

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

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### FILER

#### ACURA PHARMACEUTICALS, INC

CIK: **786947** | IRS No.: **110853640** | State of Incorpor.: **NY** | Fiscal Year End: **1231**

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SIC: **2834** Pharmaceutical preparations

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549**

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act Of 1934**

**July 21, 2011**  
Date of Report (Date of earliest event reported)

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**ACURA PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Charter)

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**State of New York**  
(State of Other Jurisdiction  
of Incorporation)

**1-10113**  
(Commission File Number)

**11-0853640**  
(I.R.S. Employer  
Identification Number)

**616 N. North Court, Suite 120**  
**Palatine, Illinois 60067**  
(Address of principal executive offices) (Zip Code)

**(847) 705-7709**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e- 4(c))
-

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 25, 2011, we entered into a Manufacturing Services Agreement dated as of July 19, 2011 with Patheon Pharmaceuticals Inc. (the “Agreement”). The Agreement provides for Patheon’s non-exclusive manufacture and supply of our 30mg Nexafed™ PSE tablets and for Patheon’s provision of certain validation and stability services. The Agreement expires on December 31, 2016, subject to automatic two-year renewal periods in the absence of at least 18 months’ prior written notice by either party. The Agreement may be terminated by either party as a result of the breach or bankruptcy of the other party, and by us as a result of certain supply interruptions or product recalls, or in certain cases if Patheon’s supply price exceeds a specified level. The Agreement contains representations, warranties and indemnity obligations customary for agreements of this type. Apart from the Agreement, Patheon has no material relationship within us.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement filed herewith.

**Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On July 11, 2011, we filed with the Securities and Exchange Commission a Form 8-K discussing, among other things, that as a result of the retirement of Mr. William Sumner from our Board and Audit Committee, we do not currently satisfy NASDAQ Market Place Rule 5605(c)(2)(A) providing that the Audit Committee of a NASDAQ listed issuer be comprised of at least three independent Board members. In our July 11, 2011 Form 8-K filing, we also described that we had notified NASDAQ of our non-compliance with such rule. On July 21, 2011 we received written notice from NASDAQ confirming that we no longer comply with NASDAQ’s audit committee requirements set forth in Listing Rule 5605, and that NASDAQ has granted us a cure period until the earlier of our next annual shareholder’s meeting or July 6, 2012. We will rely on such cure period pending our Board’s appointment of a successor to our Audit Committee. Our Board is evaluating filling the vacancy on our Audit Committee with an existing Board member, subject to the Board’s evaluation of such Board member’s independence under applicable NASDAQ and SEC rules.

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**Item 9.01      Financial Statements and Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
10.1	Manufacturing Services Agreement dated as of July 19, 2011 between Acura Pharmaceuticals, Inc., and Patheon Pharmaceuticals Inc.*

\* Certain information has been omitted and filed separately with the Securities and Exchange Commission. Confidential Agreement has been requested with respect to the omitted portion.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

### ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens  
Peter A. Clemens  
Senior Vice President & Chief Financial Officer

Date: July 25, 2011

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## EXHIBIT INDEX

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10.1	Manufacturing Services Agreement dated as of July 19, 2011 between Acura Pharmaceuticals, Inc., and Patheon Pharmaceuticals Inc.*

\* Certain information has been omitted and filed separately with the Securities and Exchange Commission. Confidential Agreement has been requested with respect to the omitted portion.

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## **Manufacturing Services Agreement**

**JULY 19, 2011**

**By and Between Acura Pharmaceuticals, Inc. and  
Patheon Pharmaceuticals Inc.**

**\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission\*\*\***

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## MANUFACTURING SERVICES AGREEMENT

**THIS MANUFACTURING SERVICES AGREEMENT (the "Agreement")** is made as of July 19, 2011 (the "**Effective Date**")

BETWEEN:

**PATHEON PHARMACEUTICALS INC.,**

a corporation existing under the laws of the State of Delaware

("Patheon"),

- and -

**ACURA PHARMACEUTICALS, INC.,** a corporation existing under the laws of the State of New York

("Client").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

### ARTICLE 1

#### INTERPRETATION

##### **1.1      Definitions.**

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", "**Active Pharmaceutical Ingredients**" or "**API**" means the materials described as such on Schedule A, under the heading "Active Materials";

"**Affiliate**" means:

- (a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or
- (b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or
- (c) a business entity, the controlling interest of which is directly common to the majority ownership of a party to this Agreement. For the purposes of this Agreement, JLL Partners will be considered an Affiliate of Patheon but GCE Holdings LLC will not be considered an Affiliate of Client;

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For this definition, "control" means possession, whether direct or indirect, of the power to direct the management and policies of an entity, whether pursuant to the ownership of voting securities or otherwise.

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

**"Annual Report"** means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

**"Annual Volume"** means the volume of Product manufactured in any Year of this Agreement as set forth in Schedule B;

**"Applicable Laws"** means all laws, statutes and regulations of any Authority in the Territory and having jurisdiction over a Party in connection with its performance under this Agreement, including, in the case of Patheon, cGMPs;

**"Authority"** means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, including without limitation, the FDA;

**"Batch"** means a specific quantity of Product that is intended to have uniform character and quality, intended to meet the Specifications, and is produced according to a single manufacturing order during the same cycle of manufacture;

**"Bill Back Items"** means the project specific items identified in Schedule G necessary for Patheon to perform the Manufacturing Services which are not included as Components herein or as Dedicated Equipment under the Capital Equipment Agreement;

**"Blister Cartons Packaging"** means Patheon's packaging of the Product as part of the Manufacturing Services;

**"Blister Cartons Packaging Price"** is provided in the table in Schedule B, under the caption "Blister Cartons Packaging";

**"Breach Notice"** will have the meaning specified in Section 8.2(a);

**"Business Day"** means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio;

**"Bulk Tablets Manufacturing"** means Patheon's Manufacturing Services in connection with the manufacture of the Product in bulk tablets;

**"Bulk Tablets Manufacturing Price"** is provided in the table in Schedule B, under the caption "Bulk Tablets Manufacturing";

**"Capital Equipment Agreement"** means the Capital Equipment and Expenditure Agreement between the parties that is attached hereto as Schedule H.

**"cGMPs"** means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations together with the latest FDA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

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**"Client Intellectual Property"** means Intellectual Property generated or derived by Client before and after entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent or relies upon, Client's Product or Client's Confidential Information;

**"Clinical Trial Agreement"** will have the meaning provided in Section 8.2(b).

**"Client Property"** will have the meaning specified in Section 8.4(e);

**"Commercial Supply Notice"** has the meaning specified in Section 5.1(b);

**"Competitor of Patheon"** means an entity whose primary business is contract development or commercial manufacturing of pharmaceutical products for human consumption;

**"Components"** means, collectively, all Active Materials, packaging components, raw materials, and ingredients (including labels, product inserts and other labelling for the Products) but excluding pallets, required to manufacture the Products in accordance with the Specifications as set forth in Schedule A;

**"Confidential Information"** has the meaning provided in Section 11.1;

**"DEA"** means the United States Drug Enforcement Administration;

**"Deficiency Notice"** has the meaning specified in Section 6.1(a);

**"Delivery Date"** means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(c);

**"Disclosing Party"** has the meaning provided in Section 11.1;

**"FDA"** means the United States Food and Drug Administration;

**"Firm Orders"** has the meaning specified in Section 5.1(c);

**"First Firm Order"** has the meaning specified in Section 5.1(b);

**"Force Majeure Event"** will have the meaning specified in Section 13.7;

**"Indemnified Party"** has the meaning provided in Section 10.5;

**"Indemnifying Party"** has the meaning provided in Section 10.5;

**"Initial Manufacturing Month"** has the meaning specified in Section 5.1(b);

**"Initial Manufacturing Period"** has the meaning specified in Section 5.1(b);

**"Initial Term"** has the meaning specified in Section 8.1;

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**"Intellectual Property"** means patents, trade marks, service marks, design rights (whether capable of registration or otherwise), including applications for any of the foregoing, copyrights, know-how, trade or business names and other similar rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world whether capable of registration or not;

**"Invention"** means any invention, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

**"Inventory"** means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products, subject to the limits of Section 5.2.

**"Late Delivery"** has the meaning specified in Section 5.5;

**"Manufacturing Services"** means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, set forth in this Agreement, required to manufacture Product or Products from Components, but specifically excluding the Stability Services and the Validation Services;

**"Manufacturing Site"** means the facility owned and operated by Patheon that is located at 2110 East Galbraith Road, Cincinnati, OH 45237-1625;

**"Materials"** means all Components, Bill Back Items, and other materials used to manufacture the Product.

**"Patheon Intellectual Property"** means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, Intellectual Property developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, the Product, Client's Intellectual Property or Client's Confidential Information, including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the Product;

**"Person"** means an individual, corporation, general partnership, limited partnership, limited liability company, limited liability partnership, association, trust or other entity or organization, including an Authority.

**"PPI"** has the meaning provided in Section 4.2(a);

**"Product(s)"** means the product(s) listed on Schedule A under the caption "Product List";

**"Product Price"** means sum of the Bulk Tablets Manufacturing Price and the Blister Cartons Packaging Price for the Products delivered to Client in accordance with this Agreement, and includes the cost of Components (**Component Price**) and the cost of the Manufacturing Services (**Manufacturing Price**) as set forth in Schedule B;

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**"Quality Agreement"** means the agreement between the parties setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client, appended as Schedule F hereto;

**"Recall"** has the meaning specified in Section 6.2(a);

**"Receiving Party"** has the meaning provided in Section 11.1;

**"Remediation Period"** has the meaning specified in Section 8.2(a);

**"Specifications"** means the standards, for each Product, which are given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to each Product, including, without limitation:

- (a) specifications for Components;
- (b) manufacturing specifications, master Batch records, directions, and processes;
- (c) storage requirements;
- (d) all environmental, health and safety information for each Product including material safety data sheets; and
- (e) the finished Product specifications, packaging and labelling specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

**"Stability Price"** means the price measured in US Dollars for annual stability testing as set forth in Schedule C;

**"Stability Services"** means the services provided by Patheon as set forth in Section 2.1(d).

**"Supply Interruption"** means [\*\*\*], in any case whether due to an act or omission of Patheon, a Force Majeure Event or other reason;

**"Technical Dispute"** has the meaning specified in Section 12.2;

**"Term"** has the meaning provided in Section 8.1;

**"Territory"** means in the geographic area of the United States of America, its territories and possessions;

**"Third Party"** means any person, other than Patheon, Client or their respective Affiliates, officers, directors, employees and agents;

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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"**Third Party Claim**" has the meaning provided in Section 10.5(a);

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Validation Batches**" has the meaning specified in Section 2.1(f);

"**Validation Price**" means the incremental price measured in US Dollars above and beyond the Product Price to be charged by Patheon for completing the Validation Services as set forth in Schedule C;

"**Validation Services**" means the services provided by Patheon as set forth in Section 2.1(f).

"**Year**" means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year,

## **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 Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule 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 or Schedule of this Agreement.

## **1.4            Singular Terms.**

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

## **1.5            Schedules.**

The following Schedules are attached to, incorporated in, and form part of this Agreement:

Schedule A	- Product List and Specifications
Schedule B	- Manufacturing Campaigns, Packaging Run Quantities, and Price
Schedule C	- Stability Services and Validation Service Fees
Schedule D	- (Reserved)
Schedule E	- Technical Dispute Resolution
Schedule F	- Commercial Quality Agreement
Schedule G	- Bill Back Items
Schedule H	- Capital Equipment Agreement



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## ARTICLE 2

### PATHEON'S SERVICES

#### 2.1 Services.

Patheon will perform (i) the Manufacturing Services (described in Sections 2.1 (a), (b), (c), and (e)), at the Manufacturing Site, for the Territory for the Product Prices specified in Schedules B to manufacture Products as requested by Client and (ii) the Stability Services and Validation Services described in Sections 2.1(d) and (f), respectively. Schedule B sets forth the Bulk Tablets Manufacturing Price and the Blister Cartons Packaging Price (including the respective Manufacturing Price and the Components Price for each) and a list of costs items that are included in the Product Price. The parties will agree in writing on the cost of any additional services that Acura may request. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. If Manufacturing Services have not started within 12 months of the date of execution of this Agreement, Patheon may amend the Product Prices set forth in Schedules B as set forth in Section 4.2. Patheon agrees to manufacture and supply and, subject to Section 5.7, Client agrees to order at least [\*\*\*] of the Client's requirements for Products offered for sale by Client in the Territory so long as Patheon is in material compliance with its obligations to Client under this Agreement. In performing the Manufacturing Services, Validation Services and Stability Services, Patheon and Client agree that:

- (a) Conversion of Components. Patheon will convert the Components into Products per the Specifications and cGMPs.

- (b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement and in accordance with the Specifications and cGMPs. Batch review and release to Client will be the responsibility of Patheon through its quality assurance group. Patheon will perform its Batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the Batch has been manufactured and tested in accordance with cGMPs and meets the Specifications. Client will have sole responsibility for the release of Products to the market. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those Batch documents is Client property.

- (c) Components. Patheon will purchase (including obtaining any procurement quotas required by the Applicable Laws) and test all Components at Patheon's expense and as required by the Specifications and in accordance with cGMPs. Patheon will purchase sufficient quantities of Components to ensure a timely supply of the Products given Client's forecasts and Firm Orders.

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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(d) Stability Services. Patheon will conduct stability testing on the Products in accordance with the protocols set forth in the Specifications and the Quality Agreement for the separate Stability Price and set forth in Schedule C (“**Stability Services**”). Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure. Client will pay for the investigative costs unless the investigation determines Patheon has failed to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and/or Applicable Laws in which case Patheon will pay for the investigative costs. Patheon will give Client all stability test data and results at Client’s request.

(e) Packaging. Patheon will package the Products as set out in the Specifications and in accordance with cGMPs. Patheon will determine and imprint the Batch numbers and expiration dates for each Product shipped in accordance with its standard operating procedures. The Batch numbers and expiration dates will be affixed by Patheon on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable governmental agencies and other third parties responsible for the approval of the Products, if required by Applicable Law. Client will be responsible for the cost of labelling obsolescence when changes occur. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Applicable Law; or (ii) Patheon consents in writing to the use of its name.

(f) Validation Services. Patheon will prepare a validation protocol for the Products consistent with cGMPs and, upon Client’s written approval of the protocol, manufacture and test three Batches of Product (the “**Validation Batches**”) in accordance with the validation protocol (“**Validation Services**”). Client will pay to Patheon the Validation Price set out in Schedule C upon the successful completion of the Validation Services. Patheon will manufacture the Validation Batches pursuant to this Section 2.1(f) in accordance with the Manufacturing Services and Client will pay for the Product at the Product Price as set forth in the Agreement. Patheon acknowledges that the Validation Batches are intended for commercial sale by Client. Patheon agrees to store the Validation Batches at the Manufacturing Site until such time as Client provides notice of a delivery request pursuant to Sections 5.4 and 5.6.

(g) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and mutually agreed upon and set forth in the Specifications. If Patheon manufactures Product in accordance with the agreed upon process specifications, master Batch record, internal process specifications and under cGMP conditions, and a Batch or portion of Batch of Product does not meet a Finished Product Specification, Client will pay Patheon the applicable Product Price for the non-conforming Product.

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## ARTICLE 3

### CLIENT'S OBLIGATIONS

#### 3.1 Payment.

Client will pay Patheon (i) for performing the Manufacturing Services according to the Product Prices specified in Schedule B for each unit of Product meeting the Specifications and delivered to Client and (ii) for performing the Stability Services and Validation Services according to the Stability Price and Validation Price as set forth in Schedule C. These prices may be subject to adjustment under Article 4 of this Agreement. Bill Back Items will be charged to Client at Patheon's cost plus [\*\*\*]. Patheon will use commercially reasonable efforts to minimize the cost of the Bill Back Items.

#### 3.2 Other Obligations

Client will provide artwork and will be responsible for the cost of artwork development.

## ARTICLE 4

### CONVERSION FEES AND COMPONENT COSTS

#### 4.1 First Year Pricing.

The Product Price, the Stability Price, and the Validation Price for the Products for the first Year ending December 31, 2011 are listed in Schedules B and C and are subject to the adjustments set forth in Sections 4.2 and 4.3.

#### 4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year of the Agreement, Patheon may adjust the Product Price effective January 1<sup>st</sup> of each Year as follows:

- (a) Manufacturing Costs. Patheon may adjust the Manufacturing Price portion of the Product Price [\*\*\*].
- (b) Component Costs. [\*\*\*]
- (c) Pricing Basis. Client acknowledges that the Product Price in any Year is quoted based upon the Manufacturing Campaigns and Packaging Run Quantities specified in Schedule B. [\*\*\*]

For all Product Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1<sup>st</sup> of each Year a revised Schedule B to be effective for the next Year.

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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#### 4.3 **Price Adjustments – Current Year Pricing.**

During any Year of this Agreement commencing with the Year beginning January 1, 2012, the Product Prices set out in Schedule B will be adjusted as follows:

Extraordinary Increases in Component Costs. [\*\*\*]

[\*\*\*]

#### 4.4 **Adjustments Due to Technical Changes.**

Amendments to the Specifications or the Quality Agreement requested by an Authority or by Client (including, without limitation, amendments requested during or resulting from the completion of the Services performed by Patheon pursuant to the Clinical Trial Agreement) will only be implemented following a technical and cost review by Patheon and are subject to Client and Patheon reaching written agreement on changes to the Product Price, Stability Price and/or Validation Price (as appropriate) required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon (including, without limitation, amendments requested during or resulting from the completion of the Services performed by Patheon pursuant to the Clinical Trial Agreement) will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. Client may reasonably withhold approval due to adverse changes in any price or inventory obsolescence. If Client accepts a proposed change in the Specifications, Quality Agreement or Manufacturing Site, as applicable, the associated change in Product Price (if any) will be implemented, and the Product Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, if the changes to the Specifications or Quality Agreement are requested by Client, Client agrees to purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory [\*\*\*], all Inventory used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. But the work-in-process portion of Inventory will not exceed the quantities provided for in the first 90 days of Client's then current forecast. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client. Patheon will use reasonable efforts to use the Inventory with other clients or otherwise minimize the obsolescence costs.

#### 4.5 **Multi-Country Packaging Requirements.**

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional Component costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

**[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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#### 4.6 **Product Pricing Adjustment Discussions.**

At least annually or anytime at Client's request the parties will meet to discuss market conditions affecting the forecast, Client's prices for the Product to its customer, the Product Prices and any adjustments thereto and any other information relevant to the demand for the Products. The parties agree to consider, in good faith, any proposals for improvement to the Product or Specifications that will reduce the Product Prices or otherwise negotiate in good faith Product Prices necessary to meet market conditions.

### ARTICLE 5

#### **ORDERS, SHIPMENT, INVOICING, PAYMENT**

#### 5.1 **Orders and Forecasts.**

- (a) Rolling 18 Month Forecast. When this Agreement is executed, Client will give Patheon a non-binding 18 month forecast of the volume of Product that Client expects to order in the first 18 months of commercial manufacture (including Validation Services) of the Product. This forecast will then be updated by Client on or before the 10th day of each month on a rolling forward basis following the commencement of commercial manufacturing. Client will update the non-binding forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than 20%. The most recent 18 month forecast will prevail.

- (b) Firm Orders for Initial Manufacturing Month. The commencement of Patheon's Manufacturing Services for commercial supply of the Product will require (i) written notice from Client specifying the commencement date of the Manufacturing Services, which will be no earlier than 90 days from the date of delivery to Patheon of Client's notice (the "**Commercial Supply Notice**"), and (ii) Client's provision to Patheon of Client's updated rolling forecast for the first three months of the commercial manufacture of the Product (the "**Initial Manufacturing Period**"). The first month of this updated forecast ("**Initial Manufacturing Month**") will constitute a firm written order in the form of a purchase order or otherwise ("**First Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture the quantity of the Product. If manufacturing has not started, Client may cancel any Batches from the First Firm Order at no cost if notice of cancellation is received by Patheon 60 days or more before the scheduled Delivery Date under the First Firm Order. If manufacturing has not started, Client may cancel any Batches from the First Firm Order if notice of cancellation is received by Patheon more than 30 days but fewer than 60 days before the scheduled Delivery Date under the First Firm Order, but [\*\*\*]. The parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above then the initial rolling 18 month forecast will also be adjusted as necessary.

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Firm Orders Thereafter. During the Initial Manufacturing Period, and on a rolling basis during the term of this Agreement, Client will issue an updated 18 month forecast on or before the 10th day of each month. The first four months of this updated forecast, including the current month, will be firm orders with the remainder of the forecast being non-binding. Concurrent with the delivery of the 18 month forecast, Client will issue to Patheon a firm written order in the form of a purchase order ("**Firm Order**") to purchase the first four months, including the current month, of the 18 month forecast taking into account any previously issued Firm Orders. Firm Orders submitted to Patheon will specify Client's Manufacturing Services purchase order number, quantities for each Product (including quantity for Bulk Tablets Manufacturing and Blister Cartons Packaging), requested delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those Firm Orders will be firm and binding on Client (upon acceptance of the Firm Order by Patheon pursuant to Section 5.1(e)) and may not be reduced by Client unless agreed to by Patheon. Patheon will accept all Firm Orders submitted by Client up to 120% of the quantities specified in the most recent forecast submitted by Client with respect to the applicable period and with a Delivery Date that is not less than 90 days from the date of receipt by Patheon.

(c) Three Year Forecast. On or before the 10<sup>th</sup> day of June of each Year, Client will give Patheon a written non-binding three-year forecast, broken down by quarters for the second and third years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the three-year period.

(d) Acceptance of Firm Order. Patheon will notify Client within ten business days of its receipt of the Firm Order if the Firm Order is accepted or rejected. Patheon must accept a Firm Order if: (i) the requested delivery date is at least 90 days from its receipt of the Firm Order, and (ii) the quantity requested in the Firm Order is no more than 120% of the forecasted amount for the month of request of delivery in the most recent Client forecast. A firm order acceptance will include, subject to confirmation from the Client, the quantity of Product to be delivered and the Delivery Date for the Product ordered and will be binding on the parties. The Delivery Date may be amended by agreement of the Parties or as set forth in Section 5.1(b) or as otherwise agreed by the Parties.

## 5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), (b), and (c) in ordering the Components required to meet the Firm Orders. Accordingly, commencing upon Patheon's receipt of the Commercial Supply Notice from Client pursuant to Section 5.1(b), Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the [\*\*\*] contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client within six months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor [\*\*\*]. But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

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(b) If Client fails to take possession or arrange for the destruction of Components within 12 months of purchase or, in the case of finished Product, within three months of manufacture, [\*\*\*]. Patheon may ship finished Product held by it longer than three months to the Client at Client's expense on 14 days written notice to the Client.

### **5.3 Minimum Orders.**

Client's Firm Order will be for quantities in even multiples of the then current amount of the Product batch size, as specified in the table in Schedule B under the caption "Bulk Tablets Manufacturing".

### **5.4 Shipments.**

Shipments of Products will be made EXW (INCOTERMS 2010) Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications. Patheon will not ship any Product that does not meet the Specifications and/or has not been manufactured in accordance with cGMPs and Applicable Laws. Patheon will ship to Client the Validation Batches upon written notice from Client requesting delivery.

### **5.5 On Time Delivery.**

(a) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the Initial Manufacturing Period. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(b) If, after the Initial Manufacturing Period, Patheon is unable to deliver the quantity of Product ordered under a Firm Order on the Delivery Date due to an act or omission by Patheon (a "**Late Delivery**"), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will [\*\*\*].

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- (c) For clarity, for purposes of the Late Delivery credit provided in Section 5.5(b), a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of Components, a delay in Product release approval from Client, inaccurate Client forecasts, or any market driven delays in deliveries from approved vendors.

## **5.6 Invoices and Payment.**

Patheon will submit invoices to Client for the Manufacturing Services, Stability Services, Validation Services, Bill Back Items and any other payments that may be agreed to by the parties to be made by Client under this Agreement. Invoices will be sent by email to [\*\*\*] or such other email address given by Client to Patheon, from time to time, in writing. Invoices for Manufacturing Services will be sent when the Product is shipped to Client (or manufactured and released by Patheon when Patheon agrees to store the Product for Client). Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within 30 days of the date of invoice. Interest on past due accounts will accrue at 1% per month which is equal to an annual rate of 12%. The Late Delivery credits set forth in this Section 5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within 45 days outstanding from the invoice date when the Late Delivery arose.

Patheon will invoice Client for the Stability Services, Validation Services, Bill Back Items and other payments due under this Agreement when the respective services have been successfully completed or the cost has been incurred. Client will pay these invoices within 30 days of the date of invoice. Interest on past due accounts will accrue at 1% per month which is equal to an annual rate of 12%. The Late Delivery credits set forth in this Section 5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within 45 days outstanding from the invoice date when the Late Delivery arose.

## **5.7 Supply Interruption.**

If a Supply Interruption occurs Patheon's right to adjust the Product Price pursuant to Section 4.2(c) will not apply for any Year in which the Supply Interruption occurs or continues. In addition, if a Supply Interruption occurs and while it continues, Client may declare a Supply Interruption by providing written notice to Patheon. Without limiting any other rights or remedies of Client for Patheon's failure to supply, upon notice to Patheon of a Supply Interruption, and until the Resumption Date (as defined below), Client may obtain all of its requirements for the Products from alternative suppliers. Patheon will have [\*\*\*] to resume its supply obligations for the Products under this Agreement. Patheon will provide Client with written notice if it is able to resume supply (the "**Resumption Notice**") within the six month period. The Resumption Notice must: (i) list the date on which Patheon will resume its timely supply obligations, and (ii) describe in reasonable detail its corrective actions to prevent further

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Supply Interruptions. Upon Client's receipt of a Resumption Notice, unless otherwise agreed to in writing by Client and Patheon, Client will resume purchasing [\*\*\*] for sale in the Territory from Patheon commencing [\*\*\*] (the "**Resumption Date**"). Client may sell all Product held by the alternative suppliers at the Resumption Date and the alternative suppliers may complete the manufacture of and Client may at anytime sell any work in process with respect to Products at the Resumption Date.

## **5.8 Customer Equipment.**

Patheon will purchase (at Client's expense), install, validate, maintain and insure the Dedicated Equipment as set forth in the Capital Equipment Agreement.

# **ARTICLE 6**

## **PRODUCT CLAIMS AND RECALLS**

### **6.1 Product Claims.**

(a) Product Claims. Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that are damaged, defective, or otherwise deviate from the Specifications, cGMPs, or Applicable Laws within 30 days after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within 30 days after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable 30 day period, then the delivery will be deemed to have been accepted by Client on the 30th day after delivery or discovery, as applicable. Except as set out in Section 6.3 and without limiting Patheon's indemnity obligations set forth in Section 10.3, Patheon will have no liability for any damage or deviations for which it has not received notice within the applicable 30 day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have ten days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within ten days after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, or Applicable Laws, then the parties will mutually select an independent laboratory or consultant to evaluate if the Products deviate from the Specifications, cGMPs, or Applicable Laws. This evaluation will be binding on the parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Client will be deemed to have accepted delivery of the Products on the 40<sup>th</sup> day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the 40<sup>th</sup> day after discovery thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

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(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the parties.

## **6.2 Product Recalls and Returns**

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which may reasonably be expected to adversely affect the marketability, safety or effectiveness of the Products or which may reasonably be expected to result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either Party to refrain from selling or shipping quantities of the Products to Third Parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any governmental or Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

## **6.3 Patheon's Responsibility for Defective and/or Recalled Products**

(a) Defective Product. Without limiting Patheon's indemnity obligations under Section 10.3, if Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1.

(b) Recalled Product. Without limiting Patheon's obligations under Section 10.3, if a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products. At Client's election Patheon will refund to Client the amounts paid for the Recalled or returned Products, or, if Patheon is able to replace the Recalled or returned Products, replace such Recalled or returned Product without cost or expense to Client. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

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(c) Except as set forth in Sections 6.3(a) and (b) above, and without limiting Patheon's indemnity obligations under Section 10.3, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (iv) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (v) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP's, and Applicable Laws, or (vi) is due to any other breach by Client of its obligations under this Agreement.

#### **6.4 Disposition of Defective or Recalled Products.**

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition.

#### **6.5 Sole Remedy.**

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, and Client's right of termination set forth in Section 8.2(h), the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws.

#### **6.6 Healthcare Provider or Patient Questions and Complaints.**

Unless otherwise provided in the Quality Agreement, Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all information reasonably requested by Client that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

### **ARTICLE 7**

#### **CO-OPERATION**

##### **7.1 Quarterly Review.**

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

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## 7.2 **Governmental Agencies.**

Client will be solely responsible to communicate with any Authority, including but not limited to Authorities responsible for granting regulatory approval for the Products, regarding the Products unless, in the opinion of Patheon's counsel, communication directly by Patheon is necessary to comply with the requirements of any Applicable Law. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

## 7.3 **Records and Accounting by Patheon.**

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with the Quality Agreement, cGMPs, Applicable Laws and manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by Applicable Laws, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Client will have the option of retaining these documents and samples at its cost. Except for samples to be retained by Patheon in connection with the Stability Services, Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

## 7.4 **Inspection.**

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection. This right to inspect may include an audit or verification by a third party of any Component Cost price increases by Patheon under Sections 4.2(b), 4.2(c) and/or 4.3. These audits will be conducted during normal business hours upon reasonable prior written notice from Client and will not unreasonably interfere with Patheon's normal business activities. The third party auditor will report its conclusions and calculations to both Parties. But the auditor will not disclose Patheon's information except to the extent necessary to verify the accuracy of the payments calculated pursuant to this Agreement. Patheon may request that the auditor enter into an appropriate non-disclosure agreement. If an audit reveals an underpayment by Acura to Patheon, Acura will remit the underpayment within 30 days of receipt of the auditor's report. If an audit reveals an overpayment by Client, Patheon will remit to Client the amount of the overpayment within 30 days of receipt of the auditor's report. Client will bear the full cost of the audit unless the audit discloses an overpayment by Client of more than \$25,000, in which case Patheon will bear the cost of the audit.

## 7.5 **Access.**

Patheon will give Client reasonable access at mutually agreeable times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of "for-cause" audits, Client will be limited each Year to one cGMP-type audit, lasting no more than two days, and involving no more than two auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of [\*\*\*]. Except for the audit rights in Section 7.4, the right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records.

**Notification of Regulatory Inspections.**

Patheon will notify Client within one Business Day of any proposed or scheduled inspections or investigations by any Authority specifically involving the Products or any process or procedure used in the manufacture, packaging, storing or testing of the Product at the Manufacturing Site. Patheon will also notify Client within 48 hours of a receipt of any form 483's or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products. Patheon will consult with Client concerning any response Patheon intends to make to the communication before Patheon sends the response to the Authority. Patheon will make available to Client those portions of inspection reports that relate specifically to the Product.

**Reports.**

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client's request, Patheon will provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

**FDA Filings.**

Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that Client, in its sole discretion, may deem to be required for the receipt and/or maintenance of Authority approval for the commercial manufacture of the Products (excluding matters and permits relating to the Manufacturing Site which will be Patheon's obligation). Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

**ARTICLE 8****TERM AND TERMINATION****Initial Term.**

This Agreement will become effective as of the Effective Date and will continue until December 31, 2016 (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two years each unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term. The Initial Term, together with any renewal term is referred to as the "**Term**".

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

**Termination for Cause.**

(a) Either party at its sole option may terminate this Agreement upon written notice to the other party where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within 60 days following receipt of a written notice (the "**Remediation Period**") of the breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice. A waiver of this 60-day termination period will not alter this Agreement or otherwise change the obligations of either party to this Agreement.

(b) Either Party may terminate this Agreement upon written notice to the other Party if the contract entitled "Clinical Trial and Registration Manufacturing Proposal (Proposal P-CRP-19073-R4) between Client and Patheon and dated concurrent with the Agreement (the "**Clinical Trial Agreement**") is terminated early according to its terms.

(c) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(d) Client may terminate this Agreement as to any Product upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client will still fulfill all of its obligations under Section 8.4 below or as otherwise agreed to by the parties.

(e) Client may terminate this Agreement upon 30 days' prior written notice to Patheon when Patheon's then current Product Price [\*\*\*].

(f) Patheon may terminate this Agreement upon nine months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement to an assignee (other than an Affiliate) that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a Competitor of Patheon; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations.

(g) Client may terminate this Agreement upon written notice to Patheon upon the occurrence of a Supply Interruption (whether or not due to a Force Majeure Event) or if a Force Majeure Event affecting Patheon, in either case which continues for more than 60 days. But if the Supply Interruption or Force Majeure event is caused by a lack of DEA quota (not attributable to a failure of Patheon to appropriately apply for quota or maintain good standing with the DEA), then Client will not be entitled to terminate this Agreement pursuant to this Section 8.2(g).

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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(h) Client may terminate this Agreement upon written notice to Patheon if any Recall is caused by Patheon as described in Section 6.3(b) and Client's out-of-pocket costs associated with all recalls, in the aggregate, exceeds the Revenue Sub-cap (as defined in Section 10.2).

### **8.3 Product Discontinuation.**

Client will give at least four months' advance notice of termination of this Agreement if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market.

### **8.4 Obligations on Termination.**

If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

- (a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed;

Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory not to exceed 5% of Patheon's actual purchase price for the Inventory), the Patheon owned Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders as provided in Section 5.2 prior to notice of termination being given. Patheon will use reasonable efforts to use this Inventory with its other clients. At Client's option, Patheon will complete the work-in-process portion of the Inventory and upon delivery to Client, Client will remit the Product Price for the finished Product. But if Client terminates this Agreement pursuant to Sections 8.2(a), (c), (g) or (h) and, as a result, Client withdraws the Product from the market for at least 12 months and to the extent that the Inventory can't be used by a subsequent supplier, Client will not be required to purchase the Inventory. Notwithstanding anything to the contrary in this Section 8.4(b), if Client terminates this Agreement under Section 8.2(c), it will not be required to purchase any Inventory which Patheon has received and has not paid for due to Patheon's insolvency, bankruptcy, or assignment of this Agreement for the benefit of creditors;

- (b)
- (c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2 (to the extent not covered in Section 8.4(b)). But if Client terminates this Agreement pursuant to Sections 8.2(a), (c), (g) or (h) and, as a result, Client withdraws the Product from the market for at least 12 months and to the extent the Components can't be used by a subsequent supplier, Client will not be required to pay for Patheon orders with its suppliers;

- (d) Client acknowledges that no Competitor of Patheon will be permitted access to the Manufacturing Site; and

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- (e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within five Business Days, all of Client's Components, Materials and Inventory (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property within five Business Days (except for Client Property that requires permits or quotas to move in which Client will use reasonable efforts to move within six months) following the completion, termination, or expiration of the Agreement Client will pay Patheon \$100.00 per pallet, per month, one pallet minimum (\$200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances or requires refrigeration) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement. For greater certainty, termination of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.4, 5.6, 7.3, 7.4, 8.4, 13.1, 13.2, 13.3, 13.15 and 13.16, all of which survive any termination.

## ARTICLE 9

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

#### **9.1 Authority.**

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and the Quality Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder or thereunder.

#### **9.2 Client Warranties.**

Client covenants, represents, and warrants that:

##### **(a) Non-Infringement.**

- (i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;
- (ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client, and (C) does not infringe and will not infringe any Third Party Rights;
- (iii) as of the date of this Agreement, there are no actions or other legal proceedings against Client, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

##### **(b) Quality and Compliance.**

- (i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;



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- (ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws may be lawfully sold and distributed in every jurisdiction in which Client markets the Products.

### 9.3

#### **Patheon Warranties.**

Patheon covenants, represents, and warrants that:

- (a) it will perform the Manufacturing Services, Validation Services and Stability Services in accordance with the Specifications, cGMPs, and Applicable Laws; and
- (b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights.

the Manufacturing Site and any other facility of Patheon or any other Person where, in accordance with the provisions of this Agreement, any Product will be manufactured, tested, packaged, distributed or stored, are in compliance with cGMP and all applicable Law, and no citation or adverse condition has been noted in any recent inspection by any Authority of the Manufacturing Site or any other facilities that would cause any Product developed, tested, manufactured, packaged, stored or shipped at or from the Manufacturing Site or any other facilities to be misbranded or adulterated within the meaning of the FD&C Act or any other Law. Patheon will maintain the Manufacturing Site, and maintain or cause to be maintained the other facilities, in compliance with cGMP and all applicable Law. Patheon has not received any FDA 483 incident report that would adversely affect its ability to develop, manufacture, package, test, store or ship any Product. Except as otherwise expressly provided in this Agreement, Patheon will obtain and maintain all necessary licenses, permits or approvals required by the FDA or other relevant Authority in connection with the manufacture, filling, packaging, storage, and shipment of the Product, including, without limitation, all material permits and Authorizations related to the Manufacturing Site;

- (c)
- (d) During the Term, it will not and will cause its Affiliates not to manufacture any pharmaceutical product containing all of (i) pseudoephedrine HCl, (ii) polyethylene oxide, (iii) ethyl cellulose, and (iv) hydroxy-propyl cellulose, along with any other pharmaceutical active or inactive ingredients, for the same indication as Client's Product, for commercialization in the Territory.

### 9.4

#### **Debarred Persons.**

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it 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* (United States).

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**9.5**                **Permits.**

Client will be solely responsible for obtaining or maintaining, on a timely basis, any necessary permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

**9.6**                **No Warranty.**

**NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS.**

**ARTICLE 10**

**REMEDIES AND INDEMNITIES**

**10.1**                **Consequential Damages.**

Except for the indemnity obligations under Sections 10.3(a) and 10.4, under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

**10.2**                **Limitation of Liability.**

Except for its indemnity obligations under Sections 10.3(a) and 10.3(b) and for Patheon's breach of its obligations under Article 11 (Confidentiality), Patheon's maximum liability directly to Client under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed in the aggregate the greater of [\*\*\*].

**10.3**                **Patheon.**

(a) Patheon agrees to defend, indemnify, and hold Client, its Affiliates and their directors, officers, employees, agents, successors and assigns harmless against any and all losses, damages, costs, claims, demands, judgments and liability (including reasonable attorneys fees) to from and in favour of third parties (other than Affiliates) resulting from, or relating to (i) a failure by Patheon to perform the Manufacturing Services, Stability Services and Validation Services, including without limitation the manufacture and supply of the Product (including Validation Batches), in accordance with the Specifications, cGMPs, and Applicable Laws, (ii) breach of this Agreement or the Quality Agreement by Patheon, including, without limitation, any representation, warranty or covenant contained herein or therein, or (iii) Patheon's negligent acts or omissions or willful misconduct, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates.

**[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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(b) Patheon agrees to defend, indemnify, and hold Client, its Affiliates and their directors, officer, employees, agents, successors and assigns harmless against any and all losses, damages, costs, claims, demands, judgments and liability (including reasonable attorneys fees) resulting from or relating to Patheon's failure or inability (including, without limitation, due to a restraining order, injunction or other limitation or restriction) to perform the Manufacturing Services due to any contractual obligation owed by Patheon or its Affiliates to any third party, or any claim, action, judgment or demand relating to any contractual obligation owed by Patheon or its Affiliates to any third party.

#### **10.4            Client.**

Client agrees to defend, indemnify, and hold Patheon, its Affiliates and, their respective directors, officers, employees, agents, successors and assigns harmless against any and all losses, damages, costs, claims, demands, judgments and liability (including reasonable attorneys fees) to from and in favour of third parties (other than Affiliates) resulting from, or relating to (i) the ownership, use, handling, distribution, marketing or sale of the Product, (ii) breach of this Agreement by Client, including, without limitation, any representation, warranty, or covenant contained herein, or (iii) Client's negligent acts or omissions or willful misconduct, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, agents, or Affiliates.

#### **10.5            Indemnification Procedures.**

(a) A Party hereto seeking indemnification hereunder (the "**Indemnified Party**") will notify the other Party (the "**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party any claim by a Third Party (a "**Third Party Claim**") for which the Indemnified Party intends to base a claim for indemnification hereunder.

(b) The Indemnifying Party will have the right, upon written notice given to the Indemnified Party within 30 days after receipt of the notice from the Indemnified Party of any Third Party Claim, to assume the defense and handling of the Third Party Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 10.5(c) below will govern.

(c) The Indemnifying Party will select counsel reasonably acceptable to the Indemnified Party to conduct the defense and handling of the Third Party Claim, and the Indemnifying Party will defend or handle the same in consultation with the Indemnified Party, and will keep the Indemnified Party apprised of the status of the Third Party Claim. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, which consent will not be unreasonably withheld, agree to a settlement of any Third Party Claim that could directly or indirectly lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder. The Indemnified Party will cooperate with the Indemnifying Party and will be entitled to participate in the defense or handling of the Third Party Claim with its own counsel at its own expense.

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- (d) If the Indemnifying Party does not give written notice to the Indemnified Party, within 30 days after receipt of the notice from the Indemnified Party of any Third Party Claim, of the Indemnifying Party's election to assume the defense or handling of the Third Party Claim, the provisions of Section 10.5(e) below will govern.
- (e) The Indemnified Party may, at the Indemnifying Party's expense, select counsel to conduct the defense or handling of the Third Party Claim and defend or handle the Third Party Claim in the manner as it may deem reasonably appropriate. The Indemnified Party will keep the Indemnifying Party timely apprised of the status of the Third Party Claim and will not settle the Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld or delayed. If the Indemnified Party defends or handles the Third Party Claim, the Indemnifying Party will cooperate with the Indemnified Party and will be entitled to participate in the defense or handling of the Third Party Claim with its own counsel and at its own expense.
- (f) In the case of an indemnity claim by Client pursuant to Section 10.3(b), Client shall provide Patheon with written notice on such claim.

## ARTICLE 11

### CONFIDENTIALITY

#### 11.1 Treatment of Confidential Information.

In carrying out its obligations under this Agreement, each Party will be sharing confidential and proprietary data and information ("**Confidential Information**") with the other Party. Except as expressly permitted by this Agreement, each Party will, and will cause its Affiliates to, treat Confidential Information received from the other Party (the "**Disclosing Party**") or its Affiliates as it treats its own proprietary information of like nature and importance. During the Term of this Agreement and for a period of five years thereafter (or in the case of trade secrets the greater of five years after the term and the time when the Confidential Information is no longer a trade secret), the Party in receipt of the Disclosing Party's Confidential Information (the "**Receiving Party**") will not disclose, divulge or otherwise communicate the Confidential Information to any Third Party, or use it for any purpose except pursuant to and in order to carry out its obligations under this Agreement. Notwithstanding the foregoing, the Receiving Party may disclose Confidential Information of the Disclosing Party to the Receiving Party's directors, officers, employees, Affiliates, consultants, subcontractors, or agents to the extent reasonably necessary to carry out its obligations under this Agreement, provided that the directors, officers, employees, Affiliates, consultants, subcontractors, or agents have been advised of the confidential nature of the information and have agreed to maintain the information as confidential to the same extent required by this Article 11.

#### 11.2 Exceptions to Definition of Confidential Information.

Confidential Information will not include information that the Receiving Party can demonstrate:

- (a) was known by the Receiving Party or its Affiliates prior to the date it was disclosed to the Receiving Party or its Affiliates by the Disclosing Party or its Affiliates, as evidenced by the prior written records of the Receiving Party or its Affiliates;

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- (b) is lawfully disclosed to the Receiving Party or its Affiliates by a Third Party rightfully in possession of the information, either before or after the date of the disclosure to the Receiving Party or its Affiliates;
  - (c) becomes generally known to the public through no act or omission on the part of the Receiving Party or its Affiliates, either before or after the date of the disclosure to the Receiving Party or its Affiliates;
  - (d) is independently developed by the Receiving Party or its Affiliates without reference to or reliance upon any Confidential Information of the Disclosing Party or its Affiliates; or
  - (e) is required to be disclosed by the Receiving Party or its Affiliates pursuant to a judicial or governmental order, provided that the Receiving Party gives the Disclosing Party sufficient notice to permit Disclosing Party to seek a protective order or other similar order with respect to the Information.

### **11.3 Exceptions.**

The restrictions set forth in this Article 11 will not prevent either Party from (i) disclosing Confidential Information in connection with preparing, filing, prosecuting or maintaining its patent rights, (ii) disclosing Confidential Information to Authorities to the extent required or desirable to obtain a regulatory approval, (iii) disclosing Confidential Information to investors (under a confidentiality agreement at least as restrictive as the provisions of this Article 11), (iv) disclosing Confidential Information to underwriters and financial advisors (under an obligation of confidentiality) in connection with the public offering of securities, or (v) disclosing Confidential Information that is reasonably determined is required to be disclosed by the Receiving Party (to comply with applicable securities or other laws) to public investors or governmental agencies in connection with the public offering of securities, provided that in all of the above cases, the Party disclosing Confidential Information of the Disclosing Party will use all reasonable efforts to provide prior written notice of the disclosure to the Disclosing Party and to take reasonable and lawful actions to avoid or limit the disclosure or to assist the Disclosing Party in avoiding or limiting the disclosure. Further, either Party may also disclose the existence and terms of this Agreement to its attorneys and advisors, to potential acquirors in connection with a potential change of control transaction or asset sale, stock sale or merger transaction and to existing and potential investors or lenders of the Party, as a part of their due diligence investigations, or to potential permitted assignees, in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement. Client may attach and disclose the content of this Agreement in its public filings (after prior review by Patheon not to exceed 10 business days)) to the extent required under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or the regulations promulgated under these Acts.

### **11.4 Previous Confidentiality Agreement.**

Notwithstanding anything contained herein to the contrary, that certain Confidentiality Agreement, dated as of July 26, 2007, by and between Patheon Inc., and its Affiliates, and Acura Pharmaceuticals, Inc., and its Affiliates, will remain in full force and effect as to the information disclosed between the Parties prior to the date hereof. In the event of a conflict the stricter provisions will control, provided however that the last sentence of Section 11.3 will control in all instances.

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## ARTICLE 12

### **DISPUTE RESOLUTION**

#### **12.1 Commercial Disputes.**

If any dispute arises out of this Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within ten Business Days from receipt of the notice of dispute, a single representative having full power and authority to solve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the ten Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

#### **12.2 Technical Dispute Resolution.**

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as practicable and in any event no later than ten Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within 30 Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Schedule E. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

## ARTICLE 13

### **MISCELLANEOUS**

#### **13.1 Inventions.**

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property solely to the extent required for Patheon to perform the Manufacturing, Stability and Validation Services under this Agreement. Except as expressly provided in this Section 13.1(a), Client does not grant to Patheon or its Affiliates any license or other rights to Client's Intellectual Property, Client's Inventions or Client's Confidential Information.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing, Stability or Validation Services, to the extent it is specific to the development, manufacture, use, and/or sale of the Product will be the exclusive property of Client. Patheon will give written notice of this Intellectual Property to Client as soon as reasonably practical.

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(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing, Stability and Validation Services to enable Client to manufacture and sell the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

### **13.2 Intellectual Property.**

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

### **13.3 Insurance.**

Each party will maintain their own commercial liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than [\*\*\*]. If requested each party will give the other a 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. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

### **13.4 Independent Contractors.**

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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**13.5            No Waiver.**

Either party's failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2.

**13.6            Assignment.**

- (a) Patheon may not assign this Agreement or any of its rights or obligations hereunder without the written consent of Client, this consent not to be unreasonably withheld. Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement with the written consent of Client, this consent not to be unreasonably withheld; provided that Patheon will be solely liable for all work and services performed by any subcontractor.

- (b) Subject to Section 8.2(e), Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on 12 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

- (c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

**13.7            Force Majeure.**

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

**13.8            Additional Product.**

Additional products may be added to this Agreement upon mutual written agreement of the Parties and the additional products will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, and C as applicable.



**Notices.**

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, portable data format (.pdf) file or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

Acura Pharmaceuticals, Inc.  
616 N. North Court, Ste 120  
Palatine, IL 60067  
Attention: President & CEO  
Telecopier No.: 847-705-5399  
Email address: [\*\*\*]

With copy to:

Acura Pharmaceutical Technologies, Inc.  
16235 State Road 17  
Culver, IN 46511  
Attention: VP Technical Affairs  
Telecopier No.: 574-842-2519  
Email address: [\*\*\*]

If to Patheon:

Patheon Pharmaceuticals Inc.  
2110 East Galbraith Road  
Cincinnati, OH 45237-1625  
Attention: Director of Legal Services  
Telecopier No.: 513-948-6927

Email address: [\*\*\*]

With a copy to:

Patheon Inc.  
4721 Emperor Boulevard  
Research Triangle Park,  
NC 27703  
Attention: General Counsel  
Telecopier No.: 919-474-2269

**[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, portable data format (.pdf) file or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

**13.10            Severability.**

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, because each provision is separate, severable, and distinct.

**13.11            Entire Agreement.**

This Agreement, together the Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Quality Agreement, and the Confidentiality Agreement.

**13.12            Other Terms.**

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

**13.13            No Third Party Benefit or Right.**

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any Third Party any benefit or the right to enforce any express or implied term of this Agreement.

**13.14            Execution in Counterparts.**

This Agreement may be executed in two or more counterparts, by original, facsimile or pdf (e-mail) signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

**13.15            Use of Client Name.**

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

**Governing Law.**

This Agreement will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. Except as expressly provided in Sections 6.1(b), 12.1 and 12.2, any unresolved dispute between the Parties relating to this Agreement, or the Quality Agreement will be resolved through arbitration under the Commercial Dispute Resolution Rules of the American Arbitration Association then in effect, by one arbitrator having experience in products supply transactions in the pharmaceuticals industry. The arbitration proceeding will be held exclusively in New York, New York. The determination of the arbitrator will be binding on the Parties and will be non-appealable. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

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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.

**APPROVED BY LEGAL**

<u>FPM</u>	<u>7-22-11</u>
Initials	Date

**PATHEON PHARMACEUTICALS INC.**

By: /s/ Eric Evans

Name: Eric Evans

Title: Chief Financial Officer

**ACURA PHARMACEUTICALS, INC.**

By: /s/ Robert B. Jones

Name: Robert B. Jones

Title: CEO

## **SCHEDULE A**

### **PRODUCT LIST, SPECIFICATIONS AND PROCESS ASSUMPTIONS**

#### **Product List**

Pseudoephedrine HCl 30mg Tablets utilizing Impede™ Technology in Cartons containing 24 tablets\*  
Pseudoephedrine HCl 30mg Tablets utilizing Impede™ Technology in Cartons containing 48 tablets\*

\* the Manufacturing Services will include packaging each Product into shipping cartons as specified in the Components.

#### **Components**

[\*\*\*]

#### **Active Materials**

[\*\*\*]

#### **Tablet Specifications**

[\*\*\*]

#### **Labeling and Packaging Specifications**

[\*\*\*]

#### **Master Batch Record(s)**

[\*\*\*]

#### **Manufacturing Assumptions**

[\*\*\*]

#### **Packaging Assumptions**

[\*\*\*]

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

**SCHEDULE B**

**MANUFACTURING CAMPAIGNS, PACKAGING RUN QUANTITIES, AND PRICE**

[\*\*\*]

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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**SCHEDULE C**

**ANNUAL STABILITY TESTING and VALIDATION ACTIVITIES**

[\*\*\*]

[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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**SCHEDULE D (Reserved)**

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## **SCHEDULE E**

### **TECHNICAL DISPUTE RESOLUTION**

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert.** Within ten Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the ten Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.
  2. **Conflicts of Interest.** Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties, after the disclosure, have confirmed his appointment in writing.
  3. **Not Arbitrator.** No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.
  4. **Procedure.** Where an expert is appointed:
    - (a) **Timing.** The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.
    - (b) **Disclosure of Evidence.** The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.
    - (c) **Advisors.** Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.
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- (d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed by mutual written agreement of the Parties and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.
- (e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.
- (f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

**SCHEDULE F**

**COMMERCIAL QUALITY AGREEMENT**

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## **SCHEDULE G**

### **BILL BACK ITEMS**

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

**[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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## **SCHEDULE H**

### **CAPITAL EQUIPMENT AGREEMENT**

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

**[\*\*\*Confidential Treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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