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**Manufacturing Agreement**

**Between**

**Antares Pharma, Inc.**

**and**

**AMAG Pharmaceuticals, Inc.**

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## MANUFACTURING AGREEMENT

This Manufacturing Agreement (“**Agreement**”) is made and entered into as of the 20th day of March, 2018 (the “**Effective Date**”) by and between Antares Pharma, Inc., a Delaware corporation, with offices located at 100 Princeton South, Suite 300, Ewing, NJ 08628 (“**Antares**”), and AMAG Pharmaceuticals, Inc., a Delaware corporation, with a corporate address at 1100 Winter Street, Waltham, MA 02451 (“**AMAG**”). Antares and AMAG are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### Recitals

**WHEREAS**, AMAG is engaged in discovering, developing and marketing pharmaceutical products, including the Drug (as defined below);

**WHEREAS**, Antares is engaged in the research and development of certain drug delivery devices, including auto-injection systems and the development and marketing of pharmaceutical products;

**WHEREAS**, AMAG Pharma USA, Inc. (f/k/a Lumara Health, Inc., (“**AMAG USA**”)), which was acquired by AMAG on November 12, 2014 and is a wholly-owned subsidiary of AMAG, and Antares entered into a certain Development and License Agreement (defined below) under which Antares granted AMAG USA an exclusive, worldwide license to Antares’ VIBEX® QuickShot® (QS) auto-injection system or similar Device (defined below) for use with the Drug, and further under which Antares and AMAG USA agreed to collaborate to develop such a product;

**WHEREAS**, contemporaneously with the execution of this Agreement, Antares, AMAG and AMAG USA are entering into a First Amendment to Development and License Agreement, pursuant to which, among other amendments set forth therein, AMAG USA assigned, and AMAG assumed, the rights and responsibilities under the Development and License Agreement (the “**First Amendment to Development and License Agreement**”);

**WHEREAS**, AMAG (as the permitted assignee of the Development and License Agreement) and Antares agreed under the Development and License Agreement to enter into this Agreement and, whereby it will provide Antares or its Subcontractor (defined below) with Prefilled Syringes (defined below) containing the Drug and Antares or its Subcontractor will incorporate the Prefilled Syringes into Devices to produce finished Products (defined below) and sample Products to supply AMAG’s requirements for such Products and sample Products; and

**WHEREAS**, AMAG wishes to purchase, and Antares wishes to supply, AMAG’s requirements of the Trainers (defined below) on the terms set forth in this Agreement.

**NOW, THEREFORE**, in consideration of the foregoing and the mutual covenants and promises contained in this Agreement, the Parties hereto agree as follows:

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## **ARTICLE 1**

### **INTERPRETATION**

**1.1** Definitions. Capitalized terms used in this Agreement and not otherwise defined in this Section 1.1 shall have the meanings set out in the Development and License Agreement. The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

“\*\*\*” has the meaning specified in Section 3.2(c);

“\*\*\*” has the meaning specified in Section 3.2(c);

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“**Agreement**” has the meaning specified in the Preamble;

“**AMAG**” has the meaning specified in the Preamble;

“**AMAG Indemnitees**” has the meaning specified in Section 9.2;

“**AMAG USA**” has the meaning specified in the Recitals;

“**AMAG Quality Tasks**” means AMAG’s quality, testing and release obligations set forth in Section 2.6(b) and in the Quality Agreement;

“**Annual Product Review Report**” means the annual product review report as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

“**Annual Report**” means the annual report as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

“**Antares**” has the meaning specified in the Preamble;

“**Antares’ Fully Burdened Manufacturing Costs**” means those costs actually incurred by Antares related directly to the acquisition of materials and their conversion into Products, sample Products or Trainers, as the case may be. \*\*\*;

“**Antares Indemnitees**” has the meaning specified in Section 9.1;

“**Batch Record**” means a detailed, step-by-step description of the entire assembly, packaging and labelling process for the Products and sample Products which explains how such Products or sample Products (as the case may be) were assembled, packaged and labelled, indicating specific types and quantities of Components, additional materials, processing parameters, in-process quality controls, and other relevant controls;

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“**Binding Forecast**” has the meaning specified in Section 3.2(a);

“\*\*\*” has the meaning specified in Section 3.2(c);

“**Business Day**” means a day other than a Saturday, Sunday or a day that is a federal holiday in the United States;

“**Calendar Quarter**” means a three-month period ending on March 31, June 30, September 30 or December 31;

“**Calendar Year**” means a calendar year occurring after the Effective Date; provided, however, the first Calendar Year means the period from the Effective Date up to and including December 31 of the same calendar year in which the Effective Date occurs;

“\*\*\*” has the meaning specified in Section 3.2(c);

“**Certificate of Analysis (Device)**” means a document signed by an authorized representative of Antares or the Subcontractor that conducted the applicable analysis, in reasonable and customary form, that: (i) describes the specifications for, and testing methods applied to, the quantity of each of the Major Device Components manufactured by or on behalf of Antares pursuant to this Agreement, and the results of such testing, and (ii) certifies that such quantity of each of the Major Device Components was manufactured in accordance with cGMP, all other Applicable Laws, and the Product Specifications;

“**Certificate of Analysis (PFS Manufacture)**” means a document signed by an authorized representative of AMAG, its agent or its permitted subcontractor that conducted the applicable analysis, in reasonable and customary form, that: (i) describes the specifications for, and testing methods applied to the Drug manufactured by or on behalf of AMAG pursuant to this Agreement, and the results of such testing, and (ii) certifies that such quantity of Drug was manufactured in accordance with cGMP, all other Applicable Laws, and the Product Specifications;

“**Certificate of Analysis (PFS ID Testing)**” means a document signed by an authorized representative of AMAG, its agent or its permitted subcontractor that conducted the applicable analysis, in reasonable and customary form, that describes the specifications for, and testing methods applied to, the Drug manufactured by or on behalf of AMAG pursuant to this Agreement for identification of the Drug, and the results of such testing;

“**Certificate of Analysis (Product)**” means a document signed by an authorized representative of AMAG, its agent or its permitted subcontractor that conducted the applicable analysis, in reasonable and customary form, that: (i) describes the specifications for, and testing methods applied to, the quantity of Product and/or sample Product manufactured by or on behalf of Antares pursuant to this Agreement, and the results of such testing, and (ii) certifies that such quantity of Product and/or sample Product was

manufactured in accordance with cGMP, all other Applicable Laws, and the Product Specifications;

**“Certificate of Conformance (Device)”** means the document provided to AMAG by Antares or the Subcontractor that conducted the applicable review, as the case may be, that certifies each batch of each of the Major Device Components was manufactured in compliance with the cGMP, all other Applicable Laws, and the Product Specifications;

**“Certificate of Conformance (Product)”** means the document provided to AMAG by Antares or the Subcontractor that conducted the applicable review, as the case may be, that certifies each batch of Product and/or sample Product was assembled, packaged and labelled in compliance with the cGMP, all other Applicable Laws, and the Product Specifications;

**“cGMP”** means current good manufacturing practice and standards as provided for (and as amended from time to time) in the “Current Good Manufacturing Practice Regulations” of the U.S. Code of Federal Regulations Title 21 (21CFR§4; 21CFR§210/211 and 21CFR§820) and in European Community Council Directive 93/42/EEC concerning medical devices, any U.S., European, or other applicable laws, regulations or respective guidance documents now or subsequently established by a governmental or regulatory authority, and any arrangements, additions, or clarifications;

**“Change Order”** has the meaning specified in Section 4.2(b);

**“Commercially Reasonable Efforts”** means, with respect to each Party, such efforts and commitment of resources in accordance with \*\*\* that such Party \*. As used in this definition of **“Commercially Reasonable Efforts”**, “reasonable” shall be measured by \*. References in this Agreement to **“commercially reasonable”** and similar formulations shall be deemed to incorporate the standard set forth in this definition of **“Commercially Reasonable Efforts”**;

**“Components”** means, collectively, \*;

**“Damages”** has the meaning specified in Section 9.1;

**“Deficiency Notice”** has the meaning specified in Section 5.1(a);

**“Delivery Date”** means the delivery date of a Purchase Order of Products, sample Products or Trainers as agreed upon by the Parties pursuant to Section 3.2(b)(i) or Antares’ proposed date if AMAG does not respond within the \* set forth in Section 3.2(b)(i);

**“Development and License Agreement”** means that certain Development and License Agreement entered into by and between the Parties dated as of September 30, 2014, as amended by the First Amendment to the Development and License Agreement, and as further amended by the Parties from time to time;

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“**Device**” means the VIBEX<sup>®</sup> QS auto-injection system device, consisting of the Major Device Components, designed and developed to incorporate a Prefilled Syringe for delivery of the Drug, and any improvements or modifications thereof made pursuant to the Development and License Agreement, or such other Antares-proprietary device as agreed to by Antares designed and developed to deliver the Drug pursuant to the Development and License Agreement, as further set forth on Exhibit B. For greater certainty, the Major Device Components are intended to be assembled with the Prefilled Syringe to produce a finished Product;

“**DHF**” has the meaning specified in the Development and License Agreement;

“**DMF**” has the meaning specified in the Development and License Agreement and is expanded to further clarify that a DMF is equivalent to an “MAF” or Master File;

“**Drug**” means 17-alpha hydroxyprogesterone caproate;

“**Effective Date**” has the meaning specified in the Preamble;

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“**Excess Order**” has the meaning specified in Section 3.2(b)(i);

“**Firm Orders**” means any Purchase Order accepted by Antares pursuant to Section 3.2(b)(i) (as evidenced by an Order Acceptance), including any Excess Orders agreed to by Antares in an Order Acceptance, with the Delivery Date as set forth in Section 3.2(b)(i);

“**First Amendment to the Development and License Agreement**” has the meaning specified in the Recitals;

“**Force Majeure Event**” has the meaning specified in Section 12.4;

“**Forecast**” has the meaning specified in Section 3.2(a);

“\*\*\*” has the meaning specified in Section 4.6;

“\*\*\*” has the meaning specified in Section 3.2(c);

“\*\*\*” has the meaning specified in Section 3.2(c);

“**Invoice**” has the meaning specified in Section 4.2(a);

“\*\*\*” has the meaning specified in Section 3.2(c);

“**Latent Defects**” has the meaning specified in Section 5.1(a);

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“**Long Lead Time Materials**” means [\*\*\*], a description of which are set forth on Exhibit A (as such exhibit may be amended from time to time by the mutual written agreement of the Parties), [\*\*\*];

“**Major Device Components**” means the following Components of the Device: [\*\*\*].

“**Manufacture(d) at Risk**” has the meaning specified in Section 3.7(a);

“**Manufacturing Services**” means the manufacturing, quality control and quality assurance, storage, labelling, packaging, assembly and related services, to be performed by Antares or its Subcontractor as contemplated in this Agreement and described in the Specifications and the Quality Agreement, required to manufacture Devices and produce and supply Trainers, Products and sample Products from such Devices, Prefilled Syringes and Components. For the avoidance of doubt, the “Manufacturing Services” specifically excludes the AMAG Quality Tasks and all other services, activities or tasks to be performed by or on behalf of AMAG set forth in this Agreement or as otherwise described in the Specifications or the Quality Agreement;

“**Manufacturing Site**” means [\*\*\*] or such other facility owned and operated by Antares or a Subcontractor on behalf of Antares under this Agreement [\*\*\*].

“**Non-Binding Forecast**” has the meaning specified in Section 3.2(a);

“**Non-Cancellable Non-Returnable Materials**” or “**NCNR Materials**” means [\*\*\*];

[\*\*\*]

“**Order Acceptance**” has the meaning specified in Section 3.2(b)(i);

“**Other Approved Antares Product**” has the meaning specified in Section 4.6(a);

“**Parties**” and “**Party**” have the meanings specified in the Preamble;

“**Person**” means any natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any Governmental Authority or any other entity or organization;

“[\*\*\*]” has the meaning specified in Section 2.1(b);

“**Prefilled Syringe**” means the prefilled syringe containing the formulated Drug for incorporation into the Device, as further set forth in the Product Specifications;

“**Prior Orders**” has the meaning specified in Section 3.2(c);

“**Product(s)**” means the fully packaged Device for auto-injection delivery of the Drug incorporating a Prefilled Syringe and other applicable Components listed on Exhibit B

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hereto, as such exhibit may be amended from time to time by the mutual written agreement of the Parties;

**“Product Specifications”** means, as set forth on Exhibit B hereto, for each Product, with AMAG having primary responsibility with respect to the Drug and Prefilled Syringe, and Antares having primary responsibility with respect to the Devices and Components, the following documents relating to such Product:

- (a) specifications for Devices, Prefilled Syringes and Components;
- (b) the Product Specifications; and
- (c) storage, packaging, prescribing information and label specifications and requirements; and

all as updated, amended and revised from time to time by the Parties in writing in accordance with the terms of this Agreement, and in all cases including compliance with all Applicable Laws and the Quality Agreement;

**“Quality Agreement”** has the meaning specified in Section 2.6(a);

**“Recall”** means any action (i) by AMAG to recover title to or possession of quantities of the Products, sample Products and/or Trainers sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products, sample Products and/or Trainers) from the market; or (ii) by any Regulatory Authorities to detain or destroy any of the Products and/or the sample Products. Recall shall also include any action by either Party to refrain from selling or shipping quantities of the Products, sample Products and/or Trainers to third parties which would have been subject to a Recall if sold or shipped;

**“Safety Stock”** has the meaning specified in Section 3.6(a);

**“Second Source Supplier”** has the meaning specified in Section 3.9;

\*\*\* has the meaning specified in Section 2.1(b);

**“Specifications”** means the Product Specifications with respect to the Product and sample Product, and the Trainer Specifications with respect to the Trainers, as the case may be;

**“Subcontractor”** has the meaning specified in Section 2.1(b);

**“Supply Failure”** has the meaning specified in Section 3.5(a);

**“Supply Failure Remedy Option”** has the meaning specified in Section 3.5(b);

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**“Term”** has the meaning specified in Section 7.1;



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“\*\*\*” has the meaning specified in Section 3.2(c);

“**Third Person**” means any Person or entity other than AMAG, Antares, or an Affiliate or sublicensee of either Party with respect to this Agreement and/or the Development and License Agreement.

“**Third Person Claim**” has the meaning specified in Section 9.1;

“**Trainer**” means a reusable version of the Product that does not incorporate the Prefilled Syringe and that is to be used to demonstrate how to operate the Product;

“**Trainer Specifications**” means, as set forth on Exhibit C hereto, for each Trainer, the requirements and print/part numbers documents relating to such Trainer, as updated, amended and revised from time to time by or on behalf of the Parties, and in all cases including compliance with all Applicable Laws;

“**Transfer Price**” has the meaning specified on Exhibit D hereto;

“**U.S. GAAP**” has the meaning specified in the definition of Antares’ Fully Burdened Manufacturing Costs; and

“**VAT**” means, in relation to any jurisdiction within the European Union, the value added tax provided for in Council Directive 2006/112/EC and charged under the provisions of any national legislation implementing that directive or Council Directive 77/388/EEC together with legislation supplemental thereto and, in relation to any other jurisdiction, the equivalent tax (if any) in that jurisdiction.

“**Yield**” has the meaning specified in Section 2.10.

- 1.2 Currency.** Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.
- 1.3 Sections and Headings.** The division of this Agreement into Articles, Sections, subsections and Exhibits and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to an Article, Section or Exhibit refers to the specified Article, Section or Exhibit to this Agreement. In this Agreement, the terms “this Agreement”, “hereof”, “herein”, “hereunder” and similar expressions refer to this Agreement and not to any particular part, Section, Exhibit or the provision hereof.
- 1.4 Singular Terms.** Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.
- 1.5 Exhibits.** The following Exhibits are attached to, incorporated in and form part of this Agreement:

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Exhibit A - Long Lead Time Materials  
Exhibit B - Product Specifications  
Exhibit C - Trainer Specifications  
Exhibit D - Transfer Price  
Exhibit E - Quality Agreement  
Exhibit F - Batch Numbering & Expiration Dates  
Exhibit G - Retained Samples  
Exhibit H - Initial Forecast  
Exhibit I - Redundancy Plan  
Exhibit J - \*\*\*  
Exhibit K - AMAG Equipment  
Exhibit L - Form of Change Order

## ARTICLE 2 MANUFACTURING AND SUPPLY OBLIGATIONS

### 2.1 **Manufacturing Services.**

- (a) Starting on the Effective Date, Antares or its Subcontractor shall provide the Manufacturing Services in order to manufacture Devices, Products, sample Products and Trainers exclusively for AMAG for the Territory, all in accordance with the Specifications, Applicable Laws, Quality Agreement and this Agreement. For the avoidance of doubt, subject to, and without limiting or amending the exclusivity restrictions and confidentiality obligations set forth in Section 6.1 and ARTICLE 17 of the Development and License Agreement, respectively, Antares or its Subcontractor may manufacture the VIBEX® QS device or other devices (other than the Device) for itself or other Persons. Antares or its Subcontractor shall conduct all Manufacturing Services at the Manufacturing Site and may change the Manufacturing Site for the Products, sample Products and Trainers only with the prior written consent of AMAG, such consent not to be unreasonably withheld, conditioned or delayed (provided that, Antares or its Subcontractor shall provide a minimum of \*\*\* prior written notice of such change of Manufacturing Site).
- (b) \*\*\*.
- (c) Antares shall have the right to specify the final assembly packaging and labeling process (subject to AMAG's provision of label content) for Products, sample Products and Trainers, including the combination of the components thereof, in accordance with the Specifications and the Quality Agreement.

### 2.2 **Prefilled Syringes.**

- (a) AMAG or its designee(s) will be responsible for manufacture, formulation and testing of any Drug and the Prefilled Syringe for assembly with the Device into the Product

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and sample Product by Antares or its Subcontractor and for final Product and/or sample Product release for sale, commercialization or use by a Third Person. AMAG shall supply Prefilled Syringes to Antares or its Subcontractor in accordance with the terms of this Section 2.2 AMAG will have sole decision-making authority regarding the use of a Third Person to manufacture any aspect of the Drug and the Prefilled Syringes. AMAG shall conduct release testing for Prefilled Syringes. Antares or its Subcontractor shall use and store all Prefilled Syringes provided hereunder in accordance with AMAG's reasonable instructions, the Quality Agreement, cGMPs and all other Applicable Laws at Antares' or its Subcontractor's storage facility at the Manufacturing Site. Antares or its Subcontractor shall conduct a visual inspection of all Prefilled Syringes received at the Manufacturing Site not later than \*\*\* after the date of receipt in accordance with the mutually agreed upon procedures. Antares or its Subcontractor shall promptly (and in any event within \*\*\* following completion of applicable inspection) notify AMAG in writing of any visual inspection failure of the Prefilled Syringes. Antares shall not allow any lien or other security interest to be imposed on the Prefilled Syringes by Antares or its Subcontractor or as a result of Antares or its Subcontractor action or inaction. Antares or its Subcontractor shall use all quantities of Prefilled Syringes provided hereunder for the sole purpose of performing the Manufacturing Services on behalf of AMAG and not for any other use or purpose.

- (b) The Parties acknowledge and agree that title to and risk of loss of all Prefilled Syringes shall at all times belong to and remain in AMAG; provided that, subject to the limitations on liability set forth in this Section 2.2(b), in the event of loss or damage of any Prefilled Syringes while they are at the Manufacturing Site, Antares shall be only responsible for the replacement costs (as evidenced by AMAG invoices) of such Prefilled Syringes if the damage, loss, theft or destruction was caused by the negligent act or omission or the willful misconduct of Antares or its Subcontractor. For the avoidance of doubt, Antares shall not be responsible for any damage, loss or destruction to the Prefilled Syringes resulting from damage, loss or destruction caused by the reasonable amount of Prefilled Syringes damaged, lost or destroyed in the manufacturing process (i.e. consistent with the Yield) or obsolescence due to changes in the manufacturing process. Not later than \*\*\* following the end of each Calendar Year, AMAG shall provide Antares with an invoice and accounting of the Prefilled Syringes that were damaged or destroyed during the prior year (following notification from Antares of such damage or destruction). Payment of undisputed portions of such invoice shall be due \*\*\* from Antares' receipt of such invoice. \*\*\*. All Prefilled Syringes in Antares' possession shall be subject to disposition by AMAG upon expiration or termination of this Agreement, and in either such event, Antares or its Subcontractor shall deliver the Prefilled Syringes to AMAG or its designee, at AMAG's

reasonable expense. AMAG shall be solely responsible and reimburse Antares for all reasonable costs and expenses associated with the storage of the Prefilled Syringes at Antares' or its Subcontractor's storage facility at the Manufacturing Site following the expiration or termination of this Agreement. Antares agrees to reasonably cooperate with AMAG, at AMAG's expense, in the filing of any UCC financing statements relating to the Prefilled Syringes as may be required under Applicable Laws.

- (c) All shipments of Prefilled Syringes made by AMAG or its designee to Antares or its Subcontractor hereunder will be delivered \*\*\* Antares' or its Subcontractor's Manufacturing Site unless otherwise mutually agreed. \*\*\*.

**2.3 Devices.** Antares or its Subcontractor shall manufacture and test all Devices as specified by the Product Specifications prior to using such Devices to manufacture Products and sample Products. Antares or its Subcontractor shall properly store the Devices at Antares' or its Subcontractor's storage facility at the Manufacturing Site pursuant to cGMP and Applicable Law.

**2.4 Components.** Antares or its Subcontractor shall purchase and inspect all Components as specified by the Specifications prior to using such Components to manufacture Products, sample Products and Trainers. Antares or its Subcontractor shall properly store the Components at Antares' or its Subcontractor's storage facility at the Manufacturing Site pursuant to cGMP and Applicable Law.

**2.5 Assembly of Devices, Prefilled Syringes and Components.** Antares or its Subcontractor shall assemble Devices, Prefilled Syringes and Components into Products, sample Products and Trainers (as applicable) in accordance with the terms of this Agreement.

**2.6 Quality Control and Quality Assurance.**

- (a) On or about the date hereof, the Parties shall amend and restate the Quality Agreement entered into on May 16, 2016 between the Parties covering the Product, sample Products, Trainers, the Device and the Prefilled Syringes, as set forth in the form of Amended and Restated Quality Agreement attached hereto as Exhibit E (as amended and restated, the "**Quality Agreement**"). The Parties shall review the Quality Agreement and shall modify the same from time to time as detailed in the Quality Agreement as necessary through a written amendment to the Quality Agreement signed by an authorized representative on behalf of each of the Parties. The Parties shall perform the quality control and quality assurance testing specified in Section 2.6(b) and the Quality Agreement. The Parties shall perform Product, sample Product and Trainer review and final release of the Product, sample Product and Trainers for sale in accordance with Section 2.6(b) and the Quality Agreement, the Specifications and Applicable Laws.

(b) Subject to, and as more fully set forth in, the Quality Agreement, the Parties agree as follows:

\*\*\*].

- 2.7 Labelling and Packaging.** Antares or its Subcontractor shall label and package the Products, sample Products and Trainers as set out in the Specifications. AMAG shall be responsible for the cost of artwork development for the Products, sample Products and Trainers. In addition, Antares or its Subcontractor shall arrange for and implement (a) the imprinting of batch numbers and expiration dates for each batch of Products and sample Products shipped, and (b) the imprinting of batch numbers for each batch of Trainers shipped. Such batch numbers and expiration dates shall be affixed on the Products, sample Products and Trainers and, on the shipping carton of each Product, sample Product and Trainer as outlined in the Specifications and, as required by cGMPs and Applicable Laws. The system used by Antares or its Subcontractor for batch numbering and expiration dates is detailed in Exhibit F hereto. AMAG shall be solely responsible for the content of the labelling and the provision of such content. Notwithstanding anything to the contrary in this Agreement, Antares' obligation to perform the Manufacturing Services is subject to AMAG's reasonably timely approval and provision of all labelling content. AMAG may, in its sole discretion, make changes to labels, product inserts and other packaging for the Products, sample Products and Trainers, which changes shall be submitted by AMAG to all applicable Regulatory Authorities from which approval of such changes is required. AMAG shall be responsible for the cost of labeling obsolescence due to changes to such labeling made by AMAG, including the reasonable cost of disposal and replacement of packaging materials. Antares' name shall appear on the label or anywhere else on the Products, sample Products and Trainers as reasonably agreed upon by the Parties, unless: (i) prohibited by Applicable Laws; or (ii) the Parties otherwise agree in writing.
- 2.8 Validation Activities.** Antares or its Subcontractor will be responsible for the development and approval of the validation protocols for analytical methods and manufacturing processes (including packaging processes) for the Products, sample Products and Trainers as described in the Specifications in accordance with the Quality Agreement and shall be approved by AMAG prior to execution thereof. \*\*\*].
- 2.9 Retained Samples.** Antares or its Subcontractor shall retain sufficient quantities of shipped Products, sample Products, Devices and Components as retained repository samples as required under the Quality Agreement and Applicable Laws at AMAG's sole cost and expense and as set forth in Exhibit G. Such retained samples shall minimally represent \*\*\* the number of samples necessary to re-execute chemical release testing and will be maintained in a suitable storage facility at Antares' or its Subcontractors' Manufacturing Site until \*\*\* or such longer period as may be required by Applicable Laws. All such samples shall be available for inspection by AMAG at reasonable intervals upon reasonable

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notice. AMAG shall advise Antares of the required quantities of shipped Products, sample Products, Devices and Components that AMAG desires to be retained. Antares shall invoice AMAG for the costs associated with performing these activities.

**2.10 Yield.** \*\*\*].

**ARTICLE 3**

**ANTARES' SUPPLY OF PRODUCT**

**3.1 Supply of Product.**

- (a) Commencing on the Effective Date and continuing during the Term, Antares shall manufacture and supply, or have manufactured and supplied by its Subcontractor, all quantities of the Products, sample Products and Trainers ordered by AMAG in the Territory pursuant to this Agreement. Commencing on the Effective Date and during the Term, AMAG shall commit to purchase its entire requirements of Product(s), sample Products and Trainers for sale in the Territory from Antares.
- (b) The Parties agree that in the event that AMAG seeks Regulatory Approval for the Product, sample Product or Trainers for a country outside of the United States, the Parties will enter into an amendment to this Agreement setting forth the terms and conditions of supply of Products, sample Products or Trainers for that country.

**3.2 Orders and Forecasts.**

- (a) Rolling Forecasts. On or before the \*\*\* after the Effective Date, AMAG shall provide Antares with an updated written \*\*\* rolling forecast of the volume of Product, sample Product and Trainers that AMAG then anticipates will be required to be produced and delivered to AMAG during \*\*\* (the “**Forecast**”). The initial Forecast is attached hereto as Exhibit H. \*\*\* of each Forecast shall constitute a firm order and be a binding commitment on AMAG to purchase the volume of Product, sample Product and Trainers set forth therein (the “**Binding Forecast**”). \*\*\* of each Forecast shall be non-binding (the “**Non-binding Forecast**”). The Non-binding Forecast shall be prepared in good faith by AMAG and represent AMAG’s reasonable expectation of its requirements of Product, sample Product and Trainers for \*\*\* of such Forecast. Each Forecast shall include an estimated delivery date of the Prefilled Syringes to Antares or its Subcontractor (such estimate to be provided by AMAG in good faith).
- (b) Purchase Orders.
  - (i) To order Products, sample Products and Trainers for supply by Antares or its Subcontractor under this Agreement, AMAG shall submit to Antares a Purchase Order (which is deemed binding on AMAG) complying with the other applicable terms of this Agreement \*\*\*]. Not later than \*\*\* after receipt of a Purchase

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Order, Antares shall confirm in writing its receipt of the Purchase Order (“**Order Acceptance**”) and the proposed delivery date to AMAG in writing; provided that Antares may reject any Purchase Order not consistent with the requirements set forth in this Agreement, including this Section 3.2(b)(i). AMAG shall notify Antares within [\*\*\*] after receipt of the Order Acceptance if such proposed delivery date is unacceptable for AMAG, and in such event, the Parties shall promptly discuss and seek to agree on an alternative delivery date. If AMAG does not respond within such [\*\*\*] period, the proposed date will be the confirmed delivery date. Antares shall not be obligated to fill any portion of any Purchase Order to the extent the volumes in such Purchase Order exceed the volumes set forth in the most recent Binding Forecast (such excess amount, the “**Excess Order**”). For any Purchase Order that contains an Excess Order, Antares shall notify AMAG in the Order Acceptance whether Antares and/or its Subcontractors will fulfill such Excess Order (or part thereof) and the expected delivery date for fulfillment. The decision to fulfill any Excess Order may be made by Antares in its sole discretion and Antares shall not be liable for any failure to deliver any Product, sample Product or Trainers set forth in any Excess Order; provided that Antares meets its obligations consistent with the Binding Forecast. AMAG’s failure to deliver a Purchase Order consistent with the volumes of Product, sample Product and/or Trainers under any Binding Forecast, shall not relieve AMAG of its obligation to purchase such volumes of Product, sample Product and/or Trainers. The terms of this Agreement shall be controlling and any additional or inconsistent terms or conditions contained on any Forecast, Purchase Order, Order Acceptance, invoice or similar documentation given or received by the Parties shall have no effect and such terms and conditions are expressly disclaimed and excluded.

- (ii) AMAG and Antares acknowledge and agree that any minor difference between the quantity of ordered and delivered quantity of Product, sample Product or Trainers (as the case may be) that falls within applicable industry standards shall be accepted by AMAG as delivery in full of the ordered quantities set forth on any Firm Order and shall not be deemed a shortage as set forth in Section 5.1(c), but in no event shall the quantity delivered deviate from the quantity ordered by more than: [\*\*\*].
- (iii) Notwithstanding anything in this Agreement to the contrary, AMAG acknowledges and agrees that Antares shall only be responsible for producing and delivering to AMAG that portion (up to the entire quantity) of Products and sample Products requested pursuant to a Purchase Order for which Antares or its Subcontractor (as the case may be) possesses, at least [\*\*\*] prior to the Delivery Date, a sufficient stock of inventory of Prefilled Syringes necessary to

fulfill such order (including any additional quantity of Prefilled Syringes necessary to account for Prefilled Syringes reasonably expected to be damaged, lost or destroyed in the manufacturing process (i.e. consistent with the Yield)) and the Certificate of Analysis (PFS Manufacture) relating thereto. In the event that Antares or its Subcontractor (as the case may be) has not received a sufficient stock of Prefilled Syringes by the dates set forth in the previous sentence, Antares or its Subcontractor shall (A) manufacture and deliver such number of Products and sample Products for which Antares or its Subcontractor (as the case may be) has Prefilled Syringes in accordance with the schedule set forth in the Firm Order, and (B) as soon as practicable (and no more than \*\*\*) following receipt of the Prefilled Syringes required for such Firm Order, Antares or its Subcontractor shall manufacture and deliver the Products and sample Products in such order taking into account any Products and sample Products manufactured and delivered pursuant to subsection (A).

(iv) Notwithstanding anything in this Agreement to the contrary, AMAG acknowledges and agrees that Antares shall not be responsible for delay in the delivery of quantity of Products, sample Products or Trainers (as the case may be) set forth in any Firm Order to the extent such delay is caused primarily due to AMAG's failure to fulfill the AMAG Quality Tasks to enable Antares and/or its Subcontractor to timely perform the Manufacturing Services.

(c) Prior Orders. \*\*\*.

**3.3 Minimum Orders.** The quantity of Products, sample Products or Trainers (as the case may be) ordered by AMAG from Antares in each shipment (as set forth in a Purchase Order) must be equal to or greater than \*\*\* units for each type of Product, sample Product and Trainers ordered. Such minimum order quantity may be updated from time to time by a mutual written agreement of the Parties. For avoidance of doubt, except for any Purchase Orders placed by AMAG and/or quantities set forth in the Binding Forecast, nothing in this Agreement requires AMAG to purchase any particular quantity of Products from Antares.

#### **3.4 Shipments.**

(a) Shipments of Products, sample Product and Trainers shall be made EXW (as such term is defined in INCOTERMS 2010) Antares' or its Subcontractor's (as the case may be) designated shipping location unless otherwise mutually agreed. The Parties acknowledge and agree that delivery of Products, samples Products and/or Trainers under this Agreement shall be deemed to be made once the Products, samples Products and/or Trainers (as the case may be) are made available at Antares' or its Subcontractor's (as the case may be) designated shipping location. \*\*\*. AMAG shall pay for shipping. AMAG shall arrange for insurance and shall select the freight



carrier to ship Products, sample Products and Trainers. Antares shall not be responsible for the payment of such insurance. Products, sample Products and Trainers shall be transported in accordance with the Specifications.

- (b) Prior to release for distribution, sale or use by AMAG pursuant to Section 2.6(b)(v)(D), AMAG, its agent or its permitted subcontractor shall test each batch of Products, sample Products and Trainers manufactured under this Agreement in accordance with Section 2.6(b)(v)(D). AMAG, its agent or its permitted subcontractor shall conduct all such testing in accordance with the procedures and using the analytical testing methodologies set forth in the Specifications, the Quality Agreement and Applicable Laws. All Products, sample Products and Trainers shipped by Antares or its Subcontractor to AMAG or AMAG's designee, including its packaging, shall meet all applicable export and customs laws, regulations and like requirements for the United States.

### **3.5 Supply Failure.**

\*\*\*].

### **3.6 Safety Stock.**

- (a) At AMAG's sole cost and expense, Antares or its Subcontractor will maintain and make available to AMAG a safety inventory of the Major Device Components necessary to assemble the Devices in the quantities set forth in this Section 3.6(a) at Antares or its Subcontractor's Manufacturing Site in accordance with this Section 3.6 ("**Safety Stock**").
  - (i) \*\*\*].
  - (ii) \*\*\*].
- (b) With respect to the initial Safety Stock (as set forth in Section 3.6(a)(i)) or any increase in Safety Stock pursuant to Section 3.6(a)(ii), upon the completion of the manufacture of such Safety Stock and delivery to AMAG of the Certificate of Analysis (Device) and the Certificate of Conformance (Device) applicable to such Safety Stock, Antares shall invoice AMAG for its \*\*\*] pursuant to invoicing and payment terms set forth in Section 4.2.
- (c) With respect to any reduction in the Safety Stock pursuant to Sections 3.6(a)(ii) or 3.6(d), to the extent such reduced quantities of Safety Stock are used in the manufacture of fully finished Products and/or sample Products, then Antares shall credit any amount previously paid by AMAG with respect to such reduced quantity in Safety Stock in the Invoice issued to AMAG pursuant to Section 4.2 for such fully finished Product and/or sample Product.

- (d) Antares or its Subcontractor shall manage the Safety Stock as part of its overall inventory and use the Safety Stock to fulfill its obligations pursuant to a Firm Orders on a first in/first out basis. As such inventory of Safety Stock is used as part of the Manufacturing Services of Product and/or sample Product, Antares shall use Commercially Reasonable Efforts to replenish the Safety Stock to the level set forth in Section 3.6(a)(i) (as adjusted pursuant to Section 3.6(a)(ii)) within \*\*\* of receipt of such Firm Order.
- (e) Title and risk of loss of the Safety Stock shall transfer to AMAG upon the delivery to AMAG of the Certificate of Conformance (Device) and Certificate of Analyses (Device) for the applicable shipment of such Safety Stock from Antares' Subcontractor that manufactured such Safety Stock. Antares shall not be responsible for any insurance with respect to the risk of loss of such Safety Stock.
- (f) In the event any Safety Stock expires, Antares or its Subcontractor shall dispose of or destroy such Safety Stock in accordance with the Quality Agreement. AMAG shall reimburse Antares for any costs or expenses incurred (without markup) in connection with such disposal or destruction.
- (g) Notwithstanding the quantities set forth in Section 3.6(a), Antares or its Subcontractor shall maintain and store the Safety Stock during the Term of this Agreement, provided that during the last \*\*\* before expiration or termination of this Agreement, Antares or its Subcontractor is only required to maintain that amount of Safety Stock as is required to deliver amounts set forth in the then-current Forecast(s) until such expiration or termination date. AMAG shall reimburse Antares for any reasonable costs or expenses incurred (without markup) in connection with maintaining or storing the Safety Stock.

### **3.7 Manufacture at Risk.**

- (a) In the event AMAG desires for Antares and/or its Subcontractor to initiate Manufacturing Services with respect to any Product or sample Product prior to the receipt of the Certificate of Analysis (PFS Manufacture) and the Certificate of Analysis (PFS ID Testing) ("**Manufacture(d) at Risk**"), AMAG shall deliver written notice of such to Antares. Notwithstanding anything in this Agreement to the contrary, Antares shall not be required to perform any Manufacturing Services with respect to the Product or sample Product until Antares receives (i) such written notice of AMAG's intention to Manufacture at Risk as set forth in the first sentence of this Section 3.7(a), or (ii) the Certificate of Analysis (PFS Manufacture) and the Certificate of Analysis (PFS ID Testing).
- (b) \*\*\*.

- 3.8 Redundancy Plan.** Antares shall, at the Party's respective costs set forth on Exhibit I, develop, implement and maintain the redundancy plan for molds, tooling and assemblies for the manufacturing of the Devices set forth on Exhibit I.
- 3.9 Qualification of Second Source Supplier(s).** Antares shall, upon AMAG's written request provided to Antares and at AMAG's cost (as set forth in this Section 3.9), identify and reasonably verify the suitability of one or more Third Persons as a "backup" supplier of Devices (each, a "**Second Source Supplier**") in addition to Antares' then-current supplier of Devices (whether Antares or its then-current Subcontractor). Within \*\*\* following the receipt of such written request, the Parties will negotiate in good faith a budget for the costs and expenses associated with the Second Source Supplier, including all costs and expenses for the establishment and qualification thereof. Within \*\*\* following the agreement by both Parties of such budget, Antares will use Commercially Reasonable Efforts to establish and qualify such Second Source Supplier; provided, however, that the Joint Project Team under the Development and License Agreement may agree to extend such time periods. AMAG shall have the right to propose a Second Source Supplier and Antares shall have the right to consent to such Second Source Supplier, which consent shall not be unreasonably withheld or delayed. Within \*\*\* of a receipt of an invoice thereof, AMAG shall reimburse Antares for all documented costs and expenses (without markup) associated with the Second Source Supplier, including all documented costs and expense for the establishment and qualification thereof; provide that such costs and expenses, in the aggregate, shall not exceed \*\*\* of the agreed-upon budget (as set forth above).
- 3.10 Right to Purchase Directly from Subcontractors or Second Source Suppliers.**
- (a) If (i) a Force Majeure Event affecting solely Antares (specifically excluding its Subcontractors or Second Source Suppliers) lasts for \*\*\* which prevents Antares from fulfilling its financial obligations to a Subcontractor or a Second Source Supplier, or (ii) Antares is otherwise in material breach of its financial obligations to a Subcontractor or a Second Source Supplier for a period of at least \*\*\* then Antares shall promptly deliver to AMAG a written notice of such event or breach. Following the receipt of such notice, or following Antares' material breach of its obligation to deliver such notice under this Section 3.10(a), AMAG may deliver written notice to Antares of its intention to exercise its rights under this Section 3.10.
- (b) For the period commencing on Antares' receipt of such notice from AMAG as set forth in Section 3.10(a) and ending \*\*\* thereafter, Antares and AMAG shall negotiate in good faith a commercially reasonable agreement with respect to the Force Majeure Event or material breach describe in Section 3.10(a)(i) or 3.10(a)(ii), respectively, which may include, AMAG advancing payment for Manufacturing Services on terms to be negotiated among the Parties (an "Alternate Arrangement"). If, following the expiration of such \*\*\* period, the Parties cannot mutually agree on a commercially

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reasonable agreement thereof, then, notwithstanding anything to the contrary in this Agreement, Antares shall use Commercially Reasonable Efforts to enable AMAG to commence purchasing Devices, Components, Products, sample Products and/or Trainers directly from Antares' Subcontractors or Second Source Supplier(s) on substantially similar terms, including price, that Antares has with such Subcontractor or Second Source Supplier(s) (as the case may be). AMAG's right to purchase Devices, Components, Products, sample Products and/or Trainers directly from Antares' Subcontractor(s) or Second Source Supplier(s) shall continue to [\*\*\*].

- (c) Provided that (i) AMAG and Antares have agreed to the terms of an Alternate Arrangement, or (ii) AMAG commences purchasing Devices, Components, Products, sample Products and/or Trainers directly from Antares' Subcontractors or Second Source Supplier(s) pursuant to the terms of Section 3.10(b), AMAG's election of its right to purchase Devices, Components, Products, sample Products and/or Trainers directly from Antares' Subcontractor(s) or Second Source Supplier(s) under this Section 3.10 shall be AMAG's sole and exclusive remedy, and Antares' sole liability, with respect to Antares' failure to supply such Devices, Components, Products, sample Products and/or Trainers for the reasons specified in Section 3.10(a); provided, that, if AMAG does not elect such right, AMAG shall not be prohibited from exercising all other rights available to AMAG under this Agreement and at law.

#### **ARTICLE 4**

##### **PRICE AND PAYMENT**

#### **4.1 Prices.**

- (a) During the Term, Antares or its Subcontractor shall deliver Products, sample Products and Trainers ordered by AMAG in accordance with this Agreement at the Transfer Prices set forth on Exhibit D.
- (b) [\*\*\*].

#### **4.2 Invoices and Payment.**

[\*\*\*].

**Records; Financial Audit Request.** With respect to audits of Antares' records relating to the establishment of the Transfer Price, [\*\*\*] or any other amounts payable by AMAG hereunder, including, without limitation, pursuant to Section 4.6, Article 11 of the Development and License Agreement is hereby incorporated by reference herein and made a part of this Agreement.

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- (a) The Transfer Price includes all taxes except (i) such sales and use taxes which Antares is required by law to collect from AMAG and (ii) to the extent imposed on the date of this Agreement or as a result of a change in law, VAT. Such VAT and taxes, if any, will be payable in addition to the Transfer Price. Where Antares is required by law to collect and/or account for such VAT and taxes from AMAG, such VAT and taxes will be separately stated in Antares's Invoice and will be paid by AMAG to Antares unless AMAG provides an exemption to Antares and, in the case of VAT, subject to Antares providing a valid VAT invoice to AMAG in the form and manner required by law to allow AMAG to recover such VAT (to the extent AMAG is allowed to do so by law). For avoidance of doubt, any increase in VAT imposed as a result of any action taken by Antares, and not consented to by AMAG, after the date of this Agreement shall not be paid by AMAG or otherwise included in the Transfer Price.
- (b) Except where AMAG is required by Applicable Law to account for any VAT to the applicable Governmental Authority, Antares shall be solely responsible for the timely payment of all such VAT and taxes to the applicable Governmental Authority
- (c) Notwithstanding the foregoing in this Section 4.4, AMAG shall be responsible for the payment of all duties, tariffs, VAT, taxes and similar charges payable on the exportation or importation of the Products, sample Products or Trainers. Without limiting any of Antares's obligations hereunder, Antares shall cooperate with and assist AMAG in all aspects of the shipment, exportation, importation and delivery process in order to ensure the expeditious delivery of the Product to the designated delivery point, including assisting in obtaining any documents that may be required.

\*~~4~~.5

\*~~4~~.6

## ARTICLE 5

### **PRODUCT CLAIMS AND RECALLS**

#### **5.1 Product Claims.**

- (a) Product Claims. [\*\*\*].
- (b) Determination of Deficiency. [\*\*\*].
- (c) Shortages. [\*\*\*].

#### **5.2 Product Recalls and Returns.**

- (a) Records and Notice. In addition to the requirements of Section 6.2, Antares and AMAG shall each maintain such records in compliance with Applicable Laws as is reasonably necessary to permit a Recall of any Products, sample Products and Trainers delivered to AMAG, AMAG's designee or customers of AMAG. Each Party shall promptly (but no later than \*\*\* of receipt of such information) notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety, or effectiveness of the Products, sample Products or Trainers and/or which might result in the Recall or seizure of the Products, sample Products, or Trainers. Upon receiving any such notice or upon any such discovery, each Party shall cease and desist from further shipments of such Products, sample Products or Trainers in its possession or control until a decision by AMAG has been made whether a Recall or some other corrective action is necessary.
- (b) Recalls. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by AMAG in its sole discretion after consultation with Antares. AMAG shall be responsible for managing all Recalls and Antares shall cooperate with AMAG as AMAG may reasonably request. Subject to Antares' obligation to cover the costs set forth in Section 5.3(b), AMAG shall be responsible for all costs incurred due to the Recall of a Product, sample Product or Trainer.
- (c) Product Returns. AMAG shall have the responsibility for handling customer returns of the Products, sample Products and Trainers.

**5.3 Antares' Responsibility for Defective and Recalled Products.**

- (a) Defective Product. \*\*\*.
- (b) Recalled Product. \*\*\*.

**5.4 Disposition of Defective or Recalled Products**. AMAG shall not dispose of any damaged, defective, returned or Recalled Products, sample Products or Trainers in relation to which it intends to assert a claim against Antares without Antares' prior written authorization to do so, unless otherwise required by Applicable Laws. Alternatively, Antares may instruct AMAG to return such Products, sample Products and Trainers to Antares at Antares' expense. Antares shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Products, sample Products or Trainers in relation to which it bears responsibility under Sections 5.1, 5.2 or 5.3 hereof. In all other circumstances, AMAG shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Products, sample Products and Trainers.

**5.5 Customer Questions or Complaints**. AMAG shall have the sole right and responsibility for responding to questions and complaints from AMAG's customers. Antares shall refer any questions and complaints (including safety and efficacy inquiries, quality complaints

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and adverse event reports) that it receives concerning the Device or the Products, sample Products or Trainers to AMAG (together with all available evidence and other information relating thereto) as soon as practicable and, in any event within \*\*\* of Antares' receipt of such question or complaint; provided that all complaints concerning Product and sample Product tampering, contamination or mix-up (e.g., wrong ingredients) shall be delivered within \*\*\* of Antares' receipt thereof. Antares shall not take any further action in connection with any such questions or complaints without the consent of AMAG, but shall cooperate in the investigation and closure of any such questions or complaints at the request of AMAG. Such assistance shall include follow-up investigations, including testing. In addition, Antares shall provide AMAG with all information to enable AMAG to respond properly to questions or complaints relating to the Products and sample Products as provided in the Quality Agreement.

## ARTICLE 6

### **CO-OPERATION; QUALITY AUDIT; REGULATORY FILINGS**

- 6.1 Governmental Agencies.** Subject to the Regulatory Authority inspection obligations set forth in Section 6.3, Antares and/or its Subcontractor(s) may communicate with any Regulatory Authority regarding the Products, sample Products and Trainers only if, in the reasonable opinion of Antares' and/or its Subcontractor's counsel, such communication is necessary to comply with the terms of this Agreement or Applicable Laws; provided, however, that unless, in the reasonable opinion of Antares' and/or its Subcontractor's counsel, there is a legal prohibition against doing so, Antares shall notify AMAG reasonably in advance of any such communication and permit AMAG to accompany Antares and/or its Subcontractor and take part in any communications with such Regulatory Authority, and provide AMAG with copies of all such communications from such Regulatory Authority.
- 6.2 Records and Accounting by Antares.** Antares shall keep records of the manufacture, testing and shipping of the Products, sample Products and Trainers and retain samples of such Products, sample Products and Trainers as are necessary to comply with cGMPs, Applicable Laws, the Quality Agreement, and manufacturing regulatory requirements applicable to Antares, as well as to assist with resolving Product, sample Product and Trainer complaints and other similar investigations. Copies of such records and samples shall be retained for the respective periods set forth in the Quality Agreement.
- 6.3 Regulatory Inspections.** Antares shall permit the FDA and other Regulatory Authorities to conduct inspections of each Manufacturing Site as they may request, including pre-approval inspections, and shall cooperate with such Regulatory Authorities with respect to the inspections and any related matters, in each case which is related to the Device, Product or sample Product. Antares shall give AMAG notice within \*\*\* of becoming aware of any such inspections, and keep AMAG reasonably informed about the results and conclusions of each regulatory inspection, including actions taken by Antares or its Subcontractor to

remedy conditions cited in the inspections, to the extent such results and conclusions relate to the Device, Product or sample Product. In addition, Antares will promptly provide AMAG with copies of any written inspection reports issued by Regulatory Authorities and all correspondence between Antares and Regulatory Authorities, including, but not limited to, FDA Form 483, Notice of Observation, and all related correspondence, in each case only to the extent relating to the Device, Product or sample Product or general manufacturing concerns related to the Device, Product or sample Product, which in all cases may be reasonably redacted by Antares to protect confidential information of Antares or its partners, licensees or licensors. Antares agrees to promptly notify and provide AMAG copies of any request, directive or other communication of the FDA or other Regulatory Authority relating to the Device, Product or sample Product and to reasonably cooperate with AMAG in responding to such requests, directives and communications.

- 6.4 Quality Audit.** The Parties rights and obligations with respect to quality assurance audits are set forth in the Quality Agreement.
- 6.5 Reports.** Antares will promptly supply on an annual basis and when reasonably requested by AMAG from time to time, at no additional charge, all available information and data in its control that AMAG reasonably requires in order to complete any filing for, or apply for, obtain or maintain, regulatory approvals under any applicable regulatory regime (including any Annual Report that AMAG is required to file with the FDA), including without limitation information relating to the Manufacturing Site, Development Report (as described in ICH guidelines), Manufacturing Services, Device, Product, sample Product, Trainers or the process, methodology, raw materials and intermediates used in the manufacture, processing, or packaging of the Device, Product, sample Product or Trainers, release test results, complaint test results, all investigations (in manufacturing, testing and storage), and all information required to be submitted in the CMC (chemistry, manufacturing and controls) section of an IND or a NDA or other regulatory filings, or required or requested to be provided to any Regulatory Authority. At AMAG's reasonable written request, Antares shall be responsible for supporting AMAG's Annual Product Review Report, consistent with cGMPs, Applicable Laws, and customary FDA or other Regulatory Authority requirements. Any additional report requested by AMAG beyond the scope of what is required or recommended under cGMPs, Applicable Laws and customary FDA or other Regulatory Authority requirements shall be subject to an additional fee to be agreed upon between Antares and AMAG. In addition, Antares shall cooperate with AMAG with respect to all reporting obligations relevant to the Product, sample Product and Trainers under Applicable Laws.
- 6.6 Regulatory Filings.** Responsibility for regulatory filings shall be as set forth in Section 4.1 of the Development and License Agreement.



**ARTICLE 7**  
**TERM AND TERMINATION**

- 7.1 Term.** Subject to early termination of this Agreement pursuant to Sections 7.2, 7.3 or 7.4, this Agreement shall become effective as of the Effective Date and shall continue until the expiration or earlier termination of the Development and License Agreement (the “**Term**”).
- 7.2 Termination By AMAG.** This Agreement may be terminated in its entirety by AMAG, upon AMAG’s prior written notice to Antares:
- (a) Subject to Sections 11.1 and 12.4, if Antares commits a material breach of this Agreement and such material breach remains uncured for [\*\*\*] following written notice of breach by Antares. Notwithstanding the foregoing, AMAG’s termination rights with respect to an Antares’ failure to supply Products, sample Products or Trainers, including a Supply Failure, are not subject this Section 7.2(a) and are set forth in Section 7.2(b);
  - (b) Subject to Section 12.4, if a Supply Failure remains uncured for [\*\*\*] following written notice of such failure to Antares; provided, however, that AMAG may not terminate this Agreement if Antares’ failure to supply Products, sample Products or Trainers is a result of Force Majeure Event under Section 12.4 or AMAG’s breach of this Agreement including, but not limited to, failure to provide adequate quantities of Prefilled Syringe;
  - (c) If Antares is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of Antares’ assets, and such petition, assignment or appointment prevents Antares (as a legal or as a practical matter) from performing its obligations under this Agreement, or such petition, assignment or appointment is not otherwise dismissed or vacated within [\*\*\*]; or
  - (d) Upon [\*\*\*] written notice to Antares in the event that AMAG permanently ceases commercializing the Product for efficacy or safety reasons, as evidenced by the placement of the Product on the Discontinued Drug Product List of the FDA Orange Book publication (“*Approved Drug Products with Therapeutic Equivalence Evaluations*”).
- 7.3 Termination by Antares.** This Agreement may be terminated in its entirety by Antares upon Antares’ prior written notice to AMAG:
- (a) Subject to Sections 11.1 and 12.4, if AMAG commits a material breach of this Agreement and such material breach remains uncured for [\*\*\*] following written notice of breach by Antares;

- (b) If AMAG is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of AMAG's assets, and such petition, assignment or appointment prevents AMAG (as a legal or as a practical matter) from performing its obligations under this Agreement, or such petition, assignment or appointment is not otherwise dismissed or vacated within [\*\*\*]; or
- (c) Upon [\*\*\*] written notice to AMAG in the event that AMAG permanently ceases commercializing the Product for efficacy or safety reasons, as evidenced by the placement of the Product on the Discontinued Drug Product List of the FDA Orange Book publication ("*Approved Drug Products with Therapeutic Equivalence Evaluations*").

**7.4 Co-Termination.** Without further action by either Party, this Agreement shall automatically terminate effective immediately upon the termination of the Development and License Agreement in its entirety, subject to the provisions that expressly survive the termination thereof.

**7.5 Remedies for Material Breach.**

- (a) Remedies for AMAG. Subject to Sections 11.1 and 12.4, in the event of an uncured material breach by Antares that would entitle AMAG to terminate this Agreement under Section 7.2(a) and Section 7.2(b), in addition to and independent of AMAG's right to terminate this Agreement, AMAG may seek monetary damages (whether or not this Agreement is terminated) for such material breach and/or equitable relief to prevent such material breach from continuing or occurring again in the future.
- (b) Remedies for Antares. Subject to Sections 11.1 and 12.4, in the event of a uncured material breach by AMAG that would entitle Antares to terminate this Agreement under Section 7.3(a), in addition to and independent of Antares' right to terminate this Agreement, Antares may seek monetary damages (whether or not this Agreement is terminated) for such material breach and/or equitable relief to prevent such material breach from continuing or occurring again in the future.

**7.6 Effects of Expiration or Termination of this Agreement.**

- (a) If this Agreement expires or is terminated for any reason, then (in addition to any other remedies either Party may have in the event of material breach by the other Party):

[\*\*\*].

- (b) [\*\*\*].

- (c) [\*\*\*].

- (d) [\*\*\*].
- (e) Except with respect to AMAG's right to sell off existing inventory as set forth in Section 7.6(d), the Parties acknowledge and agree that following any expiration or termination of this Agreement, all rights and licenses granted to AMAG under this Agreement or the Development and License Agreement shall terminate and AMAG shall cease using and selling any Products, sample Products or Trainers.
- (f) Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the Parties may have under this Agreement or Applicable Laws (except as otherwise provided in this Agreement). For greater certainty, termination of this Agreement for any reason shall not affect the obligations and responsibilities of the Parties pursuant to ARTICLE 1 (Interpretation), ARTICLE 9 (Remedies and Indemnities) (provided that, the obligation to maintain the insurance coverages set forth in Section 9.3 shall only survive for the time period set forth therein), ARTICLE 10 (Confidentiality), ARTICLE 11 (Dispute Resolution), and Sections 2.9 (Retained Samples) (for the period set forth therein), 4.4 (Taxes), 5.2 (Product Recalls and Returns); 5.5 (Customer Questions or Complaints) (for a period of [\*\*\*] from the date of termination or expiration); 6.2 (Regulatory and Accounting by Antares) (for the period set forth therein), 7.6 (Effects of Expiration or Termination of this Agreement), 12.1 (Agency), 12.2 (Assignment) 12.5 (Notices), 12.6 (Amendment), 12.7 (Waiver) and 12.10 (Governing Law), all of which survive any termination or expiration.
- (g) Termination, relinquishment or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to (or as a result of, including, without limitation, rights available under law and equity) such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement.

7.7 [\*\*\*].

## **ARTICLE 8**

### **REPRESENTATIONS, WARRANTIES AND COVENANTS**

- 8.1** Authority. Each Party hereby represents, warrants and covenants to the other Party that: (i) it has the full right and authority to enter into this Agreement and to grant to the other Party the rights granted to such other Party under this Agreement, (ii) it has obtained all necessary corporate approvals to enter and execute this Agreement, and (iii) that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

**8.2** AMAG Warranties. AMAG hereby represents, warrants and covenants to Antares as follows:

- (a) AMAG, or a Third Person manufacturing Drug and Pre-Filled Syringes on behalf of AMAG, shall manufacture the Drug and Pre-Filled Syringe in accordance with the Specifications, cGLP, cGCP, cGMP and cQSRs, this Agreement, the Quality Agreement and Applicable Laws including, without limitation, federal, state, or local laws, regulations, or guidelines governing manufacturing at the site where such manufacturing is being conducted;
- (b) AMAG, or a Third Person manufacturing Drug and Pre-Filled Syringes on behalf of AMAG, shall obtain and maintain all necessary licenses, permits and approvals required by Applicable Laws in connection with the manufacture the Drug and Pre-Filled Syringe, and supply of Drug and Prefilled Syringes to Antares or its Subcontractor;
- (c) That all Drug or Prefilled Syringes manufactured by AMAG, or a Third Person on behalf of AMAG, when delivered to Antares or its Subcontractor (i) will comply with applicable Product Specifications and Certificate of Analysis (PFS Manufacture); (ii) will not be adulterated or misbranded within the meaning of any Applicable Laws effective at the time of delivery and will not be an article which may not be introduced into interstate commerce under any Applicable Laws; (iii) will be delivered to Antares or its Subcontractor (as the case may be) free and clear of all liens and encumbrances, and (iv) will be in compliance with cGMPs and all Applicable Laws;
- (d) That all Products and sample Products, when released by AMAG for distribution, sale or use pursuant to Section 2.6(b)(v)(D): (i) will comply with applicable Product Specifications, Batch Record, Certificate of Analysis Certificate of Analysis (PFS Manufacture), the Certificate of Analysis (PFS ID Testing), Certificate of Analysis (Product) and the Certificate of Conformance (Product); (ii) will not be adulterated or misbranded within the meaning of any Applicable Laws effective at the time of delivery and will not be an article which may not be introduced into interstate commerce under any Applicable Laws; and (iii) will be in compliance with cGMPs and all Applicable Laws;
- (e) Prior to the first commercial sale by AMAG or a Third Person on behalf of AMAG of Products, sample Product and Trainers in a given market, the Products, sample Product and Trainers, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws, have received the necessary marketing approvals from applicable Regulatory Authorities for sale, distribution and use in such market;

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- (f) AMAG has the requisite legal title and ownership under its intellectual property necessary for it to fulfill its obligations under this Agreement, and that there is no pending or threatened litigation, arbitration, government proceeding, or government investigation (and AMAG has not received any communication relating thereto) which alleges that AMAG's past activities relating to the Drug or activities proposed under this Agreement infringe or misappropriate any of the intellectual property rights of any Third Person, and to AMAG's actual knowledge, there is no intellectual property of any Third Person that would be infringed or misappropriated by Antares or its Subcontractor carrying out the Manufacturing Services in accordance with this Agreement; and
- (g) AMAG agrees that federal securities law may prohibit it, its Affiliates and its representatives from purchasing or selling any securities of Antares while it is in possession of material, non-public information of Antares, and that it will not disclose any material, non-public information, directly or indirectly, to any party for the purpose of encouraging such party to trade in Antares's securities and that it will comply at all times with the applicable securities laws and regulations.

**8.3 Antares Warranties.** Antares hereby represents, warrants and covenants to AMAG as follows:

- (a) Antares or its Subcontractor shall perform the Manufacturing Services in accordance with the Specifications, cGLP, cGCP, cGMPs and cQSRs, this Agreement, the Quality Agreement and Applicable Laws including, without limitation, federal, state, or local laws, regulations, or guidelines governing manufacturing at the Manufacturing Sites;
- (b) Antares or its Subcontractor shall obtain and maintain all necessary licenses, permits and approvals required by Applicable Laws in connection with the Manufacturing Services, manufacture of Devices and supply of Products, sample Products or Trainers to AMAG;
- (c) As of the Effective Date, Antares has disclosed to AMAG any and all FDA Form 483's, warning letters or similar notices relating to the Manufacturing Site and import alerts for any other products manufactured in the Manufacturing Site issued during the last \*\*\*;
- (d) \*\*\*;
- (e) Antares has the requisite legal title and ownership of intellectual property necessary for it to fulfill its obligations under this Agreement, and that there is no pending or threatened litigation, arbitration, government proceeding, or government investigation (and Antares has not received any communication relating thereto) which alleges that Antares' past activities relating to \*\*\* devices or activities proposed under this

\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Agreement infringe or misappropriate any of the intellectual property rights of any Third Person, and to Antares' actual knowledge, there is no intellectual property of any Third Person that would be infringed or misappropriated by AMAG fulfilling any of its obligations or exercising any of its rights under this Agreement; and

(f) Antares agrees that federal securities law may prohibit it, its affiliates and its representatives from purchasing or selling any securities of AMAG while it is in possession of material, non-public information of AMAG, and that it will not disclose any material, non-public information, directly or indirectly, to any party for the purpose of encouraging such party to trade in AMAG's securities and that it will comply at all times with the applicable Federal Securities Laws and regulations.

(g) [\*\*\*].

**8.4 Debarred Persons.** Each of the Parties covenants, represents and warrants that: (i) neither it nor any of its employees or subcontractors performing Manufacturing Services have been "debarred" by the FDA, or subject to a similar sanction from another Regulatory Authority; nor have debarment proceedings against said Party or any of its employees or subcontractors performing Manufacturing Services been commenced; and (ii) it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended by the FDA as described in 21 U.S.C. §335(a) or (b). Said Party will promptly notify the other Party in writing if any such debarment proceedings have commenced or if said Party or any of its employees or subcontractors performing Manufacturing Services are debarred by the FDA or other Regulatory Authorities. Each of the Parties further covenants, represents and warrants that it does not currently have, and will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Federal Food, Drug, and Cosmetic Act.

**8.5 Permits.** As between the Parties, AMAG shall be solely responsible for obtaining or maintaining, on a timely basis, any permits or other Regulatory Approvals in respect of the Products, sample Products, Trainers, Specifications, including, without limitation, all marketing and post-marketing approvals.

**8.6 No Warranty.** NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY OR WARRANTY OF NON-INFRINGEMENT OF THIRD PERSON RIGHTS.

**ARTICLE 9**  
**REMEDIES AND INDEMNITIES**

- 9.1 Antares' Right to Indemnification.** AMAG shall indemnify each of Antares, its Affiliates, its Subcontractors and their respective successors and assigns, and the directors, officers, employees, and agents thereof (the "**Antares Indemnitees**"), defend and hold each Antares Indemnatee harmless from and against any and all liabilities, damages, losses, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation reasonable attorneys' fees) (any of the foregoing, "**Damages**") incurred by or asserted against any Antares Indemnatee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of patent or other proprietary rights, but only to the extent arising from or occurring as a result of a claim or demand made by a Third Person (a "**Third Person Claim**") against any Antares Indemnatee because of (a) breach of any warranty made by AMAG pursuant to Section 8.2 hereof; (b) the Product, sample Product or Trainer (including the content of any labelling and the decision to release the Product, sample Product or Trainer) unless attributable to an item identified in Section 9.2 below which is under the responsibility of Antares or its Subcontractors; (c) the distribution or detailing of any Product, sample Product or Trainer by or on behalf of AMAG or its sublicensees, except to the extent such claim is attributable to an item identified in Section 9.2(f) below which is under the responsibility of Antares; (d) any allegation that the manufacture, use, sale, offer for sale or importation of a Product, sample Product or Trainer infringes any patent, other intellectual property rights or other proprietary rights of a Third Person, except to the extent such infringement relates to the manufacture, use, sale, offer for sale or importation of a Device (including a Device incorporated into a Product) or any delivery system including the Device; or (e) any breach of this Agreement by AMAG, except, in each such case, to the extent that such Damages are finally determined to have resulted from the negligence or misconduct of Antares. Antares shall promptly notify AMAG of any Third Person Claim upon becoming aware thereof, and shall permit AMAG, at AMAG's cost, to defend against such Third Person Claim and to control the defense and disposition (including, without limitation, selection its counsel and all decisions to litigate, settle or appeal) of such claim, and shall cooperate in the defense thereof. Antares may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of AMAG and shall cooperate with AMAG and its insurer in the disposition of any such matter.
- 9.2 AMAG's Right to Indemnification.** Antares shall indemnify each of AMAG, its Affiliates, and their respective successors and assigns, and the directors, officers, employees, and agents thereof (the "**AMAG Indemnitees**"), defend and hold each AMAG Indemnatee harmless from and against any and all Damages incurred by or asserted against any AMAG Indemnatee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of

patent or other proprietary rights, but only to the extent arising from or occurring as a result of a Third Person Claim against any AMAG Indemnitee because of (a) breach of any warranty made by Antares pursuant to Section 8.3 hereof; (b) any alleged defect in the design or functionality of the Device; (c) the failure by Antares or its Subcontractors to provide the Manufacturing Services according to Specifications, except to the extent AMAG approved such failure pursuant to its in process acceptance activities set forth in the Quality Agreement; (d) [\*\*\*]; (e) the warehousing or shipping of a Product, sample Product or Trainer by Antares, except to the extent such claim alleges infringement of any patent, other intellectual property rights or other proprietary rights of a Third Person; (f) any allegation that the Manufacturing Services performed under this Agreement or the manufacture, use, sale, offer for sale or importation of a Device (including a Device incorporated into a Product) or any delivery system including the Device, in such cases, infringes any patent, other intellectual property rights or other proprietary rights of a Third Person; or (g) any breach of this Agreement by Antares, except, in each such case, to the extent that such Damages are finally determined to have resulted from the negligence or misconduct of AMAG or a sublicensee of AMAG. AMAG shall promptly notify Antares of any Third Person Claim upon becoming aware thereof, and shall permit Antares at Antares' cost to defend against such Third Person Claim and to control the defense and disposition (including, without limitation, selection its counsel and all decisions to litigate, settle or appeal) of such Third Person Claim and shall cooperate in the defense thereof. AMAG may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of Antares and will cooperate with Antares or its insurer in the disposition of any such matter.

**9.3 Insurance.** Each Party shall obtain and maintain commercial general liability insurance, including product liability insurance covering the obligations of that Party under this Agreement through the Term and for a period of [\*\*\*] thereafter, which insurance shall afford limits of not less than (i) \$[\*\*\*] for each occurrence; and (ii) \$[\*\*\*] in the aggregate per annum. Such insurance may be provided in more than one separate insurance policy and/or on claims made or claims made and reported forms as is common in the insurance marketplace for similar risks. If requested each Party will provide the other with a current and valid certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. If a Party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such Party, then such Party shall forthwith notify the other Party in writing and the Parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

**9.4 Limitation of Liability.**

[\*\*\*].



**ARTICLE 10**  
**CONFIDENTIALITY**

Articles 17 and 18 of the Development and License Agreement are hereby incorporated by reference herein and made a part of this Agreement.

**ARTICLE 11**  
**DISPUTE RESOLUTION**

**11.1 Commercial Disputes.** In the event of any dispute arising out of or in connection with this Agreement [\*\*\*], the Parties shall first try to solve it amicably. In this regard, any Party may send a notice of dispute to the other, and each Party shall appoint, within [\*\*\*] from receipt of such notice of dispute, a senior executive representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If the dispute has not been resolved within [\*\*\*] after the end of the [\*\*\*] negotiation period referred to above (which period may be extended by mutual agreement), then such dispute shall be subject to any other remedy available under this Agreement or at law or equity.

**11.2** [\*\*\*].

**ARTICLE 12**  
**MISCELLANEOUS**

**12.1 Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.

**12.2 Assignment.** Except as otherwise provided in this Section 12.2, neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other (which consent shall not be unreasonably withheld, conditioned or delayed); provided, however, that either Party may assign this Agreement to any wholly-owned subsidiary or to any successor by merger or sale of substantially all of its business unit to which this Agreement relates. This Agreement shall be binding upon the successors and permitted assignees of the Parties. Any purported assignment in violation of this paragraph shall be void and ineffectual and shall not operate to transfer or assign any interest or title to the purported assignee.

**12.3 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

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**12.4 Force Majeure.** Neither Party shall be liable to the other for loss or damages or shall have any right to terminate this Agreement for any default or delay attributable to any force majeure event outside of the affected Party's reasonable control, including, but not limited to, acts of God, acts of government, war, fire, flood, earthquake, terrorist acts, strike, labor dispute and the like (each, a "**Force Majeure Event**"), if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is disabled by the Force Majeure Event from performing for so long as it is so disabled; provided, however, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause throughout such disability.

**12.5 Notices.** All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by electronic mail or facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

If to AMAG, addressed to: AMAG Pharmaceuticals, Inc.

\*\*\*  
1100 Winter Street  
Waltham, MA 02451  
\*\*\*

*With a copy to:*  
\*\*\*  
AMAG Pharmaceuticals, Inc.  
100 Winter Street  
Waltham, MA 02451  
\*\*\*

If to Antares, addressed to: Antares Pharma, Inc.  
\*\*\*  
100 Princeton South, Suite 300  
Ewing, NJ 08628  
\*\*\*

*with a copy to:*  
General Counsel  
Antares Pharma, Inc.  
100 Princeton South, Suite 300  
Ewing, NJ 08628  
\*\*\*

- 12.1 Amendment.** No amendment, modification or supplement of any provision of the Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.
- 12.2 Waiver.** No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.
- 12.3 Counterparts; Electronic Copies.** The Agreement may be executed simultaneously in two or more counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. A facsimile transmission or portable document format (PDF) electronic transmission of this signed Agreement by a Party's authorized representative shall be legal and binding upon such Party.
- 12.4 Descriptive Headings.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 12.5 Governing Law; Choice of Forum.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to its conflict of law provisions. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement. Except as otherwise provided in ARTICLE 11, all claims and proceedings under this Agreement shall be brought exclusively in the state or federal courts of competent subject matter jurisdiction in New York City, State of New York. The Parties hereby waive (i) any objection which it may have at any time to the venue of the proceeding in any such court, (ii) any claim that such proceedings have been brought in an inconvenient forum, and (iii) the right to object, with respect to such proceedings, that such court does not have any jurisdiction over such Party.
- 12.6 Severability.** Whenever possible, each provision of the Agreement will be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of the Agreement is held to be prohibited by or invalid under Applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

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- 12.7 Entire Agreement of the Parties.** This Agreement, including the Exhibits attached hereto, the Quality Agreement and the Development and License Agreement constitute and contain the complete, final and exclusive understanding and agreement of the Parties hereto, and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof. In the event there is a discrepancy between the Exhibits and the Agreement, the Agreement shall control, provided that to the extent there is a discrepancy between the Quality Agreement and the Agreement, the Quality Agreement shall control with respect to quality-related matters; and this Agreement shall control with respect to all other matters. Furthermore, to the extent that any provision of this Agreement is inconsistent with any provision of the Development and License Agreement, this Agreement shall control and then only to the extent of the inconsistency. For the avoidance of doubt, this Agreement supersedes and replaces Sections 10.2 and 10.3 of the Development and License Agreement.
- 12.8 Jointly Prepared.** This Agreement has been prepared jointly by both Parties and shall not be strictly construed against either Party.

*[Signature page follows.]*

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IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement as of the date first written above.

**ANTARES PHARMA, INC.**

By: /s/ Patrick Madsen

Name: Patrick Madsen  
Title: Senior Vice President, Operations

**AMAG PHARMACEUTICALS, INC.**

By: /s/ William K. Heiden

Name: William K. Heiden  
Title: President and Chief Executive Officer

[Signature Page to Manufacturing Agreement]

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EXHIBIT A  
 LONG LEAD TIME MATERIALS

Part Name	Material Specification	Lead-Time
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

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**EXHIBIT B**

**PRODUCT SPECIFICATIONS**

\*\*\*

[Exhibit B to Manufacturing Agreement]

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**EXHIBIT C**

**TRAINER SPECIFICATIONS**

\*\*\*

[Exhibit C to Manufacturing Agreement]

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**EXHIBIT D**

**TRANSFER PRICE**

The “**Transfer Price**” to be paid by AMAG to Antares for each Product, sample Product and Trainer delivered to AMAG or AMAG’s designee under this Agreement during the Term shall be determined as follows:

[\*\*\*]

[Exhibit D to Manufacturing Agreement]

---

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**EXHIBIT E**

**QUALITY AGREEMENT**

\*\*\*

[Exhibit E to Manufacturing Agreement]

---

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**EXHIBIT F**

**BATCH NUMBERING AND EXPIRATION DATES**

\*\*\*

[Exhibit F to Manufacturing Agreement]

---

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**EXHIBIT G**  
**RETAINED SAMPLES**

<b><u>Part Number</u></b>	<b><u>Description</u></b>
***	***
***	***
***	***
***	***

[Exhibit G to Manufacturing Agreement]

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**EXHIBIT H**

**INITIAL FORECAST**

\*\*\*

[Exhibit H to Manufacturing Agreement]

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**EXHIBIT I**

**REDUNDANCY PLAN**

Item	Financial Responsibility	Primary	Back-up On Hand
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***

[Exhibit I to Manufacturing Agreement]

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**EXHIBIT J**

\*\*\*

[Exhibit J to Manufacturing Agreement]

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**EXHIBIT K**  
**AMAG EQUIPMENT**

The following molds:

Part Number	Description
***	***
***	***
***	***

[Exhibit K to Manufacturing Agreement]

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**EXHIBIT L**

**FORM OF CHANGE ORDER**

\*\*\*

[Exhibit L to Manufacturing Agreement]