AZELASTINE COMBINATION PRODUCT AGREEMENT

This AZELASTINE COMBINATION PRODUCT AGREEMENT ("Agreement") is entered into as of the 13th day of November, 2006 (the "Effective Date") by and between MedPointe Healthcare 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 ("MedPointe"), 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"). MedPointe and Cipla are sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, Cipla is the owner of an Existing Formulation (as hereinafter defined) and related Product Intellectual Property (as hereinafter defined);

WHEREAS, Cipla wishes to develop a Product (as hereinafter defined) for commercialization in the Territory (as hereinafter defined) based on the Existing Formulation;

WHEREAS, MedPointe wishes to exclusively license the Product Intellectual Property (as hereinafter defined) for the Territory to manufacture and have manufactured the Product anywhere in the world and market, sell, import and distribute the Product in the Territory for the term of this Agreement and as per the terms of this Agreement;

WHEREAS, Cipla wishes to grant MedPointe such a license for the term of this Agreement for the Territory, as well as a right of first refusal to acquire an exclusive license to market, sell, import and distribute the Product in certain Markets (as hereinafter defined); and

WHEREAS, Cipla wishes to supply, and MedPointe wishes to purchase from Cipla eighty percent (80%) of its requirements of the Product in the Territory.

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

The following capitalized terms shall have the following meanings when used in this 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:

1.1 "Affiliate" shall mean with respect to a Party a corporation, partnership, entity, person, trust, limited liability company or other business entity that controls, is controlled by, or is under common control with the referenced Party. For the purposes of this definition the word "control" (including, with correlative meaning, the terms "controlled by" or "is under the common control with") means the possession, directly or indirectly, of the power to direct the management or policies of the applicable entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance or otherwise.

1.2 "Applicable Law" shall mean any applicable federal, state, local or foreign statute, law, ordinance, rule or regulation, judicial order or industry standard imposed by regulation or law, including without limitation the laws of, and regulations promulgated under, the FDCA.

1.3 "Calendar Year" shall mean each successive twelve (12) month period commencing on January 1 and ending on December 31; provided that the first Calendar Year of this Agreement shall begin on the Effective Date and end on December 31, 2006. In the event that the termination of this Agreement does not fall on the last day of a Calendar Year, the "Final Calendar Year" shall mean the period from the first day of the then-current Calendar Year through the applicable date of termination of this Agreement.

1.4 "Certificate of Analysis" shall have the meaning set forth in Section 6.3(c).

1.5 "cGMP" shall mean all laws, guidelines and regulations applicable to the manufacturing, testing, labeling and packaging of the Product including current Good Manufacturing Practice regulations as promulgated under the applicable sections of 21 CFR (Chapters 210 and 211), as the same may be amended or re-enacted from time to time.

1.6 "Confidential Information" shall mean the existence and contents of this Agreement and any information, in whatever form (and whether tangible or intangible), disclosed by a Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with the discussions, performance or implementation of this Agreement including, without limitation, non-public Intellectual Property, any pending unpublished patent applications, patent office correspondence, new drug applications and NDA submissions, FDA or other Regulatory Authority correspondence, drug master files, batch records, quality control records, technical or clinical data, Trade Secrets, know-how, research, product plans, products, services, suppliers, customer lists, prices and costs, software, developments, ideas, techniques, business methods, photographs, sound recordings, algorithms, inventions, laboratory notebooks, processes, formulas, technology, specifications, test results, designs, drawings, engineering, marketing, finances, budgets and other actual or anticipated business, research or development information which is disclosed by the Disclosing Party to the Receiving Party and whether or not specifically designated as confidential. Confidential Information shall not include:

(a) information which at the time of disclosure is publicly known;

(b) information which, after the time of disclosure, becomes publicly known, other than by breach of an agreement between the Disclosing Party and the Receiving Party or any Third Party;

(c) information which is or was in the possession of the Receiving Party at the time of disclosure by the Disclosing Party and was not acquired directly or indirectly from the Disclosing Party or from any other party under an obligation of confidentiality to the Disclosing Party; and

(d) information which is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party as demonstrated by credible written documentation.

1.7 "Defaulting Party" shall have the meaning set forth in Section 12.2.

1.8 "Dispute" shall have the meaning set forth in Section 16.6.

1.9 "Existing Formulation" shall mean Cipla's existing formulation, for the nasal spray combination product containing azelastine hydrochloride and fluticasone propionate that is currently sold in India under the "Duonase" trademark.

1.10 "FDA" shall mean the United States Food and Drug Administration, or any successor entity thereto.

1.11 "FDCA" shall mean the Federal Food, Drug & Cosmetics Act, 21 U.S.C. 321 *et seq.*, any amendments or supplements thereto, or any regulations promulgated or adopted thereunder.

1.12 "Goa Facility" shall mean Cipla's manufacturing facility in Goa, India.

1.13 "Improvements" shall mean, with respect to a particular technology, all discoveries, innovations, improvements, enhancements, derivative works or modifications based upon such particular technology if and to the extent that the legal right to make, use, sell, copy, distribute and perform such discoveries, innovations, improvements, enhancements, derivative works or modifications would necessarily require a license (*i.e.*, a license would necessarily be required assuming that the improver of such technology is not also the owner of such technology) to such particular technology.

1.14 "indemnitee" shall have the meaning set forth in Section 14.3.

1.15 "indemnitor" shall have the meaning set forth in Section 14.3.

1.16 "Intellectual Property" shall mean: (i) patents and applications therefor, including all continuations, divisionals and continuations-in-part thereof and patents issuing thereon, along with all reissues, reexaminations and extensions thereof (collectively, "Patents"); (ii) trademarks, service marks, trade names, service names, brand names, trade dress rights, logos, corporate names, trade styles, logos and other source or business identifiers and general intangibles of a like nature, together with the goodwill associated with any of the foregoing, along with all applications, registrations, renewals and extensions thereof (collectively, "Trademarks"); (iii) copyrights whether or not registered or published, all registrations and recordations thereof and all applications in connection therewith, along with all reversions, extensions and renewals thereof (collectively, "Copyrights"); and (iv) confidential and proprietary discoveries, concepts, ideas, research and development, know-how, formulae, inventions, compositions, manufacturing and production processes and techniques, technical data, procedures, designs, drawings, batch and quality records, specifications, and databases (collectively, "Trade Secrets").

1.17 "Launch" shall mean, for each country within the Territory, the first date when the Product becomes commercially available to consumers.

1.18 "Markets" shall have the meaning set forth in Section 2.2

1.19 "Market Product" shall have the meaning set forth in Section 2.2

1.20 "MedPointe Intellectual Property" shall mean all Intellectual Property relating to azelastine, alone and/or in combination with other ingredients, as set forth on Schedule B1 for the Territory, in each case that MedPointe owns or under which MedPointe has the right to grant licenses.

1.21 "Net Sales" shall mean the gross amount invoiced to Third Parties for sale of the Product, in finished packaged form, in the Territory, less, to the extent deducted from or on such invoice consistent with generally accepted accounting principles, consistently applied, the following items: (i) quantity, trade or case discounts, chargebacks, returns, allowances, rebates (including without limitation any and all federal, state or local government rebates, such as Medicaid 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 Product; and (iv) freight, shipment and insurance costs actually incurred in transporting Product to a Third Party purchaser and separately invoiced. In the case of any sale of Product for consideration other than monetary consideration, such as barter or countertrade, such Product shall be deemed to be sold at the average sales price during the applicable reporting period generally achieved for such Product in the applicable country in the Territory when such Product is sold alone and not with other products.

1.22 "NDA" shall mean a New Drug Application, including any amendments or supplements thereto, in accordance with the requirements of the FDA.

1.21 "Non-Defaulting Party" shall have the meaning set forth in Section 12.2.

1.22 "Notice of Breach" shall have the meaning set forth in Section 12.2.

1.23 "Product" shall mean a nasal spray combination product containing azelastine hydrochloride (137 mcg) and fluticasone propionate (50 mcg) which will be developed by Cipla for MedPointe as per the terms of this Agreement.

1.24 "Product Intellectual Property" shall mean all Intellectual Property relating to the Existing Formulation and the Product, as set forth on Schedule B2, in each case that Cipla owns or under which Cipla has the right to grant licenses.

1.25 "Raw Materials" shall mean azelastine hydrochloride, fluticasone propionate and all excipients, components and other materials required to manufacture the Product, excluding packaging, labeling and inserts.

1.26 "Regulatory Authorities" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including without limitation the FDA, regulating or otherwise exercising authority with respect to the development and approval of the Products in the Territory.

1.27 "Target Formulation" shall be the nasal spray combination product containing azelastine hydrochloride and fluticasone propionate that shall serve as the basis for the formulation development work to be conducted pursuant to this Agreement as set forth in Schedule A attached hereto and made a part hereof.

1.28 "Tech Transfer" shall mean cooperation between the Cipla and MedPointe in effecting an orderly transition of manufacturing matters with respect to the Product, including transferring copies of reasonably necessary information and files, disclosing all reasonably necessary Product Intellectual Property and granting all necessary rights of reference with respect to the FDA or other applicable Regulatory Authority to MedPointe towards qualifying either MedPointe or a secondary supplier to supply twenty percent (20%) of MedPointe's commercial requirement or to supply the Product during force majeure conditions. To the extent Applicable Law requires MedPointe to control original documents, such original documents will be provided to MedPointe as part of the Tech Transfer.

1.29 "Term" shall have the meaning set forth in Section 12.1.

1.30 "Territory" shall mean the United States of America and its territories and possessions, Canada and Mexico.

1.31 "Third Party" shall mean any person or entity other than Cipla or MedPointe, or an Affiliate of either of them.

ARTICLE II - GRANT OF RIGHTS

2.1 Grant. Subject to the terms and conditions of this Agreement, Cipla hereby grants MedPointe an exclusive license, with the right to sublicense, under the Product Intellectual Property to use, have used, market, sell, import and distribute the Product in the Territory for the term of this Agreement and a non-exclusive license, with the right to sublicense, to manufacture and have manufactured the Product anywhere in the world towards manufacturing twenty percent (20%) of the Territories requirement. This license shall also include the right of MedPointe to use all of Cipla's scientific and other data relating to the Product for the Term of this Agreement. For the avoidance of doubt, for the Term of this Agreement, (a) neither Cipla nor any of its agents, licensees or Third Party distributors shall be permitted to market, sell, import or distribute the Product or any other combination azelastine hydrochloride and fluticasone propionate nasal spray product in or into the Territory other than through MedPointe; and (b) Cipla agrees not to infringe any MedPointe Intellectual Property anywhere in the Territory by manufacturing, having manufactured, using, selling, offering for sale, importing or exporting any goods or services; provided MedPointe informs Cipla of its existing MedPointe Intellectual Property.. Schedule B1 attached hereto shall serve as notice to Cipla of MedPointe Intellectual Property within the Territory, as of the Effective Date and MedPointe agrees that it shall update Schedule B1 from time to time to reflect any changes to MedPointe Intellectual Property. Notwithstanding the foregoing, Cipla has notified MedPointe that it has two existing contracts with unidentified parties, one contract for supply of a finished azelastine hydrochloride product in Canada. and the other contract for supply of a finished azelastine hydrochloride product in the U.S. and Canada, the existence of which may violate the covenant in subsection (b) by Cipla. The parties agree that actions taken by Cipla solely to carry out its obligations

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.