## FIRST AMENDMENT TO AZELASTINE COMBINATION PRODUCT AGREEMENTS

This Amendment Agreement ("Amendment Agreement") is entered into as of this 7th day of November 2011, (the "Effective Date") by and between Meda Pharmaceuticals Inc., a corporation organized under the laws of Delaware with its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120 ("Meda Pharma"), Meda AB, a corporation organized under the laws of Sweden, with its registered office at Pipers vag 2A, Box 906, SE-170 09 Solna, Sweden, ("Meda AB"), and CIPLA Ltd., a limited company organized under the laws of India and having a place of business at Mumbai Central, Mumbai 400 008, India ("Cipla"). Meda AB, Meda Pharma (together for the purposes of this Amendment Agreement the "Meda Parties") and Cipla are sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, pursuant to an agreement between Meda Pharma and Cipla dated 13th November 2006 ("American Agreement"), Cipla granted Meda Pharma (previously known as MedPointe Healthcare Inc.), an exclusive license to market, sell, import and distribute the Product in the Territory and to manufacture anywhere in the world 20% of the Product requirement for the Territory (as each term is defined in the American Agreement). The American Agreement also included a right of first refusal to acquire an exclusive license to market, sell, import and distribute the Product in certain other countries in Europe and elsewhere as stated in the American Agreement.

WHEREAS, Meda Pharma exercised such right of first refusal under the North American Agreement in respect of the relevant countries and pursuant to an agreement between Meda AB and Cipla dated 7 September 2009 ("European Agreement") Cipla granted to Meda AB an exclusive license to market, sell, import and distribute the Product in the Territory (as each term is defined in the European Agreement):

WHEREAS, The Parties have mutually agreed to amend the terms of both the American Agreement and the European Agreement on the terms of this Amendment Agreement.

NOW, THEREFORE, in consideration of the rights and obligations set forth in this Agreement, and intending to be legally bound, the Parties agree as follows:

### ARTICLE I - DEFINITIONS

Any capitalized term used in this Amendment Agreement shall have the meaning ascribed to it in the American Agreement or the European Agreement as appropriate provided always that the following capitalized terms shall have the following meanings when used in this Amendment Agreement, and all terms defined in the singular shall have the same meanings when used in the plural (and vice versa, as appropriate), unless otherwise specified:

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1.1 "Advance Authorisation" means a permission to import or export as per the provisions of the Foreign Trade policy of India;



**EXHIBIT** 

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SUBJECT TO STIPULATED PROTECTIVE ORDER



- 1.2 "Calendar Quarter" shall mean each successive three (3) month period commencing on January 1, April 1, July 1 and October 1;
- 1.3 "Sample Unit of Product" shall mean a 28 metered dose presentation of Product as further defined in Schedule A.
- 1.4 "Sample Unit of Product Transfer Price" shall mean four US Dollars (\$4.00) per Sample Unit of Product (on an FCA Mumbai basis) in respect of both the North American Agreement and the European Agreement. The Sample Unit of Product Transfer Price shall automatically increase by five percent (5%) every three (3) years with such price increase being effective from I January of the relevant year, the first such price increase shall be effective from 1 January 2015.
- 1.5 "Trade Unit of Product" shall mean a 120 metered dose presentation of Product as further defined in Schedule A together with any other unit of Product that is not a Sample Unit of Product.
- 1.6 "Trade Unit of Product Transfer Price" shall mean six US Dollars (\$6,00) per Trade Unit of Product (on an FCA Mumbai basis) in respect of the North American Agreement and five US Dollars and fifty cents (\$5.50) per Trade Unit of Product (on an FCA Mumbai basis) in respect of the European Agreement. The Trade Unit of Product Transfer Price shall automatically increase by five percent (5%) every three (3) years with such price increase being effective from 1 January of the relevant year, the first such price increase shall be effective from 1 January 2015.

## ARTICLE II - AMENDMENT OF THE AMERICAN AGREEMENT

Amendment of the definition of Net Sales. The definition of Net Sales in the American Agreement shall be deleted and replaced by the following definition:

> "Net Sales" shall mean the gross amount invoiced by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees to Third Parties for sale of the Trade Units of Product, in finished packaged form, in the Territory, less, to the extent deducted from or on such invoice consistent with IFRS, consistently applied, the following items: (i) quantity, trade or cash discounts, chargebacks, returns, allowances, rebates (including without limitation any and all federal, state or local government rebates) and price adjustments, to the extent actually allowed; (ii) sales, customs and other excise taxes and duties or similar governmental charges directly related to such sale, to the extent such items are included in the gross invoice price; (iii) amounts actually refunded due to rejected, spoiled damaged, outdated or returned Trade Units of Product; (iv) freight, shipment and insurance costs actually incurred in transporting Trade





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Units of Product to a Third Party purchaser and separately invoiced; and (v) amounts deducted in accordance with IFRS as reported in MedPointe's audited accounts. In the case of any sale of Trade Units of Product to a Third Party by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees for consideration other than monetary consideration, such as barter or countertrade, such Trade Units of Product shall be deemed to be sold at the average sales price during the applicable reporting period generally achieved for such Trade Units of Product in the applicable country in the Territory when such Trade Units of Product is sold alone and not with other products.

2.2 Amendment to Section 5.2(c)(ii). The Parties have agreed that Section 6.2(c)(ii) of the American Agreement shall be deleted and replaced by the following:

## 6.2 Purchase Orders and Forecasts.

(c)(ii) The amount specified in respect of the first two (2) Calendar Quarters in each four (4) Calendar Quarter forecast provided by MedPointe under Section 6.2(c)(1) hereof shall constitute a binding order for the Product during those Calendar Quarters in an amount equal to the forecast amount, and MedPointe shall issue Purchase Orders which shall be binding and irrevocable pursuant to Section 6.3 specifying quantities and delivery dates from time to time during such Calendar Quarters (but at least ninety (90) days prior to the expected delivery date). The amount specified in respect of the third and fourth Calendar Quarters of such four (4) Calendar Quarter forecast shall not be binding on MedPointe. Cipla shall use its commercially reasonable efforts to meet MedPointe's requested delivery dates, and shall acknowledge the Purchase Orders within ten (10) days after the date Cipla receives each applicable conforming Purchase Order and provide MedPointe with a delivery schedule. For avoidance of any doubt, if the Purchase Order quantities are less than the binding forecast, then MedPointe will pay for any surplus quantities manufactured by Cipia per the binding forecast at the Trade Unit of Product Transfer Price. Also if MedPointe cancels or modifies a Purchase Order, MedPointe shall pay for any batches already manufactured by Cipla and for the batch in progress at the Trade Unit of Product Transfer Price and the cost of any APURaw Material or packing material procured by Cipla to Meet MedPointe's Purchase Orders and forecasts where such API/Raw Material and/or packing material cannot be used for future batches.

2.3 Amendment to Section 6.6. The Parties have agreed that Section 6.6 of the American Agreement shall be deleted and replaced by the following:

### 6.6 Payments.

(a) <u>Trade Product</u>: In consideration of the supply of Product to MedPointe, MedPointe shall pay Cipla a minimum of 15% of the Net Sales of each Trade Unit of Product that is delivered to customers in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees during the Term. Such payment shall be made in the following two portions:



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- (i) MedPointe shall pay Cipla the Trade Unit of Product Transfer Price in respect of each Trade Unit of Product supplied by Cipla, payment for such Trade Units of Product shall be due within thirty (36) days of delivery of an invoice by Cipla, such invoice not to be sent prior to dispatch of the relevant Trade Units of Product.
- (ii) MedPointe shall each Calendar Quarter pay Cipla 15% of the Net Sales of each Trade Unit of Product that is delivered to customers in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees during that Calendar Quarter less any Trade Unit of Product Transfer Price paid pursuant to Section 6.6(a)(i) by MedPointe to Cipla in respect of such Trade Unit of Product. For the avoidance of doubt, where such amount is a negative number, no refund of any payment made under Section 6.6(a)(i) shall be due to MedPointe.
- MedPointe shall pay all amounts payable Payment under Section 6.6(a)(ii): under Section 6.6(a)(ii) within sixty (60) days of the end of each Calendar Quarter and at the same time MedPointe shall provide Cipla with a written statement recording the calculation of the amount payable under Section 6.6(a)(ii) in respect of such Calendar Quarter and in particular: (i) the Calendar Quarter for which such amounts were calculated; (ii) the number of Trade Units of Product delivered to customers in each country in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees during such Calendar Quarter; (iti) the number of Frade Units of Product manufactured by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees delivered to customers in each country in the Territory by or on behalf of MedPointe, any of its Affliates and/or any of its sublicensees during such Calendar Quarter; (iv) the total amount invoiced to customers in respect of the Trade Units of Product delivered to customers in each country in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees during such Calendar Quarter, (v) the Net Sales Price of each Trade Unit of Product delivered to customers in each country of the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees during such Calendar Quarter; and (vi) the amount under Section 6.6(a)(ii) due and payable in respect of such Calendar Quarter.
- (c) Right of Audit: MedPointe shall keep proper records and books of account showing the Net Sales Price of each Trade Unit of Product delivered to customers in each country in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees for three Calendar Years after the Calendar Year in which such deliveries are made. Such records and books shall be open during normal business hours to inspection and audit by an independent accountant appointed by Cipla and reasonably acceptable to MedPointe, There shall be a maximum of one audit per Calendar Year and no audit shall be undertaken more than three Calendar Years after the Calendar Year to which it relates, if such inspection or audit should reveal that MedPointe has underpuid the amounts payable under this agreement, MedPointe shall immediately make up the shortfall and in the event that such underpayment is more than five percent of the amount paid MedPointe shall reimburse Cipla in respect of any professional charges incurred for such audit or inspection. Such obligation to keep



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records and the right of inspection of Cipla shall remain in effect for a period of one (1) year after the termination of this agreement.

- (d) Annual Statement— Within one hundred and twenty (120) days of the end of each Calendar Year, MedPointe shall submit to Cipla a written statement certified by MedPointe's auditors of the aggregate Net Sales Price of Trade Units of Product delivered to customers in the Territory by or on behalf of MedPointe, any of its Affiliates and/or any of its sublicensees in that Calendar Year and the amount due to be paid for that Calendar Year under this clause 5.6. If such statement shows that the amount due by MedPointe is more than the amount paid, MedPointe shall pay to Cipla within seven (7) days of the submission of the statement an amount equivalent to the difference between the amount paid and the amount due. If such statement shows that the amount due by MedPointe is less than the amount paid, MedPointe shall be entitled to deduct such amount from any future payments due to Cipla. For avoidance of doubt, no adjustment or deductions of such amount can be made from payment made under Section 6.6(a)(i) by MedPointe.
- (e) <u>Samples</u>: In consideration of the supply of Sample Units of Product to MedPointe, MedPointe shall pay Cipla the Sample Unit of Product Transfer Price in respect of each Sample Unit of Product supplied by Cipla, payment for such Sample Units of Product shall be due within thirty (30) days of delivery of an invoice by Cipla, such invoice not to be sent prior to dispatch of the relevant Sample Units of Product.
- (f) Limits on Sample Units of Products: For the first three (3) years following Launch in the US, the Sample Unit of Product Transfer Price shall apply to a maximum of Sample Units of Product equal in number to the Trade Units of Product purchased by MedPointe. In each successive twelve (12) month period, the first of which commencing on the third (3<sup>rd</sup>) anniversary of the Launch of the Product in the US the Sample Unit of Product Transfer Price shall apply to a maximum of Sample Units of Product equal to thirty percent (30%) of the total number of Units of Product purchased by MedPointe in such twelve month period and any Sample Units of Product ordered in excess of these limits shall be paid for at the relevant Trade Unit of Product Transfer Price.
- (g) Azelastine Cost: The Unit of Product Transfer Prices set out in this Clause 6.6 do not include the cost of Azelastine API which will be supplied by MedPointe free of charge to Cipla at MedPointe's cost (including any cost related to obtaining an Advance Authorisation or duties or taxes related to the importation of Azelastine API into India) as per the terms of this Agreement.

#### ARTICLE III - AMENDMENT OF THE EUROPEAN AGREEMENT

3.1 <u>Amendment of the definition of Net Sales</u>. The definition of Net Sales in the European Agreement shall be deleted and replaced by the following definition:



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