

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2017-01-17** | Period of Report: **2017-01-17**
SEC Accession No. [0001615774-17-000139](#)

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FILER

HEMISPHERX BIOPHARMA INC

CIK:[946644](#) | IRS No.: **520845822** | State of Incorpor.:**DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-27072** | Film No.: **17531068**
SIC: **2836** Biological products, (no disgnostic substances)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
January 17, 2017 (May 20, 2016)

HEMISPHERX BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(state or other juris-
diction of incorporation)

0 - 27072
(Commission
File Number)

52-0845822
(I.R.S. Employer
Identification No.)

1617 JFK Boulevard, Suite 500, Philadelphia, PA
(Address of principal executive offices)

19103
(Zip Code)

Registrant's telephone number, including area code: **(215) 988-0080**

1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103
(Former name or former address, if changed since last report)

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 (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 1.01 Entry into a Material Definitive Agreement.

On January 3, 2017, Hemispherx Biopharma, Inc. (the "Company") entered into a purchase order with Jubilant Hollister Stier ("Jubilant") pursuant to which Jubilant will manufacture a commercial batch of Ampligen[®] for the Company. Pursuant to the order, Jubilant will perform tooling and validation activities as well as final fill and finish services.

In addition, a copy of the previously disclosed May 20, 2016 Amended And Restated Early Access Agreement with Impatiens N.V. (under the brand myTomorrows) is filed herewith.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

10.1 May 20, 2016 Amended And Restated Early Access Agreement with Impatiens N.V.*

* Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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 hereunto duly authorized.

HEMISPHERX BIOPHARMA, INC.

January 17, 2017

By: /s/ Thomas K. Equels
Thomas K. Equels, President

AMENDED AND RESTATED EARLY ACCESS AGREEMENT

This exclusive Early Access Agreement (“Agreement”) is made and entered into the 20th day of May, 2016, (“**Effective Date**”) by and between

Hemispherx Biopharma, Inc, a company formed and registered under the laws of Delaware and located at One Penn Center, 1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103, U.S.A. (hereinafter referred to as “**HEMISPHERX**”),

and

Impatients N.V., a company formed and registered under the laws of the Netherlands, and located at Pilotenstraat 45, 1059 CH, Amsterdam, The Netherlands (hereinafter referred to as “**IMPATIENTS**”),

hereinafter each of HEMISPHERX and IMPATIENTS, referred individually as a “Party” and collectively as the “Parties”.

RECITALS

WHEREAS, HEMISPHERX has developed, and is developing the Product (as defined below), and owns or controls certain patent rights, and technical and scientific information relating to, and the global exclusive rights to distribute, market and sell Product,

WHEREAS, IMPATIENTS specialises under the brand myTomorrows in services related to the supply and distribution of products to patients in Early Access Programs (also referred to as EAP and as defined below) through a patient and physician platform (hereinafter referred to as the “myTomorrows platform”),

WHEREAS, HEMISPHERX is willing to grant IMPATIENTS the exclusive right to develop and execute Early Access Programs in the Territory (as defined below) and to supply quantities of Product to IMPATIENTS for these Early Access Programs in the Territory,

WHEREAS, IMPATIENTS agrees to accept such right and to use the Product for Early Access Programs from HEMISPHERX pursuant to the terms of this Agreement, and

WHEREAS, the Parties wish to set forth the terms and conditions under which HEMISPHERX grants the exclusive right and supplies the Product and IMPATIENTS implements the Early Access Program.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereto, intending to be legally bound, agree as follows:

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

1. Definitions

The following terms when used in this Agreement, shall have the meanings set forth in this clause:

- 1.1 “**Accounting Standards**” with respect to a Party means that such Party shall maintain records and books of accounts in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.
- 1.2 “**Affiliate**” means, as to any person or entity, any other person or entity, which controls, is controlled by, or is under common control with such person or entity. A person or entity shall be regarded as in control of another entity only if it owns or controls, directly or indirectly, at least fifty percent (50%) of the equity securities or other ownership interests in the subject entity entitled to vote in the election of directors or with the power to direct or elect management of such subject entity.
- 1.3 “**HEMISPHERX Patents**” means all of the Patents that are (a) under Control by HEMISPHERX or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) reasonably necessary or useful (or, with respect to Patent applications, would be reasonably necessary or useful if such Patent applications were to issue as Patents) for the development, manufacture, or use or sale of the Product.
- 1.4 “**Applicable Law**” means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity and/or country or other jurisdiction hereunder.
- 1.5 “**Confidential Information**” means any Information provided orally, visually, in writing or other form by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement, the Product (including the Regulatory Documentation and Regulatory Data), any use of the Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (a) jointly owned Know-How shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto; and (b) after IMPATIENTS proceeds with the EAP, all Regulatory Documentation developed by IMPATIENTS shall be deemed to be the Confidential Information of HEMISPHERX, and HEMISPHERX shall be deemed to be the disclosing Party and IMPATIENTS shall be deemed to be the receiving Party with respect thereto.
- 1.6 “**Control**” means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right existing on or after the Effective Date and during the Term, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue, or otherwise (other than by operation of the license and other grants herein), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any third party; provided, however, neither Party shall be deemed to Control any item of Information, Regulatory Documentation, material, Patent, or other property right of a third party if access requires or triggers a payment obligation.

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- 1.7 “**Early Access Program**” or “**EAP**” means the activities directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization through named-patient use, compassionate use, expanded access and hospital exemption (b) patient and physician outreach related to the platform, (c) the securing of Early Access Approvals, for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance activities in accordance with the Pharmacovigilance agreement, attached as Exhibit 6 and/or (f) to the extent permitted by Applicable Law, the collection of data, including but not limited to patient-reported outcomes, doctor-reported experiences and registry data as set out in more detail in Exhibit 9.
- 1.8 “**EAP Plan**” means the plan to be agreed by the JSC for the initiation and performance of an Early Access Program for Product in the Field. The EAP Plan will be attached hereto as Exhibit 1.
- 1.9 “**Early Access Approvals**” means the permissions, exemptions, approvals, authorizations and/or waivers required by Regulatory Authorities for medical treatments, not subject of a Marketing Authorization in the relevant country, to be sold to a pharmacy or wholesaler, to be dispensed to a physician, to be administered to and/or used by a patient.
- 1.10 “**Field**” means treatment of chronic fatigue syndrome.
- 1.11 “**First Commercial Sale**” means, with respect to a Product and a country, the first sale for monetary value for ultimate use by the patient of such Product in such country after Marketing Authorization for such Product has been obtained in such country. Sales prior to receipt of Marketing Authorization for such Product, such as so-called “treatment IND sales,” “named patient sales,” or other “compassionate use sales,” shall not be construed as a First Commercial Sale.
- 1.12 “**Good Manufacturing Practice**” or “**GMP**” means the current good manufacturing practices applicable from time to time to the manufacturing of a Product or any intermediate thereof pursuant to Applicable Law.
- 1.13 “**Information**” means knowledge of a technical, scientific, business, and other nature, including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Regulatory Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays, and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.14 “**Joint Steering Committee or JSC**” means the joint steering committee to be established by the Parties as referred to in Clause 2.

1.15 “**Know How**” means information and materials, whether or not confidential, including, but not limited to, pharmaceutical, chemical, products, economic and commercial information, including and not limited to all market information, strategies and tactics relevant to the Product in the Territory and any lists of physicians and/or clinicians active in the Field in the Territory, technical and non-technical manufacturing process and equipment data and information, product and process validation data, the results of tests on products, reports and results of product assays, pre-clinical and clinical studies, and drawings, plans, diagrams, specifications and/or other documents containing said information relating to the Product.

1.16 “**Manufacturer**” means the legal entity that physically manufactures and/or fills and/or finishes and/or labels and/or stockpiles cGMP grade Product.

1.17 “**Marketing Authorization**” means, with respect to a country, region or other jurisdiction in the Territory and in the Field, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market Product in the Field in such country or other jurisdiction, including, where applicable, (a) pre- and post-approval regulatory approvals (including any prerequisite manufacturing approval or authorization related thereto), and (b) approval of Product labeling in the Field.

1.18 “**Material Event**” means, in the context of the EAP, any event which would, in HEMISPHERX’s reasonable opinion, (a) adversely affect HEMISPHERX’s ability to market and distribute the Product outside of the EAP, including but not limited to its ability to obtain Marketing Authorisation in any country or region, (b) adversely effect HEMISPHERX’s ability to use its intellectual property relating to its brand or the Product, or (c) bring HEMISPHERX’s business into disrepute. For the avoidance of doubt, a Material Event shall not include any event relating to the performance of pharmacovigilance activities in relation to which the Parties have entered into the Pharmacovigilance Agreement.

1.19 “**Net EAP Sales**” means the gross amount invoiced by IMPATIENTS or its affiliates to non-affiliated third parties for the sale of Product, less the following reasonable and customary deductions consistent with IMPATIENTS’ cash or accrual accounting method to the extent applicable to such invoiced amounts (to the extent each is actually incurred and included in the invoiced gross sales price) in accordance with Accounting Standards:

- (a) all mutually agreed trade discounts or rebates;
- (b) amounts for claims, allowances or credits for rejections or returns;
- (c) packaging, handling fees and costs of freight, insurance, sales taxes, duties and other governmental charges (including value added tax), but excluding what is commonly known as income taxes.

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The specific deductions, as set out in Exhibit 8, taken under, and the general provision of, (a) through (c) above may be adjusted periodically after agreement between both Parties as necessary to reflect amounts actually incurred.

1.20 “**Net Sales**” means the gross amount invoiced by HEMISPHERX or its affiliates to non-affiliated third parties for the sale of Product, less the following reasonable and customary deductions consistent with HEMISPHERX’s cash or accrual accounting method to the extent applicable to such invoiced amounts (to the extent each is actually incurred and included in the invoiced gross sales price) in accordance with Accounting Standards:

- (a) all mutually agreed trade discounts, or rebates;
- (b) amounts for claims, allowances or credits for rejections or returns;;
- (c) packaging, handling fees and costs of freight, insurance, sales taxes, duties and other governmental charges (including value added tax), but excluding what is commonly known as income taxes.

The specific deductions taken under, and the general provision of, (a) through (c) above may be adjusted periodically after agreement between both Parties as necessary to reflect amounts actually incurred.

For the avoidance of doubt, Net Sales shall not include sales for resale to Affiliates of HEMISPHERX.

For purpose of this definition 1.20, a sale shall also include a transfer or other disposition for consideration other than cash, in which case such consideration shall be valued at the fair market value thereof. Transfers or dispositions for charitable purposes or for pre-clinical, clinical, regulatory or governmental purposes prior to receiving Marketing Authorization are not considered a "sale".

1.21 “**Patents**” means (a) all national, regional and international patent applications, including provisional patent applications, and all applications claiming priority therefrom, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (b) any and all national patents issued or granted from the foregoing patent applications, including utility patents, utility models, petty patents and design patents and certificates of invention; (c) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a) and (b)); and (d) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.22 “**Patient on Treatment**” means patients that have met all the criteria to receive the Product under an EAP as set out in the EAP Plan and who have had the Product prescribed for them.

1.23 “**Pharmacovigilance Agreement**” or “**PhVA**” means the pharmacovigilance agreement attached as Exhibit 6.

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- 1.24 “**Price**” means the price of Product invoiced by IMPATIENTS to third parties other than Affiliates of IMPATIENTS in accordance with Exhibit 4 excluding any VAT or other taxes or levies that are applicable.
- 1.25 “**Product**” means all available stock-keeping units (SKU)’s of the product referred to as of the Effective Date, as Ampligen®, a double-stranded RNA product, supplied ready packed and labeled, such labeling to include the Ampligen Trademark and the fact that the Product is manufactured and supplied by HEMISPHERX on both primary and secondary containers, quality tested and QP released in accordance with applicable pharmaceutical law and regulations.
- 1.26 “**Quality Agreement or QA** ” means the quality agreement attached as Exhibit 5 to this Agreement.
- 1.27 “**Regulatory Authority**” means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., the FDA, EMA and PMDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement.
- 1.28 “**Regulatory Data**” shall have the meaning given to it in Clause 4.2 of this Agreement.
- 1.29 “**Regulatory Documentation**” means all (a) applications (including all INDs and Drug Approval Applications and other regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) pre-clinical and clinical data, and data contained or relied upon in any of the foregoing, in each case (a), (b), and (c) relating to Product.
- 1.30 “**Specifications**” means all data necessary to manufacture the Product and contained in the most recent version of the product specification file, IMPD or IND.
- 1.31 “**Territory**” means all the countries of the European Union and Turkey.
- 1.32 “**Trademark**” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names whether or not registered.

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2 – EAP activities & management

2.1 EAP Activities.

IMPATIENTS shall perform EAP activities, including selling and distributing the Product in the Territory. IMPATIENTS shall use reasonable commercial efforts to assure that all requested and relevant information is presented to regulatory authorities, decision makers, patients and/or responsible medical specialists, including informing patients and health care practitioners in general about their opportunities to apply for Early Access Approvals in the Territory.

2.2 Collaborative Committees.

As soon as practical after the Effective Date, but no later than thirty (30) days thereafter, the Parties shall establish a joint steering committee (the “Joint Steering Committee” or “JSC”), which shall (a) oversee the EAP plan for the Product in the Territory, (b) resolve Disputes that may arise in any subcommittees formed by the JSC, (c) coordinate the Parties’ activities under this Agreement, including oversight of any subcommittees formed by the JSC, and (d) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement. The details of the composition, operating procedures and responsibilities of the Collaborative Committees are described in Exhibit 2.

2.3 Packaging.

Subject to the provision by HEMISPHERX of appropriately labeled and packaged Product and associated materials, IMPATIENTS shall ensure that such amounts of the Product and its associated materials as are supplied and distributed under the EAP Program shall prominently display the Product Trademark, together with the information that the Product is manufactured and supplied by HEMISPHERX.

3 – Grants of rights, disclosure of know how

3.1 Appointment.

3.1.1 HEMISPHERX hereby appoints IMPATIENTS as its exclusive service provider to perform EAP activities for Product in the Field in the Territory.

3.1.2 HEMISPHERX hereby grants IMPATIENTS an exclusive, non-transferable, royalty-free right to reproduce and use the Product’s Trademarks solely in connection with performing the EAP activities for Product in the Field in the Territory, subject to the terms and conditions set forth herein, including in Exhibit 3.

3.2 IMPATIENTS Know How Contribution.

IMPATIENTS undertakes to contribute its Know How to perform the EAP, including but not limited its EAP technical and business knowledge regarding patient and physician outreach, regulatory and legal support, pharmacovigilance, reimbursement, data collection, logistics and marketing.

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3.3 HEMISPHERX Know How Disclosure.

Immediately after the Effective Date, HEMISPHERX shall collaborate with IMPATIENS make available to IMPATIENS, in whatever form IMPATIENS may reasonably request, Regulatory Documentation, HEMISPHERX Know How, and any other Information relating directly or indirectly to the Product and reasonably required to implement and manage the EAP in the Territory (including, but not limited to, information related to Manufacturing), to the extent not done so already, and thereafter immediately upon the availability of such Regulatory Documentation, HEMISPHERX Know How, or other Information. For the avoidance of doubt, where necessary, HEMISPHERX will and shall cause its Affiliates and collaborators, without additional compensation, to make available to IMPATIENS relevant information agreed upon with IMPATIENS under this Clause 3.3.

3.4 HEMISPHERX Know How Assistance.

HEMISPHERX, at its sole cost and expense, shall provide IMPATIENS with reasonable assistance required in order to transfer to IMPATIENS the Regulatory Documentation, HEMISPHERX Know How and other Information required to be produced hereunder, in each case in a timely manner. HEMISPHERX shall reasonably assist IMPATIENS with respect to the implementation of the EAP for the Product.

4 - Regulatory matters

4.1 Regulatory Activities.

IMPATIENS shall have the sole and exclusive right to make contact with patients and physicians relating to the EAP of Product, and to file applications for Early Access Approvals therefor (including the setting of the overall regulatory strategy therefor), and to communicate with the Regulatory Authorities to secure Early Access Approvals for Product in the Territory.

4.1.1 HEMISPHERX shall support IMPATIENS as may be reasonably necessary in obtaining Early Access Approvals for the Product, and in the activities in support thereof, including providing necessary documents or other materials required by Applicable Law to obtain Early Access Approvals, in each case in accordance with the terms and conditions of this Agreement.

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4.1.2 HEMISPHERX shall collaborate with IMPATIENS to provide IMPATIENS with (a) access to or copies of all material written or electronic correspondence (other than regulatory filings) relating to the development of Product in the Field received by HEMISPHERX or its Affiliates, collaborators or licensees from, or filed by HEMISPHERX or its Affiliates, collaborators or licensees with, the Regulatory Authorities, and (b) copies of all meeting minutes and summaries of all meetings, conferences, and discussions held by HEMISPHERX or its Affiliates, collaborators or licensees with the Regulatory Authorities relating to the development or commercialization of Product in the Field, including copies of all contact reports produced by HEMISPHERX or its Affiliates or licensees, in each case ((a) and (b)) within fifteen (15) Business Days of its receipt, forwarding or production of the foregoing, as applicable. If such written or electronic correspondence received from any such Regulatory Authority relates to the withdrawal, suspension, or revocation of a Regulatory Approval or Early Access Approval for Product in the Field, the prohibition or suspension of the supply of a Product in the Field, or the initiation of any investigation, review, or inquiry by such Regulatory Authority concerning the safety and quality of a Product in the Field, the notified Party shall notify the other Party and provide the other Party with copies of such written or electronic correspondence as soon as practicable.

4.1.3 HEMISPHERX shall, in accordance with the Quality Agreement, make every reasonable effort to notify IMPATIENS promptly following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Product in the Territory in the Field, and shall include in such notice the reasoning behind such determination, and any supporting facts. HEMISPHERX (or its licensee) shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory. If a Regulatory Authority in the Territory mandates a recall, market suspension, or market withdrawal, then HEMISPHERX (or its licensee) shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 4.1.3, HEMISPHERX or its licensee, whichever responsible for the recall, market suspension, or market withdrawal, shall be solely responsible for the execution thereof, and IMPATIENS shall reasonably cooperate in all such recall efforts.

4.2 Regulatory Data.

Within the Field, each Party shall promptly provide to the other Party copies of, or access to all non-clinical and clinical data, and other information, results, and analyses with respect to any development activities that are carried out by or on behalf of or otherwise controlled by such Party or any of its Affiliates, collaborators or licensees (collectively, "Regulatory Data"), when such Regulatory Data becomes available. For the avoidance of doubt, the requirements under this Clause 4.2 shall include that HEMISPHERX shall provide IMPATIENS with copies of up-to-date versions of (a) the EU GMP certificate of the manufacturing site, (b) if applicable, the Product's GMP certificate, (c) the Manufacturer's manufacturing license for the Product, (d) Product stability data and certificate of analysis, together with all other Know How that IMPATIENS is required to include, or may need to include, in its Early Access Approval applications.

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4.3 Pharmacovigilance.

Parties shall enter into a separate agreement related to the responsibility and performance of pharmacovigilance activities related to the Product. This Pharmacovigilance Agreement is attached as Exhibit 6.

4.4 Compliance.

Each Party shall perform or cause to be performed, any and all of its development activities, in good scientific manner and in compliance with all Applicable Law.

4.5 Records.

4.5.1 Each of HEMISPHERX and IMPATIENTS shall, and shall ensure that its third party providers shall, maintain records in sufficient detail and in good scientific manner appropriate for regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its activities. HEMISPHERX or IMPATIENTS shall and retain all such records, as the case may be, for at least three (3) years after termination of this Agreement, or for such longer period as may be required by Applicable Law.

4.5.2 Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and make copies of all records of the other Party that pertain to the subject matter of this Agreement and that are reasonably required by such Party, except, without limitation, for files that cannot be shared due to applicable privacy regulations or that are subject to the attorney-client privilege. The inspecting Party shall maintain such records and the information disclosed therein in accordance with the confidentiality clauses of Clause 9 of this Agreement.

4.5.3 Without prejudice to the provisions of Clause 2, the JSC shall determine what reports shall be generated to track the EAP activities, including the content and timing thereof.

5 – Exclusive distribution, supply and manufacture

5.1 Distribution.

HEMISPHERX hereby appoints IMPATIENTS as its sole and exclusive distributor in respect of EAP use of Product for use in the Field in the Territory, limited to EAP use of Product in accordance with Early Access Approvals.

5.2 Product Supply.

5.2.1 HEMISPHERX undertakes and agrees to supply to IMPATIENTS on an exclusive basis, IMPATIENTS' requirements of Product ordered in accordance with the terms of this Agreement, for distribution and sale in the Territory, limited to EAP use of Product in accordance with Early Access Approvals.

5.2.2 IMPATIENTS undertakes and agrees to obtain its requirements of Product for use in the Field from HEMISPHERX in accordance with the terms of this Agreement.

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5.3 Product Manufacturing.

5.3.1 Manufacturing.

HEMISPHERX shall solely be responsible for the manufacturing, fill & finish, labeling and, if applicable, stockpiling of cGMP grade Product in compliance with the Quality Agreement attached as Exhibit 5, and shall exert its reasonable commercial best efforts to provide quantities of cGMP Product sufficient to meet the requirements of the EAP. If HEMISPHERX contracts the manufacturing and/or filling and/or finishing and/or labeling and/or stockpiling of Product to a third party, such third party shall be considered a Manufacturer. HEMISPHERX will ensure that all relevant obligations deriving from this Agreement (including the Quality Agreement) between Parties are part of the contractual relationship between HEMISPHERX and any Manufacturer. HEMISPHERX shall provide all required documentation to IMPATIENS related to the manufacturing for purposes of furthering the activities of the EAP.

5.3.2 Interruption of Supply.

If HEMISPHERX is unable to meet IMPATIENS' requirements for Product, HEMISPHERX will notify IMPATIENS and the JSC will meet as soon as possible to negotiate a possible resolution.

6 - Supply of Product and Invoicing

6.1 Notification of Requirements.

IMPATIENS shall notify HEMISPHERX of its estimated Product requirements for the following {***} months {***} days before the start of {***} ("Rolling Forecast"). Said estimate shall not constitute a firm commitment by IMPATIENS. HEMISPHERX shall, within 10 business days of receipt of such Rolling Forecast, indicate to IMPATIENS if it agrees to such Rolling Forecast. The enrollment of patients into the EAP and the Rolling Forecast shall be mutually agreed between the Parties.

6.2 Available Stock.

HEMISPHERX shall use its best efforts to ensure that sufficient quantities of Product for 6 months of treatment for all patients then enrolled in the EAP are in stock at the warehouse of IMPATIENS's logistics service provider ("LSP"). In addition, HEMISPHERX shall use reasonable commercial efforts to ensure that sufficient quantities of Product for the following six months projected sales, based on the most recent Rolling Forecast, as agreed in accordance with Clause 6.1, are in stock at the warehouse of IMPATIENS' LSP. The legal ownership of the stock in the warehouse of IMPATIENS' LSP (further referred to as "Consignment Stock") shall remain with HEMISPHERX and will at no time be transferred to IMPATIENS or the LSP. At the time of IMPATIENS' delivery of the Product through its LSP to its clients, legal ownership of the Product will directly transfer from HEMISPHERX to the relevant client of IMPATIENS. Any costs related to the keeping Consignment Stock shall be at the expense of IMPATIENS.

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6.3 Product Shipment.

HEMISPHERX shall deliver the Product DDP (INCOTERMS 2010) at the Consignment Stock warehouse address of IMPATIENTS' LSP. At the warehouse of IMPATIENTS' LSP, Product will be made ready for delivery to IMPATIENTS' clients, in a manner controlled by IMPATIENTS and in accordance with the Quality Agreement.

6.4 Shipment Authorization.

HEMISPHERX hereby authorizes IMPATIENTS to order its LSP to use Product from the Consignment Stock for the fulfilling of orders from IMPATIENTS' clients without further approval from HEMISPHERX. HEMISPHERX shall make sure the Consignment Stock is replenished in a timely manner to comply with the stock level requirement as mentioned in Clause 6.2.

6.5 Invoice.

IMPATIENTS shall notify HEMISPHERX at the beginning of {***} of all fulfilled Product orders and Net EAP Sales (in Euros (€)) of Product from the preceding {***}. HEMISPHERX shall send IMPATIENTS an invoice in Euros (€) for 65% of Net EAP Sales in such {***} and IMPATIENTS shall pay the amount of such invoice to HEMISPHERX in Euros (€) within {***} days of receipt.

6.6 Product Pricing.

The Price of the Product is specified in Exhibit 4. Prices are stated excluding VAT or other taxes or levies.

7 – Compensation to IMPATIENTS for agreed services

7.1 Royalty Obligation.

7.1.1.1 During the EAP, IMPATIENTS shall, to the extent permitted by Applicable Law, collect information and data, including but not limited to patient-reported outcomes, doctor-reported experiences and registry data, and shall provide support services useful for Marketing Authorization applications in the Territory. As a compensation for the collection of such information and data, and/or the performance of such services, HEMISPHERX will pay to IMPATIENTS a royalty as further provided in this Clause 7.1.

7.1.1.2 In the event that HEMISPHERX or any of its Affiliates receives Marketing Authorization in the Field for the Product in any country in the Territory, then HEMISPHERX shall pay IMPATIENTS (or its successors or assigns) a royalty of up to a maximum of {***}% of Net Sales of Product in the countries in the Territory for which Marketing Authorization is granted. In the event that {***} patients are entered into the EAP, such royalty percentage shall be calculated in accordance with the following formula:

{***}

{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 7 sets out a number of worked examples for this calculation.

7.1.2 Royalties payable in respect of Net Sales shall be payable on a {***} basis for a period starting from the receipt of Marketing Authorization and ending the date {***} years from the {***} of such Product {***}.

7.1.3 HEMISPHERX shall not be entitled to assign, sell or dispose of its rights in respect of the Product in the Field to a third party (including granting a third party the right to file for a Marketing Authorization based on HEMISPHERX's rights and know how) unless such third party undertakes in writing to IMPATIENTS to be bound by the provisions of this Clause 7 as if such third party were a party to this Clause 7 instead of HEMISPHERX. For the avoidance of doubt, by third party in this Clause 7 is meant any person or entity that is not a Party to this agreement, including any Affiliate of HEMISPHERX.

7.1.4 For the purposes of the calculation of the royalty payment under this Clause 7.1, Product Net Sales shall be reported, and royalties based on such Product Net Sales shall be paid, to IMPATIENTS within {***} after the end of each {***} during which Product has been sold. HEMISPHERX, its Affiliates, licensees, successors and/or assigns shall maintain accurate records of Product sales for a period of no less than seven years. Such records may be audited for accuracy once a year by an independent public accounting firm, acceptable to both Parties, which accounting firm would be allowed reasonable access at reasonable times to review all relevant records.

8 – Warranties and Undertakings, Liability and Indemnity

8.1 Mutual Representations and Warranties.

The Parties represent and warrant and, where relevant, undertake to each other, as of the Effective Date, as follows:

8.1.1 Organization.

It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

8.1.2 Authorization.

The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, articles of association or other organizational documents, (b) any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

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8.1.3 Binding Agreement.

This Agreement is a legal, valid, and binding obligation of such Party, enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

8.1.4 No Inconsistent Obligation.

It is not under any obligation, contractual or otherwise, to any person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

8.2 Product Warranty and Undertaking.

HEMISPHERX warrants and undertakes that all Product supplied to IMPATIENS under this Agreement shall comply with the Specifications; be manufactured, filled, finished, labeled and packed in GMP facilities and in accordance with the Quality Agreement and all Applicable Laws; be free from contamination or adulteration; be adequately packed to withstand transportation. At the time of delivery, each Product shall have no less than 9 (nine) months of the Product's registered shelf life remaining.

8.3 Product Liability.

HEMISPHERX represents and warrants to IMPATIENS that HEMISPHERX is legally bound to retain responsibility and liability for the manufacture of the Product at all times and undertakes that it shall maintain product and general liability insurance covering any loss, costs, expenses, liability, actions, demands, claims or proceedings relating to the Product.

8.4 Indemnity.

Each Party shall indemnify and hold the other Party harmless from any claims, suits, demands, judgments, actions, liabilities, (including strict liability and infringement of a third party's patent rights) expenses (including reasonable attorney's fees) and damages relating to the Product and caused directly or indirectly by any act or omission of the other Party and its officers, directors, employees, subcontractors, agents or suppliers, or (in the case of HEMISPHERX only) the Manufacturer. This indemnity shall not apply if any such liability, loss, damage, cost or expense is due to the gross negligence or default in performance by the indemnified Party, its officers, directors, employees, subcontractors, agents or suppliers.

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8.5 Waiver of consequential or punitive damages.

Save as for intentional wrongdoing by a Party, neither Party, nor any of their respective directors, officers, employees or agents shall have any liability towards the other Party, for any indirect or consequential damages claimed by the other Party, including, but not limited to the loss of opportunity, loss of use, and/or loss of revenue or profit, in connection with or arising out of this Agreement or breach thereof.

8.6 Insurance

Each Party shall maintain at its own cost at all times during the term of this Agreement, policies of insurance in such amounts and to cover such risks as are reasonable, prudent and/or potentially foreseeable hereunder. Maintenance of such insurance coverage will not relieve a Party of any responsibility under this Agreement for damages in excess of insurance limits or otherwise.

9 - Confidentiality

9.1 The Parties will continue to abide by the confidentiality agreement signed by both Parties dated 11 June 2015, provided that the term of the confidentiality agreement shall be extended as long as necessary so as not to expire before the expiration or termination of this Agreement. The terms of confidentiality respecting Information shall not impede the appropriate use thereof in IMPATIENTS's submission of Information in Early Access Approvals applications with Regulatory Authorities, in HEMISPHERX's submission of Information in Marketing Authorization Applications with Regulatory Authorities, or in execution of the EAP of Product according to the EAP Plan.

9.2 HEMISPHERX acknowledges that the EAP Plan involves the publication of safety and efficacy information relating to the Product, including HEMISPHERX Confidential Information included in the Regulatory Documentation, and the patient- and doctor-reported outcomes and registry data generated and collected during the performance of the EAP. Therefore, HEMISPHERX hereby consents to IMPATIENTS publishing such HEMISPHERX's Confidential Information as is required in accordance with Applicable Laws.

9.3 HEMISPHERX and IMPATIENTS agree to use all Confidential Information received under this Agreement solely for the purpose set forth herein and agree not to otherwise interfere in the business of the other in any respect.

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10 - Duration, termination

- 10.1 This Agreement will become legally effective on the Effective Date and, unless earlier terminated pursuant to the terms hereof, shall continue in full force and effect for an initial period of {***} years. This initial period may be extended upon mutual written agreement between the Parties and in the absence of a notice to the other Party (to be given with at least 90 days notice) from a Party that it does not agree to the extension of this Agreement under this Clause 10.1, shall be extended each anniversary by 12 months until commercial availability of the Product in the Territory following receipt by HEMISPHERIX or one of its Affiliates of appropriate Marketing Authorization.
- 10.2 Subject to any mandatory provision of law, this Agreement may be terminated by a Party, without any liability to the other, if the other Party is dissolved or liquidated, files or has filed against it a petition under any applicable bankruptcy or insolvency law, makes a general assignment for the benefit of its creditors, or has a receiver appointed for substantially all of its assets.
- 10.3 Following expiry of the initial {***}-year term as set out in Clause 10.1, either Party may terminate this Agreement, provided the non-terminating Party is provided with 6 (six) months written notification.
- 10.4 HEMISPHERIX shall have the right to terminate this agreement at any time during the Term provided that it shall provide IMPATIENTS with ninety (90) days written notification.
- 10.5 In the event that HEMISPHERIX does not provide notification of ability to supply the Product for the EAP under Clause 6.2 within twelve (12) months of the Effective Date, IMPATIENTS shall be entitled to terminate this Agreement with thirty (30) days written notification.
- 10.6 Each Party reserves the right to immediately terminate this Agreement if the other Party is in breach of its material obligations under this Agreement and fails to remedy such breach within 6 (six) months written notification by the other Party of said breach. In the event of a breach not being capable of remedy within 6 (six) months of written notification, the parties shall negotiate in good faith to agree a period for remedy after which, if the breach remains, the Party whose obligations are not in such continuing breach shall be entitled to terminate this Agreement.
- 10.7 Consequences of Termination.
- 10.7.1 In the event of a termination of this Agreement under Clauses 10.1 to 10.5 (inclusive), HEMISPHERIX shall permit IMPATIENTS to continue to distribute and sell the Product until such time that the entire quantity of the Consignment Stock has been sold.
- 10.7.2 In the event of termination of this Agreement pursuant to Clause 10.1, termination by HEMISPHERIX pursuant to Clause 10.3 or by IMPATIENTS pursuant to Clause 10.5, Clause 7.1 shall survive such termination and the royalty rate to be applied to Net Sales of Product shall be the percentage as calculated in accordance with such Clause 7.1 {***}.
- 10.7.3 In the event of termination of this Agreement by HEMISPHERIX pursuant to Clause 10.4, Clause 7.1 shall survive such termination and the royalty rate to be applied to Net Sales of Product shall be set according to the Termination Algorithm outlined in Exhibit 7.

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10.7.4 Upon termination of this Agreement by IMPATIENTS pursuant to Clause 10.3 or by HEMISPHERX pursuant to Clauses 10.5 or 10.6, Clause 7.1 shall not survive termination and no royalty shall be payable to IMPATIENTS under such provision.

10.8 Survival.

In addition to and subject to the provisions of Clause 10.6, Clause 1, Clauses 4.5.1 and 4.5.2, Clause 6.5 and Clauses 8 to 11 shall survive termination of this Agreement.

11 – Miscellaneous

11.1 Entire Agreement.

This Agreement, together with the Confidentiality Agreement dated 11 June 2015 and signed by the Parties prior to the Effective Date, constitutes the entire agreement between the Parties as regards the Product, and any former agreement relating to the same subject matter hereby becomes null and void. In the event of any inconsistencies between the terms of these Agreements, the terms of this Agreement shall prevail.

11.2 Amendments.

Modifications to this Agreement shall be made in writing only, and shall only take effect when signed by both Parties.

11.3 Press releases

Each Party shall have the right to disclose the existence of this Agreement, but not any of its material terms (which shall remain Confidential Information of both Parties), provided that such disclosing Party shall provide to the other Party the proposed text of any press release for review not less than five (5) days prior to public disclosure.

11.4 Independent Contractors.

It is understood that both Parties hereto are independent contractors and engage in the operation of their own respective businesses. Neither Party hereto is to be considered the agent of the other Party for any purpose whatsoever, and neither Party has any authority to enter into any contract or assume any obligation for the other Party or to make any warranty or representation on behalf of the other Party. Each Party shall be fully responsible for its own employees, servants and agents, and the employees, servants and agents of one Party shall not be deemed to be employees, servants and agents of the other Party for any purpose whatsoever.

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11.5 Remedy; Waiver.

Exercise by any Party of any of its rights under this Agreement shall not be deemed to limit any other right or remedy that such Party may have in law or equity. The waiver by either Party of a breach of any of the provisions of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions, nor shall any delay or omission by either Party in exercising any right that it may have under this Agreement operate as a waiver of any breach or default by the other Party.

11.6 Formalities.

Each Party agrees to execute deliver and/or do such further papers, agreements or acts as may be necessary or desirable to give effect to this Agreement and its purpose and to carry out its provisions.

11.7 Choice of Law and Dispute Resolution.

This Agreement shall be governed by and interpreted under the laws of the Netherlands. All disputes arising out of or in connection with this Agreement shall be submitted to the International Court of Arbitration of the International Chamber of Commerce and shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators appointed in accordance with the said Rules. Any such arbitration shall take place in Amsterdam, the Netherlands and in the English language.

11.8 Language.

This Agreement is executed in the English language. The language used in this Agreement shall be deemed to be the language chosen by the Parties hereto to express their mutual intent and no rule of strict construction against either Party shall apply to any term or condition of this Agreement. The definitive language of this Agreement is English and no reliance shall be placed upon any translation into any other language.

11.9 Assignment; Assumption.

Subject to the provisions of Clause 7.1.3, neither this Agreement nor any rights or obligations hereunder may be assigned or duties delegated (other than specified in the EAP Plan) by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Any assignment in violation of this clause shall be null and void. Any permitted assignee shall, upon the request of the other Party hereto, expressly acknowledge, by written agreement, its assumption of all obligations and liabilities under this Agreement.

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11.10 Force Majeure.

Should a Party be unable to perform any of its obligations under this Agreement due to an event of force majeure as determined by law such Party shall be excused to perform its obligation during the period of such force majeure event provided always that it gives the other Party prompt written notice of such force majeure event. If the event of force majeure were to prevent such Party performing its obligations in connection with this Agreement for a continuous period of more than three (3) months, the other Party may terminate the Agreement at its sole option by giving written notice thereof, without any indemnity to be paid by either Party. The termination would then take effect without further notice, at the date of receipt of the above notice. In no event shall this provision relieve either Party of its obligation to make payment when owing.

11.11 Severability.

If any provision of this Agreement is found to be invalid or unenforceable by any court or administrative body of competent jurisdiction, then the invalidity or unenforceability of such provision shall not affect the other provisions of this Agreement, and all provisions not affected by such invalidity or unenforceability shall remain in full force and effect. The Parties agree to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision, which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision. If any provision of this Agreement conflicts with applicable legislation, then the Parties shall modify such provision in order to comply with said legislation. This modification shall not affect the other provisions of this Agreement.

11.12 Notice.

All formal notices to be given pursuant to this Agreement shall be in writing and in English and shall be delivered by hand, sent by registered mail return receipt, or by express courier service to the address of the Party to receive such notice as set out below (or such other address as may be notified by a Party to the other from time to time). Notices shall be deemed to have been received at the time of delivery by hand, at the date affixed on the return receipt or 3 (three) business days after sending if sent by express courier service.

For HEMISPHERX:

HEMISPHERX:
Attn: Thomas Equels
1617 JFK Boulevard
Suite 500
Philadelphia, Pa. 19013

For IMPATIENTS:

Impatients N.V.:
Attn.: {***}
Pilotenstraat 45
1059 CH
Amsterdam
The Netherlands
Email: {***}

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11.13 Construction.

Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean “including, but not limited to,” and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

IN WITNESS WHEREOF, the Parties have executed this Agreement by their respective, duly authorized, representatives:

For HEMISPHERX:

s/Thomas Equels
Thomas Equels
CEO

For IMPATIENS:

s/Ronald Brus
Ronald Brus
CEO

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 1. – EAP Plan

(to be inserted after being agreed by JSC)

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 2 – JSC and subcommittees

1 JSC.

1.1 Composition.

The JSC shall consist of {***}, each with the requisite experience and seniority to enable such person to make decisions on behalf of a Party with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one or more of its representatives to the JSC on written notice to the other Party. {***}. The chairperson shall appoint a secretary of the Joint Steering Committee, who shall be {***}.

1.2 Specific Responsibilities.

The JSC shall oversee the EAP for the Product in the Territory, and shall serve as a forum for the coordination of activities for the Product for the Territory. In particular, the JSC shall:

- (a) periodically (no less often than annually) review and serve as a forum for discussing the EAP, and review and approve amendments thereto;
- (b) oversee the conduct of EAP activities;
- (c) serve as a forum for discussing and coordinating strategies for obtaining Early Access Approvals and Regulatory Approvals for the Product in the Territory;
- (d) establish secure access methods (such as secure databases) for each Party to access Regulatory Documentation and other JSC related Information as contemplated under this Agreement; and
- (e) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.
- (f) Approve HEMISPHERX Know-How and Regulatory Documentation to be shared with Regulatory Authorities and physicians both under relevant confidentiality mechanisms.

1.3 Disbandment.

Upon Marketing Authorization of the Product in all countries of the Territory, unless otherwise mutually agreed in writing, the JSC shall have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties.

1.4 Subcommittees.

From time to time, the JSC may establish and delegate duties to sub-committees or directed teams (“Subcommittees(s)”) on an “as-needed” basis to oversee particular projects or activities (for example, joint project team, joint finance group, and/or joint intellectual property group). Each such Subcommittee shall be constituted and shall operate as the JSC determines; provided that each Subcommittee shall have equal representation from each Party, unless otherwise mutually agreed. Subcommittees may be established on an *ad hoc* basis for purposes of a specific project or on such other basis as the JSC may determine. Each Subcommittee and its activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. In no event shall the authority of the Subcommittee exceed that specified for the JSC. All decisions of a Subcommittee shall be by unanimous agreement.

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2 General Provisions Applicable to committees.

2.1 Meetings and Minutes.

The committees shall meet quarterly by telephonic or tele video means, or, when necessary as agreed between the Parties, face-to-face, with the location of such face-to-face meetings alternating between locations designated by HEMISPHERX and locations designated by IMPATIENTS. The chairperson of the applicable committee shall be responsible for calling meetings on no less than thirty (30) Business Days' notice. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least ten (10) Business Days in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld or delayed. The chairperson of the committee shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the committee. If the Parties cannot agree on the content of the minutes the objecting party shall append a notice of objection with the specific details of the objection to the proposed minutes.

2.2 Procedural Rules.

Each committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on a committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. Each committee shall take action by unanimous agreement of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party. Employees or consultants of either Party that are not representatives of the Parties on a Committee may attend meetings of such committee; *provided, however*, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the Committee, and (b) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Section 11.1 of the Agreement.

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2.3 Committee Dispute Resolution.

If a subcommittee cannot, or does not, reach unanimous agreement on an issue at a meeting or within a period of ten (10) Business Days thereafter or such other period as the Parties may agree, then the dispute shall be referred to the JSC for resolution and a special meeting of the JSC may be called for such purpose. If the JSC cannot, or does not, reach unanimous agreement on an issue, including any dispute arising from the JSC, then the dispute shall first be referred to the senior officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the senior officers shall be conclusive and binding on the Parties.

2.4 Limitations on Authority.

Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No committee shall have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 11.2 of the Agreement.

2.5 Alliance Manager.

Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of each committee and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "Alliance Manager"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

3 Discontinuation of Participation on a Committee.

Each committee shall continue to exist until the first to occur of: (i) the Parties mutually agreeing to disband the committee; or (ii) upon receipt of Marketing Authorization of the Product in the last country of the Territory.

4 Expenses.

Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, a committee.

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Exhibit 3 – Trademark usage conditions

1. Product Trademark License Terms.

- IMPATIENTS acknowledges HEMISPHERX's exclusive right, title, and interest in and to the Product Trademarks and acknowledges that (i) neither this Agreement, nor its use of the Product Trademarks hereunder, shall be construed to accord to
- 1.1. IMPATIENTS any rights in the Product Trademarks other than the limited license rights granted herein, and (ii) the goodwill generated thereby will inure solely and entirely to the benefit of HEMISPHERX.

- Should it be necessary to record IMPATIENTS as a registered licensee of the Product Trademarks in any jurisdiction,
- 1.2. HEMISPHERX shall do so at IMPATIENTS's expense, and IMPATIENTS will cooperate with HEMISPHERX to effect such recordation.

2. Trademark Use.

IMPATIENTS may use the Product Trademarks solely in conjunction with the Product EAP.

2.1. Product Trademarks Usage Requirements.

IMPATIENTS agrees to comply with the Product Trademarks usage requirements of this Exhibit 2.1.

- 2.2. The Product Trademarks may not be used in connection with the display, advertising, or promotion of Product for any purpose IMPATIENTS has not been appointed for.

- 2.3. The Product Trademarks may not be altered. The Product Trademarks are not to be used in conjunction with any other mark or design, i.e., the Product Trademarks must stand alone in terms of the commercial impression generated by the particular usage; *provided, however*, that IMPATIENTS's trademarks may be used along with the Product Trademarks as long as such trademarks do not combine, superimpose or overlap with the Product Trademarks.

- 2.4. IMPATIENTS must exercise care in the use of the Product Trademarks so as not to indicate to the public that IMPATIENTS is a division or affiliate of HEMISPHERX or otherwise related to HEMISPHERX.

- 2.5. IMPATIENTS shall not use as its own trademark any word(s) or design(s) confusingly similar to the Product Trademarks.

3. Protection of Interest.

If IMPATIENTS becomes aware of any unauthorized use of the Product Trademarks by a third party, IMPATIENTS, subject to its confidentiality obligations to other parties, agrees to promptly notify HEMISPHERX and to cooperate fully, at HEMISPHERX's expense, in the enforcement of HEMISPHERX's rights against such a third party. Nothing contained in this Section shall be construed as to require HEMISPHERX to enforce any rights against a third party or to restrict HEMISPHERX's rights to license or consent to such a third party's use of the Product Trademarks.

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Exhibit 4 – Price of Product

Product Price to be invoiced by IMPATIENTS to third parties (excluding VAT):

USD {***} for a {***} course of treatment of {***} vials {***}. Meaning {***} vials in total, with an equivalent price of USD {***} per vial

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 5 - Quality Agreement

(to be inserted after being agreed by JSC)

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 6 -Pharmacovigilance Agreement

(to be inserted after being agreed by JSC)

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 7 –Royalty Payment Example Calculations

For the purposes of illustration of the calculation of the royalty payments under Clause 7.1, the formula(s) would be calculated in the following situations as follows:

{***}

This demonstrates that if, during the course of the EAP, {***} patients have been admitted to the EAP the maximum royalty percentage will have been reached.

In the event of termination of this Agreement by HEMISPHERX pursuant to Clause 10.4, Clause 7.1 shall survive such termination and the royalty rate to be applied to Net Sales of Product shall be set according to the following Termination Algorithm:

If Hemispherx terminates without cause:

Royalty Rate on Hemispherx Commerical Sales As a Function of EAP Performance and Time

Cumulative EAP Patients **>6 mos <1 year** **>1 yr <2 yrs** **>2 yrs <3yrs** **>3 yrs <4 yrs** **>4 yrs <5 yrs**

{***}

For the avoidance of doubt, where the Termination Algorithm matrix above provides that, on termination by Hemispherx in accordance with clause 10.4, the royalty rate shall be calculated in accordance with the formula, then such formula shall be the formula set out in Clause 7.1 {***}.

{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 8 –List of Deductions

Trade discounts or rebates, mutually agreed between the Parties

Amounts reserved for claims, allowances or credits connected with rejections or returns of Product

Packaging, handling fees and costs of freight, insurance, sales taxes duties and other governmental charges (which sums shall include value added tax and its equivalents, but shall not include income taxes)

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 9 – Data to be collected

To the extent permitted by Applicable Law, IMPATIENTS shall use its reasonable commercial efforts to collect the following data in relation to the EAP:

- 1) Patient completed SF-36 questionnaire and Karnofsky Performance questionnaire every 8 weeks
- 2) Physician's Karnofsky performance score (based on patient questionnaire) every 8 weeks.
- 3) Physician completed Chronic Fatigue Syndrome questionnaire
- 4) Safety / adverse events in accordance with the Pharmacovigilance Agreement

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*