable request or if required by law.

#### 9. REJECTION

9.1 <u>General</u>. In the event that any portion of the Device delivered to PURCHASER by SELLER shall fail to conform with the Device Specifications, PURCHASER may

- reject that portion by giving written notice within [...\*\*\*...] following receipt of Products and sending, at SELLER's expense, the defective samples to SELLER after SELLER's acceptance of rejection. Failure to report claim within that period, PURCHASER shall be considered as having accepted delivery and SELLER shall not be held liable with respect to the defective Device.
- 9.2 Unattributed Defects. In case the Device does not comply with the Device Specifications due to hidden or latent defects that were not noticeable at the time of inspection by PURCHASER pursuant to Section 8.2, PURCHASER shall immediately inform SELLER of its claims in this respect, at the latest within the later period of [...\*\*\*...] following the discovery of the defect or any third party or regulatory claim or liability arising from the defect. Failing any claims within [...\*\*\*...] in this respect, it shall not be possible to engage SELLER's liability. Notwithstanding the foregoing, SELLER shall not be liable for any defect appearing more than [...\*\*\*...] after the Device (stored and handled in accordance with commercially reasonable standards) is received at PURCHASER's premises.
- 9.3 <u>Claims.</u> Any and all claims shall be substantiated and explained in reasonable detail as to the nature of the defects or failure of the Device to comply with the Device Specifications. PURCHASER shall reasonably provide SELLER with any and all substantiation regarding the reality of the anomalies recorded, notably with defective samples and shall ensure that SELLER has reasonable means of confirming the existence of such anomalies.
- 9.4 Rejected Device. If PURCHASER rejects the Device in accordance with this Section 9, and after SELLER's formal acceptance of such rejection, then, at SELLER's expense and discretion, PURCHASER shall return to SELLER any such shipment, or any part thereof, that does not comply with the Device Specifications, and receive in exchange therefore at the option of PURCHASER or SELLER, either (i) a complete refund of the Purchase Price, taxes paid and not recoverable, and shipping costs associated with the Device in form of a credit note, or (ii) fully compliant replacement Device. If the Parties so agree, PURCHASER shall destroy any non-conforming Device, at SELLER's expense and in accordance with all applicable legal requirements. While SELLER is investigating the rejection, payments of purchased goods subject to such rejection shall be put on hold until claim response is given.
- 9.5 <u>Disputes</u>. If SELLER disputes PURCHASER's rejection, the Parties shall submit samples of the rejected Device to a mutually acceptable independent laboratory for analysis, whose decision in the matter shall be final and binding. The costs of such analysis shall be borne by SELLER unless such analysis shows that the Device conforms to the Device Specifications, in which case PURCHASER shall bear the cost of such analysis.

#### 10. WARRANTY

10.1 SELLER's Warranty.

- 10.1.1 SELLER warrants to PURCHASER that the Device, at the time of delivery to PURCHASER as provided in Section 5.2, will conform in all respects to the Device Specifications.
- 10.1.2 SELLER does not warrant that the Device may be suitable for the manufacture of any intermediate or finished product (including the Finished Product).
- 10.1.3 It is the exclusive responsibility of PURCHASER to ensure that (i) the Device shipped from SELLER according to the Device Specifications is adapted to the use which it is intended for, (ii) that the Device Specifications are adapted to the storage of the Device, (iii) that the Device is compatible with the Drug Product, and (iv) that the Drug Product and the Finished Product (other than the Device) comply with all applicable laws.
- 10.1.4 SELLER may, but is not required to, perform tests for compatibility between the Device and the Drug Product. SELLER MAKES NO REPRESENTATION OR WARRANTY THAT ANY TESTS PERFORMED BY OR ON BEHALF OF SELLER ARE ADEQUATE OR SUFFICIENT FOR PURCHASER'S PURPOSES. PURCHASER AGREES NOT TO HOLD SELLER RESPONSIBLE FOR THE ADEQUACY OR SUFFICIENCY OF SUCH TESTS, OR THE RESULTS DERIVED FROM SUCH TESTS.
- 10.2 Exclusions. The warranty provided under Section 10.1(a) shall not apply to any Device that (i) has been tampered with or otherwise altered by PURCHASER, its Affiliates or their customers, distributors agents; (ii) has been subjected to misuse, negligence, malice or accident by PURCHASER, its Affiliates or their customers, distributors agents; or (iii) has been stored, handled or used by PURCHASER, its Affiliates or their customers, distributors agents in a manner contrary to the Device Specifications and the Device Specifications or SELLER's written instructions which can, among others, define maximum periods for the use of the Device.
- 10.3 <u>Limitations on Warranty.</u> THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES OF QUALITY AND PERFORMANCE, WRITTEN, ORAL OR IMPLIED, AND ALL OTHER WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, ARE HEREBY DISCLAIMED BY SELLER.

#### 10.4 LIMITATION OF LIABILITY

10.4.1 No Consequential Damages. IN NO EVENT SHALL SELLER BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, whether in warranty, contract, negligence, tort, strict liability, or otherwise including, but not limited to, loss of profits or revenue, delays, or

- claims of customers of PURCHASER or its Affiliates or other third parties for such or other damages. This limitation of liability shall not apply to claims of liability for death or personal injury caused by SELLER's gross negligence, willful act, or omission.
- 10.4.2 <u>Limitation of Liability.</u> Each Party's cumulative liability to the other Party for all claims relating to the Device and this Agreement, including any cause of action based on any theory of contract, tort, or strict liability, shall not exceed One Million US Dollars (\$1,000,000). This limitation of liability shall not apply to claims of liability for death or personal injury caused by either Party's gross negligence, willful act, or omission. In this respect, PURCHASER expressly undertakes to inform all of its customers, Affiliates or other third parties of the conditions and maximum periods defined for the use of the Device, by any appropriate means making it possible to inform the said customers, Affiliates or other third parties, prior to use of the Device.

#### 11. INDEMNIFICATION

- 11.1 <u>SELLER</u>. Subject to the liability limitations set forth in clause 10.4, SELLER shall defend, indemnify and hold PURCHASER and its Affiliates, and their shareholders, directors, officers, employees and agents harmless from and against any and all liability, loss, damage, recalls, causes of action, suits, claims, demands, settlements, costs and expenses or judgments arising from injury or death to persons or damage to property, of any nature whatsoever, resulting from the failure of the Device to conform to the warranty set forth under Section 10.1, provided that PURCHASER shall have given prompt notice in writing to SELLER of any such claim.
- 11.2 PURCHASER. PURCHASER shall defend, indemnify and hold SELLER and its Affiliates, their shareholders, directors, officers, employees and agents harmless from and against any and all liability, loss, damage, expense, causes of action, suits, claims, demands, settlements, costs and expenses or judgments of any nature whatsoever, resulting from the Finished Product or its marketing, sale, clinical testing, clinical use or other use or misuse, including any defect, failure to warn or other Device liability claims, except to the extent SELLER is required to indemnify PURCHASER under Section 10.1 of this Agreement, provided that SELLER shall have given prompt notice in writing to PURCHASER of any such claim.
- 11.3 Insurance. Each of SELLER and PURCHASER will use its best efforts, by itself or through its Affiliates' group insurance policies and at its sole cost and expense, to procure and maintain adequate General & Products Liability Insurance. In addition, SELLER will use its best efforts, by itself or through its Affiliates' group insurance policies and at its sole cost and expense, to procure and maintain adequate Property All Risks Insurance in order to cover the value of the Device Equipment and any components thereof in SELLER's possession or for which SELLER bears the risk of loss.

# 12. REPRESENTATIONS

12.1 Each Party hereby represents and warrants that it has the full power and authority to enter into and perform this Agreement, and each Party knows of no contract, agreement, promise, undertaking or other fact or circumstance that would prevent the full execution and performance of this Agreement.

#### 13. TERM AND TERMINATION

- 13.1 <u>Term.</u> This Agreement shall, unless otherwise terminated, remain in full force and effect for a period of five (5) years from the Effective Date (the "<u>Initial Term</u>"), at which time, the Parties shall discuss in good faith negotiations an extension of this Agreement.
- 13.2 <u>Early Termination.</u> Without prejudice to any other rights it may have hereunder or at law or in equity, either Party may terminate this Agreement:
  - 13.2.1 immediately if the other Party makes an assignment for the benefit of its creditors or a receiver or custodian is appointed for it or its business is placed under attachment, garnishment or other process involving a significant portion of its business;
  - 13.2.2 after [...\*\*\*...] written notice from the terminating Party specifying an alleged material breach (including payment breach) and stating its intent to so terminate, if the other Party fails to commence and diligently pursue to remedy any such material breach of this Agreement;
  - 13.2.3 immediately if the other Party becomes insolvent, an order for relief is entered against the other Party under any bankruptcy or insolvency laws or laws of similar import; or
  - 13.2.4 upon [...\*\*\*...] written notice from the terminating Party if the Device does not receive FDA Approval by January 1, 2013
- 13.3 <u>Effect of Termination</u>. Neither termination nor non-renewal of this Agreement shall release either Party from fulfilling any obligations it may have incurred prior to any such termination, nor prejudice any other rights or remedies that either Party may have at law or in equity.

In case of early termination by PURCHASER not due to a breach by SELLER, PURCHASER will compensate SELLER for any costs directly related to the value of the goods or components already incurred by SELLER on the basis of the Purchase Orders received from PURCHASER according to Section 5.1 above. PURCHASER will also compensate SELLER for any costs associated with stock at SELLER's or at SELLER's sub suppliers, including, but not limited to, rubber stoppers, glass vials, and steel needles; provided SELLER and SELLER's sub suppliers shall be obligated to take all commercially reasonable measures to mitigate the damages resulting from such remaining inventory.

13.4 <u>Surviving Clauses</u>. Notwithstanding any such termination, any provision set forth in this Agreement remaining to be performed in whole or in part, capable of taking effect following termination, or which by its nature is contemplated to survive the termination of this Agreement shall survive and continue in full force and effect despite termination.

#### 14. MISCELLANEOUS

14.1 Notices. All notices, requests, demands, waivers, consents, approvals or other communications to any Party hereunder shall be in writing and shall be deemed to have been duly given if delivered personally to such Party or sent to such Party by facsimile transmission, overnight courier or by registered or certified mail, postage prepaid, to the addresses set forth below (or to such other addresses as the addressee may have specified in notice duly given to the sender as provided herein):

#### If to SELLER:

AptarGroup, Inc. 475 West Terra Cotta, Suite E Crystal Lake, IL 60014-9695 USA Attn: Chief Operating Officer Phone No.: (815) 477-0424 Fax No.: (815) 477-0481

#### With cc to:

Aptar Congers, a division of AptarGroup, Inc. 250 North Route 303 Congers, NJ 10920-1408 USA Attn: President, Aptar Pharma North America Phone No.: (845) 639-3700

# Fax No: (845) 639-3900 If to PURCHASER:

Name: INSYS

10220 South 51st Street, Suite 2 Pheonix, AZ 85044 USA

Attn: President

Phone No.: (602) 910 2617 x9021

Fax No.: (602) 910-2627

Such notice, request, demand, waiver, consent, approval or other communications will be deemed to have been given as of the date so delivered, sent by facsimile transmission with receipt confirmed, or [...\*\*\*...] after so mailed.

14.2 <u>Choice of Law</u>. This Agreement, along with the Schedules and Exhibits attached, incorporated and referenced herein and all Purchase Orders issued hereunder shall be governed and interpreted, and all rights and obligations of the Parties shall be determined, in accordance to the laws of the State of New York.

- 14.3 Force Majeure. Neither Party shall be responsible or liable in any way for failure or delay in carrying out the terms of this Agreement resulting from any cause or circumstance beyond that Party's reasonable control, including, but not limited to, fire, flood, other natural disasters, war, labor difficulties, interruption of transit, accident, explosion, civil commotion, and acts of any governmental authority; nor shall SELLER be responsible or liable in any way for failure or delay in carrying out the terms of this Agreement if due to any shortage or inability to obtain any raw materials (including energy), equipment or transportation; provided, in each case, that the affected Party shall give prompt notice thereof to the other Party. No such failure or delay shall terminate this Agreement, and each Party shall complete its obligations hereunder as promptly as reasonably practicable following cessation of the cause or circumstances of such failure or delay; provided, that if any of the above conditions continues to exist for more than [...\*\*\*...] after the date of any notice given with regard thereto, either Party may terminate this Agreement forthwith upon notice to the other.
- 14.4 Severability. In the event that any provision of this Agreement shall be found in any jurisdiction to be in violation of public policy or illegal or unenforceable at law or in equity, such finding shall in no event invalidate any other provision of this Agreement in that jurisdiction, and this Agreement shall be deemed amended to the minimum extent required to comply with the law of such jurisdiction, such provision being adjusted rather than voided if possible.
- 14.5 Entire Agreement. This Agreement, including any Schedules and Exhibits attached, incorporated or referenced herein, the Quality Agreement, and the confidentiality agreement referenced in Section 14.9 set forth the entire agreement reached between the Parties with respect to the transactions contemplated hereby. This Agreement (including all Schedules and Exhibits) may not be amended or modified except by written instrument duly executed by the Parties hereto stating that it is an amendment to this Agreement.
  - With the reservation of the specific provisions of this Agreement and of the Quality Agreement, SELLER's general conditions of sales, attached as Exhibit E, shall apply to all sales closed in the framework of this Agreement, to the exclusion of any and all general conditions of purchase which may be communicated by PURCHASER.
  - The terms of this Agreement shall take precedence over the Qualtiy Agreement, the confidentiality agreement referenced in Section 14.9 or the standard terms and conditions set forth in Exhibit E if there is any conflict between them.
- 14.6 No Waiver. The failure of either Party hereto to enforce at any time, or for any period of time, any provision of this Agreement shall not be construed as a waiver of such provision or of the right of such Party thereafter to enforce each and every provision. Any waiver by a Party of any of its rights under this Agreement in one or more instances shall be in a writing signed by such Party and shall not be construed as constituting a continuing waiver or as a waiver in other instances.

- 14.7 <u>Assignment, Binding Effect.</u> Neither Party shall assign this Agreement nor any of its respective rights or obligations hereunder without the prior written consent of the other Party, which consent will not be unreasonably withheld, except to any Affiliate of the assigning Party or by operation of law or as otherwise permitted hereunder. Any such attempted assignment without such consent shall be void. This Agreement and the rights herein granted shall be binding upon and shall inure to the benefit of PURCHASER and SELLER and their respective successors and permitted assigns.
- 14.8 <u>Arbitration.</u> Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity hereof, that the Parties are unable to resolve between themselves, shall be settled by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. Such proceedings shall take place in New York, USA, and shall be conducted in English. The decision of the arbitration proceeding shall be final and binding upon the Parties. This clause shall not be construed to limit the right of either Party to apply to any court of competent jurisdiction for injunctive relief for unauthorized use of confidential information.
- 14.9 <u>Confidentiality.</u> A separate agreement signed April 16, 2010 relating to confidentiality has been entered into by the Parties and that agreement constitutes the entire agreement and understanding of the Parties relating to the subject matter of confidentiality and supersedes any previous agreement or understanding between the Parties in relation to such subject matter.

[Signature page follows].

IN WITNESS WHEREOF, this Agreement has been duly executed and delivered as of the day and year first above written.

/s/ Stephen J. Hagge

APTARGROUP, INC. Name: Stephen J. Hagge

Title: Exec. V.P. & Chief Operating Officer

Date: May 26, 2011

/s/ Michael Babich

INSYS THERAPEUTICS, INC.

Name: Michael Babich Title: President and CEO

Date: 5/31/11

[Signature page of Supply Agreement between AptarGroup, Inc. and Insys Therapeutics, Inc.]

# **EXHIBIT A: DEVICE SPECIFICATION**

[...\*\*\*...]

\*\*\*Confidential Treatment Requested

# EXHIBIT B: SELLER CERTIFICAT OF ANALYSIS + SELLER STANDARD SPECIFICATION

[...\*\*\*...]

\*\*\*Confidential Treatment Requested

#### **EXHIBIT C: PURCHASE PRICE**

[The purchase price for the Device ("Purchase Price") is based on the procured annual quantities of the Device in accordance with Table C1 below:

# **Table C.1 Device Purchasing Price Levels**

Price Level	Quantities (pieces)	Price ([***])
1	[***]	\$[***]
2	$[\dots^{***}\dots]$	\$[***]
3	$[\dots^{***}\dots]$	\$[***]
4	$[\dots^{***}\dots]$	\$[***]
5	$[\dots^{***}\dots]$	\$[***]

Notwithstanding the above, SELLER grants PURCHASER a Purchase Price equal to Price Level [...\*\*\*...] subject to PURCHASER's procurement of the yearly quantity of units of the Device from the SELLER as described below in Table C.2. Year 1 is defined as the time period leading up to FDA Approval and the first year from the date of FDA Approval of the Finished Product. For this time period a price of \$[...\*\*\*...] will be offered as long as Year 1 Minimum Yearly Quantity is met. Year 2 is defined as the second year from the date following FDA Approval. For this time period a price of \$[...\*\*\*...] will be offered as long as Year 2 Minimum Yearly Quantity is met. Year 3 is defined as the third year from the date following FDA Approval of the Finished Product. For this time period a price of \$[...\*\*\*...] will be offered as long as Year 3 Minimum Yearly Quantity is met. Year 4 is defined as the fourth year from the date following FDA Approval of the Finished Product. For this time period a price of \$[...\*\*\*...] will be offered as long as Year 4 Minimum Yearly Quantity is met.

# **Table C.2 Minimum Yearly Quantities**

	Minimum Yearly	Cumulative Yearly	
Year	Quantity	Quantity	Price ([***])
1	[***]	[***]	\$[***]
2	[***]	[***]	\$[***]
3	[***]	[***]	\$[***]
4	[***]	[***]	\$[***]

In case PURCHASER has not met the Minimum Yearly Quantities set forth in Table C.2 for any reason other than for SELLER's fault, pricing for the quantities purchased will be adjusted to the appropriate pricing level as outlined in Table C.1 above and a supplemental invoice will be issued for the difference retroactively at the end of Year 1, Year 2, Year 3 and Year 4 and PURCHASER will pay the resulting difference to SELLER. At the end of the then current Year, SELLER shall calculate the Minimum Yearly Quantities based on the quantities of the Device delivered to PURCHASER pursuant to Purchase Orders placed for such year. At such time, if PURCHASER has not met the Minimum Yearly Quantities, then SELLER shall send an invoice setting forth (i) a calculation of the actual shipped quantities of the Device at the applicable Purchase Price and (ii) the difference between such due amount and any amounts paid by

PURCHASER as of such date. PURCHASER shall pay such invoiced amount in full within [...\*\*\*...] of the date of SELLER's invoice.

In the event that Purchaser fails to fulfill the Minimum Yearly Quantities for [...\*\*\*...] and [...\*\*\*...], SELLER retains the right to reevaluate the Price Levels as set forth above in Schedule C.1, taking into account the Producer Price Index ("All Other Plastics Product Manufacturing") from the US Bureau of Labor Statistics.

The Parties agree to meet in good faith to discuss extension of supply no later than [...\*\*\*...] prior to the end of the Year 4 as set forth in this Agreement. SELLER agrees to extend the supply term in one-year increments, beginning Year 5, provided, SELLER and PURCHASER find an agreement on terms and conditions similar to the ones set forth in this Agreement. In particular prices need to be agreed by SELLER prior to any extension of this Agreement. Year 5 is defined as the fifth year following FDA Approval of the Finished Product.

The Parties agree that prices may be adjusted annually based on the Producer Price Index ("All Other Plastics Product Manufacturing") from the US Bureau of Labor Statistics.

The lot size for the Device is no less than [...\*\*\*...] units and no more than [...\*\*\*...] units.

The SELLER's standard packaging and packing specifications are attached in Exhibit F.

# Currency Adjustments.

SELLER shall calculate the impact of such evolution and inform PURCHASER accordingly. For purposes of clarity, this mechanism is designed for the parties to share the risk of currency fluctuations.

Currency adjustments only apply for products related to the Device made and imported from Europe ("Imported Products"). As of the Effective Date, two (2) components of the device are imported from Europe.

On [...\*\*\*...] of each year of this Agreement (the "Currency Adjustment Date"), the Purchase Price of Imported Products only will be revised to reflect fluctuation of the currency exchange rate between the US Dollar and the Euro, compared to the initial base exchange rate on December 31st, 2009, which shall be [£1 =US\$1.40] (the "Base Rate"). On each Currency Adjustment Date, the average exchange rate of the Euro to the US Dollar shall be calculated since the Effective Date or for the prior twelve (12) months. If such floating average differs from the Base Rate then in effect by at least [...\*\*\*...] then, and only then, will the percentage change (positive or negative) to the exchange rate over such twelve (12) month period shall be computed and [...\*\*\*...] of such percentage change shall be multiplied by the then current US Price to determine the actual US Price that SELLER will invoice to PURCHASER

for all Devices shipped to PURCHASER for after such Currency Adjustment Date. Examples of the calculation of the currency adjustment described herein are set forth below.

# Sample Calculation for Currency Pricing Adjustment

- 1) If the Floating Average Rate as of [...\*\*\*...] = [...\*\*\*...], then NO CHANGE ([...\*\*\*...] g 1.40 < [...\*\*\*...]).
- 2) If the Floating Average Rate as of [...\*\*\*...] = [...\*\*\*...], the Price will be adjusted as follows:

# **Device Equipment Contribution**

The Device Equipment Contribution to be paid by PURCHASER to SELLER is US-\$ [...\*\*\*...]. This contribution includes SELLER's standard validation process. Any extra work, such as, but not limited to, analytical testing, performance studies or extractable studies, shall be subject to reasonable commercial terms.

# Invoice Milestones for Device Equipment Costs

First Payment: US-\$[...\*\*\*...] Milestone: the Effective Date.

Second Payment: US-\$[...\*\*\*...]

Milestone: first available samples of all components out of moulds.

Third payment: US-\$[...\*\*\*...]

Milestone: qualified components within specification.

Fourth payment: US-\$[...\*\*\*...]

Milestone: Operational Qualification, Installation Qualification, Performance Qualification of assembly equipment.

All prices for Device Equipment are calculated using an exchange rate of  $1 \in 1.40$  US-\$. On any day that any milestone payment for the Device Equipment is invoiced by SELLER to PURCHASER, the US-\$ amount shall be calculated utilizing an exchange rate equal to the final daily exchange rate as published in the Wall Street Journal, or if the Wall Street Journal ceases to publish an exchange rate, such comparable publication.

#### **EXHIBIT D: EXCLUSIVITY**

SELLER is willing to supply the Device to PURCHASER on an exclusive basis ("<u>Exclusivity</u>") for the specific application defined below and in accordance with the following terms:

# 1. Application, Drug molecule

For sublingual/buccal unit dose application of liquid formulations of Fentanyl.

# 2. Exclusivity Payments

Notwithstanding the provisions set forth in **Exhibit C** or further provisions set forth in this **Exhibit D**, to retain the exclusive rights to the Device globally will be as follows.

Upon receipt of FDA Approval of the Finished Product, a Success Fee of [...\*\*\*...] will be paid by the PURCHASER to the SELLER. The Success Fee will be paid by the PURCHASER in [...\*\*\*...], with [...\*\*\*...]. This will grant PURCHASER Exclusivity from the date of NDA submission of the Finished Product to end of the first year from the date following FDA Approval of the Finished Product, Year 1.

To maintain Exclusivity in the United States for all subsequent years, an annual purchase and delivery requirement of the Device shall be a minimum of [...\*\*\*...] (the "Exclusivity Quantity or Exclusive Quantities"). Commercially available IMS data will be purchased by the PURCHASER and distributed to the SELLER on a [...\*\*\*...] basis of the non-extended release Fentanyl products. This includes the currently existing non-extended release Fentanyl products and future launched non-extended release Fentanyl products. To maintain Exclusivity in the rest of the world, PURCHASER, in addition to the purchase of the minimum Exclusive Quantities, must actively seek Marketing Approval (e.g. public press release, European clinical trials, or public licensing announcements) for the Finished Product in one or more major markets in Europe (e.g. France, Germany and the United Kingdom) within [...\*\*\*...] of the FDA Approval of the Finished Product.

In the event that the PURCHASER has not purchased the Exclusivity Quantity, Purchaser will pay shortfall compensation to Seller in the amount of [...\*\*\*...] of Devices not procured, with payment in full due within fifteen (15) days of notification from SELLER (the "Shortfall Fee"). In the event that Purchaser fails to fulfill the Exclusivity Quantity requirement for [... \*\*\*...] consecutive [...\*\*\*...], SELLER retains the right to terminate any and all Exclusivity terms previously granted to Purchaser and reevaluate the pricing set forth in **Exhibit C** of this Agreement.

The SHORTFALL FEE shall be calculated on [...\*\*\*...] basis, starting with [...\*\*\*...] with the issue of the first purchase order by PURCHASER. If the number of Devices per [...\*\*\*...] exceeds the Exclusivity Quantity for the previous [...\*\*\*...], such exceeding quantities shall not be taken into consideration for the following [...\*\*\*...]. In no event shall SHORTFALL FEE be due or owing in the event of a failure or inability of Seller to supply the Device during such [...\*\*\*...] period.

Exclusivity expires immediately, should regulatory approval be revoked or should the Finished Product be withdrawn from the market in the US.

# 3. <u>Territory</u>

To the extent permitted by applicable law and as otherwise provided herein, the territory of Exclusivity granted by SELLER is valid worldwide.

# 4. <u>Timeline</u>

Based on payment of the Success Fee and on the minimum quantities purchased set forth above, Seller is willing to grant Exclusivity to Purchaser commencing upon date of NDA submission of the Finished Product, unless by the date of signature of this contract SELLER has entered into other obligations with third parties which may be adversely affected by granting such Exclusivity. Exclusivity terms as stated in this Exhibit D are granted until the end of [...\*\*\*...] or [...\*\*\*...], whichever comes first ("Exclusivity Term"). The Parties agree to meet in good faith to discuss extension of Exclusivity no later than [...\*\*\*...] prior to the end of the Exclusivity term as set forth in this Agreement.

#### **EXHIBIT E: STANDARD TERMS AND CONDITIONS**

# Aptar 🚄

#### APTARGROUP, INC. TERMS AND CONDITIONS OF SALE

# 1. CONFLICTING TERMS AND CONDITIONS

The following are the terms and conditions of sale (collectively, "Conditions of Sale") The all products (the "Products") sold by Aptargroup, Inc. (the "Company") to the buyer ("Buyer"). Any Company quotation (each, a "Quotation") or order confirmation (each, an "Order Confirmation") is an offer subject to and expressly conditioned upon these Conditions of Sale, except to the extent otherwise stated or agreed by the Company in writing Any provisions, conditions, or terms contained in Buyer's purchase order (each, a "Purchase Order") which are in addition to or not consistent with the Company's offer and these Conditions of Sale, are null and void and not binding on the Company. Buyer and Company agree that these Conditions of Sale are the exclusive terms and conditions of sale between Buyer and Company with respect to the Products, that they apply to all Purchase Orders accepted by Company as provided in Section 2.c below (each, an "Order") and that they supersede and replace all other prior and contemporaneous quotes, proposals, and other communications and understandings between the parties, whether oral, written, electronic or implied, relating to the subject matter hereof. In the event of any conflict between these Conditions of Sale and Company's special terms as set out in a Quotation and/or an Order Confirmation and/or any other separate written document issued by Company, the provisions of such special terms shall prevail over the provisions of the Conditions of Sale.

#### 2. PRICES, ORDERS, INVOICES AND PAYMENT

- Unless otherwise specified, prices quoted are for the Products only, and do not include any amount for freight, insurance, fees, custom duties, or Federal, State or Local excise, sales, use, service, occupation, gross income, property or similar became server, seek, size, seek responsibility of the Buyer. The Company shall have the right to include taxes which may be applicable to the prices for the Products in the event that Buyer does not supply the Company, prior to sale of the Products to Buyer, appropriate sales, use, excise or other applicable tax exemption certificates. Prices quoted are subject to change or cancellation at any time without notice and in any event expire thirty (30) days following the date of the quote, unless otherwise indicated therein or extended in writing by Company.
- Company reserves the right to make adjustments to pricing. Product offerings and Product warranties for reasons including, without limitation, changing market conditions, Product discontinuation, Product and raw material unavailability, manufacturer price changes, supplier price changes and errors in quotes or advertisement
- All Purchase Orders are subject to acceptance by Company. Company shall not be bound to sell any Products to Buyer unless Company has accepted a Purchase Order by issuing a written Order Confirmation to Buyer or by shipping Product
- Order by Issuing a written County of the Super and Company in writing, Company invoices shall be due and payable in U.S. Dollars thirty (30) days from the date of Company's invoice, without deduction, withholding or set-off. If Buyer at any time is delinquent in the payment of any invoice, Company may in its sole discretion, and without prejudice to its other rights, withhold shipment of any Order. Any sum not paid by Buyer when the shall bear interest until paid at a rate of 1.5% per month or the maximum rate permitted by applicable law, whichever is lower. In the event of a payment default, Buyer shall be responsible for all of Company's costs of collection including, but not limited to, court costs, filling fees and attorneys fees. Partial payments shall be applied in the following order of priority. (i) outstanding invoices (oldest first); (ii) any late payment interest, and
- (iii) payment of expenses incurred by Company in recovering late payments.

  The Quotation is subject to the Company's current credit policies and practices. The Company reserves the right, in its sole discretion, to approve, disapprove, or change Buyer's credit limit or to impose credit terms, including without limitation the requirement that Buyer make full or partial advance payment. In the event of a complete or partial failure to pay, the Company may, at its option, revoke any credit extended to Buyer, suspend all shipments under open Orders until Buyer's account is current, or offset such amount against any payments due or that become due from the Company or its Affiliates to Buyer including without limitation payment due to Buyer.
- For good and valuable consideration, the receipt and sufficiency of which Buye hereby acknowledges. Buyer grants to the Company a security interest and right of possession in and to the Products covered hereby, and all accessions, replacements, proceeds, and products thereto or therefrom to secure payment of the purchase price of such Products until Buyer makes full payment. Buyer will cooperate in whatever manner necessary to assist the Company in perfecting and recording such security interest.

For shipments within the United States, all Product deliveries are made F.O.B. the Company's shipping location, freight collect. For international shipments, deliveries are made in accordance with the 2010 Incoterm of the International Chamber of Commerce as set forth in the applicable Quotation. Title and risk of loss or damage to Products shipped within the United States shall pass to Buyer upon delivery of the Products to the Buyer at the F.O.B. delivery point, shipment for sales within the United States. For international shipments, title and risk of loss or damage to the Products will pass to Buyer upon delivery of the Products to the applicable Incoterms 2010 delivery point. Should Buyer or its carrier fail to

pick up the Products on the scheduled delivery date, the Company reserves the right to invoice Buyer reasonable storage fees for the Products from and after such date. Company may also give Buyer notice of its intent to sell the Products, set a reasonable grace period for pick-up and then sell the Products at a commercially reasonable price without prejudice to its right to claim damages from Buyer for any shortfall resulting from such sale or account to the Buyer for any excess achieved over the price in the Order Confirmation, in both cases having taken into

Delivery dates for Products provided by Company are not guaranteed dates for delivery dates for Products. Lead times for deliveries, if provided in the Quotation, shall not commence until Buyer has provided Company with all technical information necessary to process the Order and/or set up the means of credit or

payment provided for in the Order Confirmation.

Buyer shall arrange for receipt of the Products per the acknowledged and accepted. scheduled delivery date noted on the Order Confirmation. Failure to take delivery of Products on the scheduled date will result in a storage fee assessed at a monthly rate of 2.5% of the value of the Products.

Unless otherwise agreed to by Company in writing, the quantity of every Order for Products delivered by Company may be up to five percent (5%) greater or less than the quantity specified in the Order Confirmation, and Company may invoice Buyer, and Buyer shall pay Company, for such greater or lesser quantity

Company reserves the right to ship and invoice Orders in installments.

Any claim for short shipment must be made in writing to Company within three

(3) days following the date of delivery of the relevant shipment of Products.

Buyer shall accept or reject Products within thirty (30) days following delivery. In the event that Buyer fails to notify Company in writing of rejection and the specific grounds therefor within such time period, Buyer shall be conclusively deemed to have accepted such Products without qualification.

#### 4. CHANGE OR CANCELLATION OF ORDERS

Upon receipt of the Purchase Order from the Buyer, the Company reserves the right to immediately procure materials and start production. The Buyer shall be liable for any raw materials, components or finished goods purchased or produced at the time of any Purchase Order change or cancellation.

#### 5. PRODUCT SUTTABILITY

- It is the Buyer's sole responsibility to (i) choose the Products and define any special or customised technical or packaging specifications for the Products, (ii) ensure that the Products that it orders from the Company are suited for their intended use, (iii) ensure the Products are compatible with the content that the Buyer is to put in the finished packaging and products sold by the Buyer and (iv) ensure compliance with all applicable regulations of the finished products that
- IT IMERSES.

  Company may perform tests for compatibility, such testing, however, is not a duty of Company. COMPANY MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, THAT ANY TESTS BY COMPANY ARE ADEQUATE OR SUFFICIENT FOR BUYER'S PURPOSE, AND BUYER AGREES NOT TO HOLD COMPANY RESPONSIBLE FOR SUCH ADEQUACY OR SUFFICIENCY.

#### 6. WARRANTY

- Prototypes, samples and other development Products are sold "AS-IS" and without any representation or warranty, express or implied.
- Products sold hereunder are warranted by the Company to be free from defects under normal use and conform to the specifications provided by Company along with the Quotation for the Products or, with respect to orders for Products set out in an Order Confirmation, to Buyer's written specifications previously accepted by the Company in writing. Unless otherwise agreed upon by the parties in writing. Buyer's rights under this warranty are extended for a period of one (1) year from and after the date of delivery of the Products to Buyer. Company is not responsible for normal wear and tear of the Products, Buyer's negligence or any non-conformity or defect in the Products that (i) is created after the Product is shipped by Company, including any non-conformity/defect resulting from Buyer's negligence, handling, maintenance or failure to properly use, maintain or store the Products; (iii) results from modifications to the Products by Buyer or a third party, or (iii) results from components or materials provided by or on behalf of Buyer. Briver's sole and exclusive remedy, and the Company's sole and exclusive obligation under this warranty, is to at Company's option, repair, replace or issue to Buyer a credit for the purchase price for any Products sold hereunder with any defect or non-conformity warranted against, provided the Company receives written notice of the defect during the period of warranty and Buyer returns the defective Products to the Company at a location designated by the Company accompanied by Company's formal written return authorization. If the Company determines that the Product conforms to the Order Confirmation, the Product will be returned at Buyer's expense.
- The Company disclaims any and all liability for equipment, materials and software not farmished by the Company which is attached to, or used in conjunction with, the Products and the Company disclaims all liability for operation of the system, if

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any, of which the Products are a part.

The warranty provided in paragraph 6, b) above is extended by the Company to Buyer only, and is the complete and exclusive warranty for Products manufactured by the Company. Company specifically excludes any warranty of suitability, adaptability or compatibility of the Products with the Buyer's needs for the purposes of manufacturing finished, semi-finished or intermediate products, for the purposes of incorporating the Products into other products. EXCEPT AS SPECIFICALLY SET FORTH HEREIN, ALL WARRANTIES EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXCLUDED. COMPANY ALSO DISCLAIMS ANY WARRANTY OF NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES WITH RESPECT TO THE PRODUCTS. This warranty shall not be enlarged and no obligation or liability shall arise out of the Company's rendering of technical advice and/or assistance.

The Buyer represents and warrants that any customized specifications for the Products provided to the Company do not and will not infininge the rights of third parties (including but not limited to any third party Intellectual Property Rights).

#### 7. LIMITATION OF LIABILITY

No action shall be brought for any breach of this agreement more than one (1) year

after the accrual of such cause of action.

Buyer's exclusive remedy shall be for damages and Company's maximum liability shall not in any case exceed the purchase price for the relevant Products giving rise to the claim, regardless of whether the claim is based on contract, breach of warranty, negligence (including gross negligence), strict liability, statutory violation, or otherwise, notwithstanding any fulure of essential purpose or of any limited remedy. Under no circumstances AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY REMEDY SET FORTH HEREIN shall COMPANY OR ITS AFFILIATES be liable for any consequential, incidental, special, punitive, or exemplary damages, lost profits, OR interruption of business losses, costs, or expenses of any kind, EVEN IF THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. The parties expressly agree that the above limitation on damages is an allocation of risk constituting in part the consideration for this agreement.

# 8. LICENSES: INTELLECTUAL PROPERTY RIGHTS AND INDEMNIFICATION

The sale of the Products furnished hereunder does not convey any license by implication, estoppel or otherwise under any proprietary, patent right or other implication property Rights (as defined below) of the Company covering the Products or combination of the Products with other elements. Unless otherwise agreed to in writing, the Company retains all title and all rights to insellectual Property Rights relating to the Products. Except as specifically provide herein, the sale of Products conveys no license to Buyer under any Intellectual Property Rights of the Company. Buyer shall defend, indemnify and hold harmless Company and the entities that control, are controlled by, or are under common control with Company (such entities, "Affiliates"), and its and their directors, officers, employees, successors and assigns from and against any claims, demands, lawsuits, losses, damages, habilities, costs and expenses (including reasonable fees and disbursements of counsel), and judgments and settlements of every kind that may be made by any third party arising out of or relating to any claim that the specifications, designs, processes or requirements for the Products provided by Buyer infringes or misappropriates any third party intellectual Property Rights. For purposes hereof, the term <u>intellectual Property Rights</u> mean, collectively, copyright rights (including, without limitation, the exclusive right to use, reproduce, modify, distribute, publicly display and publicly perform the copyrighted work). trademark rights (including, without limitation trade names, trademarks, service marks, and trade dress), patent rights (including, without limitation, the exclusive right to make, use and sell), trade secrets, moral rights, right of publicity, authors' rights, goodwill and all other intellectual property rights as may exist now and/or hereafter come into existence and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States, or any other state, country or jurisdiction.

#### 9. CONFIDENTIAL INFORMATION

Unless the Buyer and Company are parties to an existing agreement governing the confidentiality of information to be transferred between the parties (an "Existing Confidentiality Agreement"), in which case the Existing Confidentiality Agreement shall govern the treatment of such information in connection with these Conditions of Sale in lieu of this Section 9. Bayer hereby undertakes for the duration of its relationship with Company and for five (5) years after termination thereof for any reason whatsoever, to keep absolutely confidential and not disclose to any furd parties any information or materials of any kind provided by Company to Buyer or its agents verbally, in writing or in any other form including, but not limited to, information or materials of a commercial, financial or legal nature concerning Company, its know-how or its Intellectual Property Rights relating to the design, matural acture, studies, plans, drawings, documents, models, prototypes, objects or other materials relating to the Products, all of which Buyer shall return to Company

upon Company's request.

Confidentiality obligations shall not extend to information that is in the public i. domain, has become public domain other than by Buyer's breach of confidentiality,

that is lawfully received from third parties, or to the extent Buyer is held to disclose information under the law or by governmental or judicial order.

#### 10. IMPORTATION AND EXPORTATION

Buyer shall comply with all applicable export control laws and shall not, directly or indirectly export, reexport, resell, ship, or divert any Product, material, service, technical data, or software furnished hereunder to any person, entity, project, use, or country in violation of the laws or licensing requirements of the United States or any other appropriate national authority. Buyer shall indemnify and hold the Company harmless for any and all claims, demand, cost, fines, penalties, fees, expenses, or losses arising from Buyer's failure, intentional or unintentional, to comply with the foregoing

#### 11. ARBITRATION

Any claim, dispute, or controversy (whether in contract, tort or otherwise, whether presenting, present or future, and including, without limitation, statutory, common law, intentional tort and equitable claims) arising from or related to the Products purchased by Buyer from Company, the interpretation of these Conditions of Sale or any Quotation, Order Confirmation or Order entered into in connection herewith or the breach, termination, or validity of these Conditions of Sale of any such Quotation, Order Confirmation or Order, or the relationships which result from these Conditions of Sale or any Quotation, Order Confirmation or Order (including, to the full extent permitted by applicable law, relationships with third parties who are not signatories hereto), or Company's or any of its Affiliates advertising or marketing (collectively, a "Chaim")
WILL BE RESOLVED, UPON THE ELECTION OF COMPANY, BUYER OR THE
THIRD PARTIES INVOLVED, EXCLUSIVELY AND FINALLY BY BINDING
ARBITRATION. If arbitration is chosen, it will be conducted pursuant to the rules of the American Arbitration Association. If arbitration is chosen with respect to any Claim, neither Company nor Buyer will have the right to litigate that Claim in court or have a jury trial of that Claim or to engage in pre-arbitration discovery, except as provided in the applicable arbitration rules or by agreement of the parties involved. Further, Buyer will not have the right to participate as a member or representative of any class of claimants pertaining to any claim. Notwithstanding any choice of law provision included in these Conditions of Sale, this arbitration agreement is subject to the Federal Arbitration Act (9 U.S.C. Sections 1-16). The arbitration will take place exclusively in Chicago, Illinois. Any court having jurisdiction may enter judgment on the award entered by the arbitrator(s). Each party will bear its own cost of any legal representation, discovery or research required to complete arbitration. The enistence or results of any arbitration will be treated as confidential. NOTWITHSTANDING ANYTHING ELSE TO THE CONTRARY CONTAINED HEREIN, ALL MATTERS PERTAINING TO THE COLLECTION OF AMOUNTS DUE TO COMPANY ARISING FROM PRODUCTS WILL BE LITIGATED IN COURT RATHER THAN THROUGH ARBITRATION.

#### 12. GENERAL

No modifications hereto shall be effective unless they are agreed upon in writing by both parties. No course of prior dealings between the parties and no usage of trade will be relevant to determine the meaning of these Conditions of Sale or any Quotation, Order Confirmation, Order or invoice, or any document in electronic or written form that is signed and delivered by each of the parties.

The failure of the Company to insist, in any one or more instances, upon the performance of any of the terms or conditions of these Conditions of Sale, or to exercise any right herein, shall not be construed as a waiver or relinquishment of the future performance of any such term or condition or the future exercise of such

No right, interest or obligation these Conditions of Sale may be assigned or

delegated by either party without the written permission of the other party.

These Conditions of Sale shall be governed and interpreted in accordance with the laws of the State of Illinois, without reference to principles of choice and conflicts of laws.

Company shall not be responsible for and no liability shall result to Buyer for any delays in delivery or in performance which result in circumstances beyond Company's reasonable control including, without limitation, product unavailability, carrier delays, delays due to fire, flood, storm, severe weather conditions, pandemics, failure of power, labor problems, acts of war, terrorism, embargos, acts of God, shortages of supplies of raw materials or components or acts of any government or agency (each an "Event of Force Majeure"). Company may cancel any Order upon written notice to Buyer should an Event of Force Majeure continue for a period of sixty (60) or more consecutive days.

The Company may exhibit to in any public event such as trade fairs, exhibitions or shows, in any advertising and commercial documents, and to Company investors and potential investors, the Products made for Buyer.

The relationship between Company and Buyer is that of independent contractors and not that of employer/employee, partnership or joint venture

If any term of these Conditions of Sale is found by a court of competent jurisdiction to be invalid, illegal or otherwise unemforceable, the same shall not affect the validity, legality or enforceability of the other terms and conditions hereof or thereof or the whole of these Conditions of Sale.

This Section and the following Sections shall survive the expiration or termination of these Conditions of Sale: 1, 2a, 2d, 2e, 2f, 3a, and 4 through 12.

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# **EXHIBIT F: STANDARD PACKAGING AND PACKING SPECIFICATIONS**

# 1. Packing

- 1.1. Bag Preparation
  - 1.1.1.[...\*\*\*...]
  - 1.1.2.[...\*\*\*...]
  - 1.1.3.[...\*\*\*...]
  - 1.1.4.[...\*\*\*...]
- 1.2. Carton Sealing
  - 1.2.1.[...\*\*\*...]
- 1.3. Carton filling/ Pharmaceutical Packaging Area
  - 1.3.1.[...\*\*\*...]
  - 1.3.2.[...\*\*\*...]
  - 1.3.3.[...\*\*\*...]
  - 1.3.4.[...\*\*\*...]
  - 1.3.5.[...\*\*\*...]
- 1.4. Labeling and closing of carton
  - 1.4.1.[...\*\*\*...]
  - 1.4.2.[...\*\*\*...]
  - 1.4.3.[...\*\*\*...]
  - 1.4.4.[...\*\*\*...]
- 1.5. Packaging Records
  - 1.5.1.[...\*\*\*...]
- 1.6. Palletization
  - 1.6.1.[...\*\*\*...]
  - 1.6.2.[...\*\*\*...]
- 1.7. Shipment preparation
  - 1.7.1.[...\*\*\*...]

- 1.7.2.[...\*\*\*...]
- 1.7.3.[...\*\*\*...]
- 1.7.4.[...\*\*\*...]
- 1.7.5.[...\*\*\*...]
- 1.7.6.[...\*\*\*...]
- 1.7.7.[...\*\*\*...]
- 1.8. Stretch Wrap
  - 1.8.1.[...\*\*\*...]
  - 1.8.2.[...\*\*\*...]
  - 1.8.3.[...\*\*\*...]
- 1.9. Paperwork
  - 1.9.1.[...\*\*\*...]
  - 1.9.2.[...\*\*\*...]
  - 1.9.3.[...\*\*\*...]
- 1.10. Bill of Lading
  - 1.10.1.[...\*\*\*...]
  - 1.10.2.[...\*\*\*...]
- 1.11. Pick up by carrier
  - 1.11.1.[...\*\*\*...]

- 1.11.2.[...\*\*\*...]
- 1.11.3.[...\*\*\*...]
- 1.12. Communication of Shipment
  - 1.12.1.[...\*\*\*...]
  - 1.12.2.[...\*\*\*...]
  - 1.12.3.[...\*\*\*...]
- 1.13. Palletization of Finished Products:
  - 1.13.1.[...\*\*\*...]
  - 1.13.2.[...\*\*\*...]
  - 1.13.3.[...\*\*\*...]
  - 1.13.4.[...\*\*\*...]
  - 1.13.5.[...\*\*\*...]
  - 1.13.6.[...\*\*\*...]
  - 1.13.7.[...\*\*\*...]
  - 1.13.8.[...\*\*\*...]
  - 1.13.9.[...\*\*\*...]