

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

FORM 10-Q/A  
(Amendment No. 1)

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-15911

**CELSION CORPORATION**  
(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**52-1256615**

(I.R.S. Employer Identification Number)

**997 Lenox Drive, Suite 100**  
**Lawrenceville, NJ 08648**  
(Address of principal executive offices)

**(609) 896-9100**  
(Registrant's telephone number, including area code)

**NA**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check One):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 18, 2015, the Registrant had 23,005,186 shares of Common Stock, \$0.01 par value per share, outstanding.

## EXPLANATORY NOTE

This Amendment No. 1 on Form 10-Q/A (this “Amendment”) of Celsion Corporation, a Delaware corporation (the “Company”), amends the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on May 11, 2015 (the “Form 10-Q”), and is being filed to replace Exhibit 10.1 originally filed with the Form 10-Q and indicate that confidential treatment with respect to specific portions of the exhibit has been requested. The exhibit was revised to disclose certain information that was originally redacted and that the Company has determined to disclose in connection with the processing of the confidential treatment application with the SEC.

No other changes were made to the Form 10-Q other than those described above. This Amendment does not reflect subsequent events occurring after the original filing date of the Form 10-Q or modify or update in any way disclosures made in the Form 10-Q. Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, as a result of this Amendment, the certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed as exhibits to the Form 10-Q have been re-executed and re-filed as of the date of this Amendment and are included as exhibits hereto. Because no financial statements have been included in this Amendment and this Amendment does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4 and 5 of such certifications have been omitted.

## PART II: OTHER INFORMATION

### Item 6. Exhibits.

- 10.1+\* Early Access Agreement dated as of January 13, 2015, by and between the Company and Impatiens N.V.
- 31.1+ Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2+ Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- + Filed herewith.
- 101\*\*\* The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets, (ii) the unaudited Consolidated Statements of Operations, (iii) the unaudited Consolidated Statements of Comprehensive Loss, (iv) the unaudited Consolidated Statements of Cash Flows, (v) the unaudited Consolidated Statements of Change in Stockholders’ Equity (Deficit), and (vi) Notes to Consolidated Financial Statements.
- \* Confidential treatment with respect to specific portions of this Exhibit has been requested, and such portions are omitted and have been filed separately with the SEC.
- \*\* Previously furnished with the Company’s Quarterly Report on Form 10-Q filed on May 11, 2015.
- \*\*\* Previously filed with the Company’s Quarterly Report on Form 10-Q filed on May 11, 2015.
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**SIGNATURES**

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

June 19, 2015

CELSION CORPORATION

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Registrant

By: /s/ Michael H. Tardugno  
Michael H. Tardugno  
Chairman, President and Chief Executive Officer

By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description of Documents</b>
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**	Previously furnished with the Company's Quarterly Report on Form 10-Q filed on May 11, 2015.
***	Previously filed with the Company's Quarterly Report on Form 10-Q filed on May 11, 2015.

**EARLY ACCESS AGREEMENT**

This exclusive Early Access Agreement (“Agreement”) is made and entered into the 13<sup>th</sup> day of January 2015 (“**Effective Date**”) by and between

**Celsion Corporation**, a company formed and registered under the laws of Delaware, USA and located at 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648 (hereinafter referred to as “**CELSION**”), 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 CELSION and IMPATIENTS, referred individually as a “Party” and collectively as the “Parties”.

**RECITALS**

WHEREAS, CELSION 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 (as defined below) through a patient platform (hereinafter referred to as the “myTomorrows platform”),

WHEREAS, CELSION 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 acquire the Product for Early Access Programs from CELSION pursuant to the terms of this Agreement, and

WHEREAS, the Parties wish to set forth the terms and conditions under which CELSION 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:

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE “COMMISSION”) PURSUANT TO RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH “\*\*\*\*\*”.

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## Article 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 “**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.
  - 1.4 “**CELSION Patents**” means all of the Patents that are (a) under Control by CELSION 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.
  - 1.5 “**Change of Control**” means when an unaffiliated third party gains control over the management decisions of a Party relating to this Agreement by virtue of (a) the sale of all or substantially all of the assets of the Party to said unaffiliated third party; (b) a sale resulting in more than fifty (50) % of the equity of the Party being held by said unaffiliated third party; (c) a merger, consolidation, recapitalization or reorganization of the Party with or into an unaffiliated third party; (d) the assignment of the rights and obligations pursuant to the Agreement to said unaffiliated third party.
  - 1.6 “**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 CELSION, and CELSION shall be deemed to be the disclosing Party and IMPATIENTS shall be deemed to be the receiving Party with respect thereto.
  - 1.7 “**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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- 1.8 “**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 Authorisation through named-patient use, hospital exemption or compassionate use, (b) patient recruitment, (c) the securing of Early Access Approvals, for the use of such treatments, (d) the distribution and sale of Product for such treatments pursuant to such Early Access Approvals, (e) inventory management, accountability and control, (f) pharmacovigilance activities as set forth in the Pharmacovigilance Agreement set forth in Exhibit 6 and/or (g) the collection of data, including but not limited to patient-reported outcomes, doctor-reported experiences and registry data
- 1.9 “**EAP Plan**” means the plan as 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.
- 1.10 “**Early Access Approvals**” means the permissions, exemptions, approvals, authorisations and/or waivers required by Regulatory Authorities for medical treatments, not the subject of a Marketing Authorisation, to be sold to pharmacy or hospital or medical treatment center, to be dispensed to a physician, to be administered to and/or used by a patient.
- 1.11 “**Field**” means treatment of Recurrent Chest Wall (“RCW”) Breast Cancer.
- 1.12 “**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 Authorisation for such Product has been obtained in such country. Sales prior to receipt of Marketing Authorisation 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.
- 1.13 “**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.
- 1.14 “**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.
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- 1.15 “**Joint Steering Committee or JSC**” means the joint steering committee to be established by the Parties as referred to in article 2.
- 1.16 “**Know How**” means information and materials, whether or not confidential, including, but not limited to, pharmaceutical, chemical, products, economic and commercial information, 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.
- 1.17 “**Manufacturer**” means the legal entity that physically manufactures and/or fills and/or finishes and/or labels and/or stockpiles GMP grade Product.
- 1.18 “**Marketing Authorisation**” means, with respect to a country, region or other jurisdiction in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorisations of any Regulatory Authority necessary to commercially distribute, sell, or market Product in such country or other jurisdiction, including, where applicable, (a) pre- and post-approval regulatory approvals (including any prerequisite manufacturing approval or authorisation related thereto), and (b) approval of Product labelling.
- 1.19 “**Net EAP Sales**” means the gross amount invoiced by IMPATIENS or its affiliates to non-affiliated third parties for the sale of Product less the following reasonable and customary accrual-basis deductions 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 trade discounts or rebates (including without limitation Medicaid rebates);
  - (b) amounts for claims, allowances or credits for rejections or returns;
  - (c) packaging, handling fees and prepaid 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.

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- 1.20 “**Net Sales**” means the gross amount invoiced by CELSION or its affiliates to nonaffiliated third parties, in the Field, in the Territory for the sale of Product less the following reasonable and customary accrual-basis deductions 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:
- (d) all trade discounts, or rebates (including without limitation Medicaid rebates);
  - (e) amounts for claims, allowances or credits for rejections or returns;;
  - (f) packaging, handling fees and prepaid 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 or to licensees or sales agents acting on behalf, and in the name of CELSION, or transfer to an independent non-purchasing agent/distributor of Products.

For purpose of this definition 1.21, 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 Authorisation 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 (c) 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 “**Pharmacovigilance Agreement**” or “**PhVA**” means the pharmacovigilance agreement attached as exhibit 6.
- 1.23 “**Price**” means the price of Product, established by CELSION at its sole discretion, invoiced by IMPATIENTS to third parties other than Affiliates of IMPATIENTS as specified in exhibit 4 excluding discounts, any VAT or other taxes or levies that are applicable.
- 1.24 “**Product**” means stock-keeping units (SKU)’s of a temperature-sensitive liposomal doxorubicin product, referred to as of the Effective Date, as ThermoDox<sup>®</sup>, supplied ready packed and labelled, quality tested and QP released in the Territory in accordance with applicable pharmaceutical law and regulations.
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- 1.25 “**Quality Agreement or QA** “ means the quality agreement attached as exhibit 5.
- 1.26 “**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.
- 1.27 “**Regulatory Documentation**” means all (a) applications (including all INDs and Drug Approval Applications and other regulatory filings), registrations, licenses, authorisations, 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.
- 1.28 “**Revenue**” means all cash and non-cash consideration *de facto* received by CELSION from its licensees related to the Product and/or Net Sales of the Product, in the Territory.
- 1.29 “**Specifications**” means all data necessary to manufacture the Product and contained in the most recent version of the product specification file or IMPD/IND.
- 1.30 “**Territory**” includes at the Effective Date the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the UK. and Switzerland
- 1.31 “**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.

## Article 2 – Early Access Program activities & management

### 2.1 EAP Activities.

IMPATIENTS shall exert its reasonable commercial efforts to perform EAP activities, including selling distributing, and inventory control and management of the Product in the Territory. IMPATIENTS shall use reasonable commercial efforts to identify the treatment centers in the Territory and assure that all relevant information is presented to decision makers, patients and/or responsible medical specialists, including informing decision makers and/or responsible medical specialists about their opportunities to apply for Early Access Approvals in the Territory.

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2.2 Collaborative Committees.

As soon as practical after the Effective Date, but no later than thirty (30) days, 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.

**Article 3 – Grants of rights, disclosure of know how**

3.1 CELSION Licenses.

3.1.1 CELSION hereby grants to IMPATIENTS:

- a. an exclusive, non-transferable, royalty-free right to perform EAP activities for Product in the Field in the Territory; and
- b. an exclusive non-transferable, royalty-free right of reference, under the Regulatory Approvals and any other Regulatory Documentation that CELSION or its Affiliates may Control with respect to the Products as necessary for purposes of performing EAP activities for Product in the Field in the Territory; and
- c. an exclusive, non-transferable, royalty-free right to reproduce and use the Product 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.

3.1.2 The countries in the Territory can be changed by mutual written consent between the Parties. \*\*\*\*\*

3.1.3 CELSION hereby grants IMPATIENTS a right of first negotiation to be a distributor of Product (co-promotion, co-marketing, and/or distribution) in all or part of the Territory subsequent to the Product receiving Marketing Authorisation in a country in the Territory.

THE COMPANY HAS REQUESTED AN ORDER FROM THE COMMISSION PURSUANT TO RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH “\*\*\*\*\*”

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3.2 IMPATIENTS Know How Contribution.

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

3.3 CELSION Know How Disclosure.

Immediately after the Effective Date, CELSION shall, and shall cause its Affiliates and collaborators to, without additional compensation, disclose and make available to IMPATIENTS, in whatever form IMPATIENTS may reasonably request, Regulatory Documentation, CELSION Know How, and any other Information relating, directly or indirectly, to the Product (including, but not limited to, all information related to Manufacturing), to the extent not done so already and thereafter immediately upon the availability of such Regulatory Documentation, CELSION Know How, or other Information necessary to the implementation of the EAP for the Product, or required by Applicable Law to obtain Early Access Approval and execution.

3.4 CELSION Know How Assistance.

CELSION, at its sole cost and expense, shall provide IMPATIENTS with all reasonable assistance required in order to transfer to IMPATIENTS the Regulatory Documentation, CELSION Know How, and other Information required to be produced hereunder, in each case in a timely manner, and shall reasonably assist IMPATIENTS with respect to the implementation of the EAP for the Product. Without prejudice to the generality of the foregoing, if visits of CELSION' representatives to IMPATIENTS's facilities are reasonably requested by IMPATIENTS for purposes of transferring the Regulatory Documentation, CELSION Know How, or other Information to IMPATIENTS or for purposes of IMPATIENTS acquiring expertise on the practical application of such Information or assisting on issues arising during such Exploitation, CELSION shall send, at its expense, appropriate representatives to IMPATIENTS's facilities.

#### **Article 4 - Regulatory matters**

4.1 Regulatory Activities.

4.1.1 Subject to review and input from the JSC, which will reasonably be considered, IMPATIENTS shall have the sole and exclusive right to recruit patients for 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 Products in the Territory. CELSION shall support IMPATIENTS, 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 CELSION shall provide IMPATIENTS 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 CELSION or its Affiliates, collaborators or licensees from, or filed by CELSION 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 CELSION 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 CELSION 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, with CELSION's obligation being limited to matters that involve or have an impact on the EAP.

4.1.3 CELSION shall, in accordance with the Quality Agreement, make every reasonable effort to notify IMPATIENTS 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. CELSION (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 recall, market suspension, or market withdrawal is mandated by a Regulatory Authority in the Territory, CELSION (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, CELSION (or its licensee) responsible for the recall, market suspension, or market withdrawal shall be solely responsible for the execution thereof, and IMPATIENTS shall reasonably cooperate in all such recall efforts.

#### 4.2 Regulatory Data.

Each Party shall promptly provide to the other Party copies of or access to all non-clinical data and clinical data, and other information, results, and analyses with respect to any development activities that are controlled by such Party or any of its Affiliates, collaborators or licensees (collectively, "Regulatory Data"), when and as such Regulatory Data becomes available. At the very least, CELSION shall provide IMPATIENTS with the GMP certificate of the manufacturing site, if applicable the Product's GMP certificate, the Manufacturer's manufacturing license for the Product, Product stability data and certificate of analysis, and all other Know How that IMPATIENTS is required to include, or may need to include, in its Early Access Approval applications.

#### 4.3 Pharmacovigilance.

Parties will 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.

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#### Compliance.

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

#### 4.4 Records.

4.4.1 Each of CELSION and IMPATIENTS shall, and shall ensure that its third party providers, 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. CELSION or IMPATIENTS shall retain such records, as the case may be, for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law.

4.4.2 Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of the other Party, except for files that cannot be shared due to applicable privacy regulations. The inspecting Party shall maintain such records and the information disclosed therein in accordance with the confidentiality clauses of Article 9 of this Agreement.

4.4.3 Without limiting Section 2, the JSC shall determine what reports shall be generated to track the EAP activities, including the content and timing thereof.

### **Article 5 – Exclusive distribution, supply and manufacture**

#### 5.1 Distribution.

CELSION 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 CELSION 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 all of its requirements of Product from CELSION in accordance with the terms of this Agreement.

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5.3 Product Manufacturing.

5.3.1 Manufacturing.

CELSION shall be solely 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 CELSION 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. CELSION will ensure that all relevant obligations deriving from this Agreement (including the Quality Agreement) between Parties are part of the contractual relationship between CELSION and any Manufacturer. CELSION shall provide all required documentation to IMPATIENTS related to the manufacturing for purposes of furthering the activities of the EAP.

5.3.2 Labeling

If CELSION is not able to supply the Products with the appropriate labels for the designated countries in the Territory, IMPATIENTS can accommodate the relabeling of the Product. All reasonable costs related to this relabeling will be for the account of CELSION, provided that IMPATIENTS will propose and offer market rates, to be reviewed and approved by CELSION before IMPATIENTS engages in such relabeling. IMPATIENTS will provide instructions regarding labeling in accordance with the Quality Agreement attached as exhibit 5.

5.3.3 Interruption of Supply.

If CELSION is unable to meet IMPATIENTS' requirements for Product, CELSION, without penalty, will notify IMPATIENTS and the JSC will meet as soon as possible to negotiate a possible resolution.

## **Article 6 - Supply of Product**

6.1 Notification of Requirements.

IMPATIENTS shall notify CELSION of its estimated Product requirements for \*\*\*\*\* ("Rolling Forecast"). Said estimate shall not constitute a firm commitment by IMPATIENTS.

6.2 Available Stock.

CELSION will make all reasonable commercial efforts to ensure sufficient quantities of

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Product for the following \*\*\*\*\* projected sales, based on the most recent Rolling Forecast, are in stock at the warehouse of IMPATIENTS's logistics service provider ("LSP"). The legal ownership of the stock in the warehouse of IMPATIENTS' LSP (further referred to as "Consignment Stock) shall remain with CELSION and will at no time be transferred to IMPATIENTS or the LSP. At the time of IMPATIENTS' delivery of the Product through its LSP to its clients legal ownership of the Product will directly transfer from CELSION to the relevant client of IMPATIENTS. Any costs related to the stock keeping itself (including loss and shrinkage due to error of IMPATIENTS or its service providers, but excluding shipment by CELSION to Consignment Stock) shall be at the expense of IMPATIENTS.

#### Product Shipment.

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

#### 6.3 Shipment Authorisation.

CELSION hereby authorises IMPATIENTS to order its LSP to use Product from the Consignment Stock for the fulfilling of orders from IMPATIENTS' clients without further approval from CELSION. CELSION shall make all reasonable commercial efforts to ensure that the Consignment Stock is replenished in a timely manner to comply with the stock level requirement as mentioned in clause 6.2.

#### 6.4 Invoice.

IMPATIENTS shall notify CELSION at \*\*\*\*\* of all fulfilled Product orders and Net EAP Sales of Product from the past month. CELSION shall send IMPATIENTS an invoice in Euros (€) \*\*\*\*\* and IMPATIENTS shall pay such invoice to CELSION in Euros (€) within \*\*\*\*\*.

#### 6.5 Product Pricing.

The Price of Products, established by Celsion at its sole discretion, is specified in Exhibit 4. Prices are stated excluding discounts, VAT or other taxes or levies.

### **Article 7 – Compensation to IMPATIENTS for market development**

#### 7.1.1 Royalty Obligation. For each country in which IMPATIENTS has met its contractual obligations in full, IMPATIENTS is entitled to a royalty compensation for its EAP activities that will be calculated in accordance with clause 7.1.2 or 7.1.3, whichever calculation will have the highest outcome and to be calculated in accordance with 7.1.5 and 7.1.6.

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- 7.1.2 If the Product receives Marketing Authorisation in the Field, in the Territory then CELSION, its successors and/or assigns, shall pay IMPATIENTS (or its successors and/or assigns) the following royalty: a) for all Net Sales of Product in the countries for which Marketing Authorisation in the Field is granted up to \*\*\*\*\*: a royalty of \*\*\*\*\*% of Net Sales of Product in these countries for which Marketing Authorisation is granted in the Field for a period of 10 years from the First Commercial Sale of Product in any country in the Territory. The royalty percentage will be calculated in accordance with the royalty stipulations of Exhibit 4, sub 2. b) for all Net Sales of Product in the countries for which Marketing Authorisation in the Field is granted above \*\*\*\*\*: a royalty of \*\*\*\*\* % of Net Sales of Product in these countries for which Marketing Authorisation is granted in the Field for a period of 10 years from the First Commercial Sale of Product in any country in the Territory.
- 7.1.3 If the Product receives a Marketing Authorisation in the Territory, in any field, then CELSION, its successors and/or assigns, shall pay IMPATIENTS (or its successors and/or assigns) the following royalty: a) for all Revenue of Product in the countries in any field for which Marketing Authorisation is granted up to \*\*\*\*\*: a royalty of \*\*\*\*\* % of Revenue of Product in these countries for which Marketing Authorisation is granted for a period of 10 years from the First Commercial Sale of Product in any country in the Territory. The royalty percentage will be calculated in accordance with the royalty stipulations of Exhibit 4, sub 3. b) for all Revenue of Product in the countries for which Marketing Authorisation is granted above \*\*\*\*\*: a royalty of \*\*\*\*\*% of Revenue of Product in these countries for which Marketing Authorisation is granted for a period of 10 years from the First Commercial Sale of Product in any country in the Territory.
- 7.1.4 CELSION shall not be entitled to assign, sell or dispose of its business in respect of the Product to a third party (including granting a third party the right to file for a Marketing Authorisation based on CELSION's rights and know how) unless such third party undertakes in writing to IMPATIENTS to be bound by the provisions of this Article 7 as if such third party were a party to this article 7 instead of CELSION. For the avoidance of doubt, by third party in this Article 7 is meant any person or entity that is not a Party to this agreement, including any Affiliate of CELSION.
- 7.1.5 Following Marketing Authorisation and subsequent First Commercial Sale of Product in the Territory, Product Net Sales and Revenues shall be reported, and royalties based on such Net Sales or Net Revenues shall be calculated within \*\*\*\*\*. The highest outcome of the royalty calculations as referred to in this clause 7 shall be paid to IMPATIENTS within \*\*\*\*\*.
- 7.1.6 At the end of \*\*\*\*\* period dictated in 7.1.5, IMPATIENTS shall be obligated to choose one royalty compensation clause, either 7.1.2 or 7.1.3, at its discretion, to be used to calculate the remainder of the royalty term. CELSION, its Affiliates, licensees, successors and/or assigns shall maintain accurate records of Product sales for a period of \*\*\*\*\*. Such records may be audited for accuracy once a year by an independent public accounting firm, acceptable to both parties, which would be allowed reasonable access at reasonable times to review such records.

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## Article 8 - Warranties, liability and indemnity

### 8.1 Mutual Representations and Warranties.

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

#### 8.1.1 Organisation.

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

#### 8.1.2 Authorisation.

The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorised by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, articles of association or other organisational documents, (b) in 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.

#### 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 fulfilment of its obligations hereunder.

### 8.2 Product Warranty.

CELSION warrants that Product supplied to IMPATIENTS 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 12 months of the Product's registered shelf life remaining.

### 8.3 Product Liability.

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

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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 CELSION 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.

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.

**Article 9 - Confidentiality**

9.1 The Parties will continue to abide by the confidentiality agreement signed by both Parties dated 26 August 2014. The terms of confidentiality respecting Information shall not impede the appropriate use thereof in IMPATIENS's submission of Information in Early Access Approvals applications with Regulatory Authorities, or in execution of the EAP of Product according to the EAP Plan.

CELSION acknowledges that the EAP Plan involves the publication of safety and efficacy information relating to the Product, including CELSION 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, CELSION hereby consents to IMPATIENS publishing such CELSION's Confidential Information only in accordance with Applicable Laws as required.

**Article 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 5 (five) years and will automatically be renewed for consecutive periods of 2 years, unless one of the Parties gives written notice not to extend at least 3 months before the contract is to be renewed.

10.2 Subject to 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 Each Party may terminate this Agreement for convenience, provided the non-terminating Party is provided with 6 (six) months written notification (or 2 (two) months as set forth in Section 2.3 of Exhibit 2).

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10.4 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 120 days by written notification by the other Party of said breach.

10.5 Consequences of Termination.

10.5.1 CELSION will allow IMPATIENTS to continue to distribute and sell the Product until such time that the entire quantity of the Consignment Stock has been sold provided there are no breaches of material obligations by IMPATIENTS under this Agreement.

10.5.2 Upon termination of this Agreement pursuant to Clause 10.1 or by IMPATIENTS pursuant to Clause 10.4, Clause 7 shall survive such termination and the royalty rate shall be the percentage as specified.

10.5.3 Upon termination of this Agreement pursuant to Clause 10.3 by CELSION, the royalty obligation of clause 7.1.1 to 7.1.3 will be replaced with the following royalty obligation:

Royalty Obligation. IMPATIENTS is entitled to a royalty compensation for its EAP activities that will be calculated in accordance with clause 10.5.3.1. or 10.5.3.2. whichever calculation will have the highest outcome and to be calculated in accordance with 7.1.5 and 7.1.6.

10.5.3.1 If the Product receives Marketing Authorisation in the Field, in the Territory, then CELSION, its successors and/or assigns, shall pay IMPATIENTS (or its successors and/or assigns) the following royalty:

a) for all Net Sales up to \*\*\*\*\*, in the countries for which Marketing Authorisation in the Field is granted: a royalty of \*\*\*\*\*% of Net Sales of Product in the Field in these countries for a period of 10 years from the First Commercial Sale of such Product in the Field in any country in the Territory.

b) for all Net Sales above \*\*\*\*\*, in the countries for which Marketing Authorisation in the Field is granted: a royalty of \*\*\*\*\*% of Net Sales of Product in the Field in these countries for a period of 10 years from the First Commercial Sales of Product in the Field in any country in the Territory.

10.5.3.2. If the Product receives a Marketing Authorisation in the Territory, in any field, then CELSION, its successors and/or assigns, shall pay IMPATIENTS (or its successors and/or assigns) the following royalty:

a) for all Revenue of Product up to \*\*\*\*\*, in the countries for which Marketing Authorisation is granted: a royalty of \*\*\*\*\* % of Revenue of Product in these countries for which Marketing Authorisation is granted for a period of 10 years from the first Commercial Sale of Product in any country in the Territory.

b) for all Revenue of Product, above \*\*\*\*\*, in the countries which Marketing Authorisation is granted, a royalty of \*\*\*\*\* % of Revenue of Product in these countries for which Marketing Authorisation is granted for 10 years from the first Commercial Sale of Product of such Product in any country in the Territory.

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- 10.5.4 At the end of \*\*\*\*\* period dictated in 7.1.5, IMPATIENTS shall be obligated to choose one royalty compensation clause, either 10.5.3.1 or 10.5.3.2, at its discretion, to be used to calculate the remainder of the royalty term. CELSION, its Affiliates, licensees, successors and/or assigns shall maintain accurate records of Product sales for a period of \*\*\*\*\*. Such records may be audited for accuracy once a year by an independent public accounting firm, acceptable to both parties, which would be allowed reasonable access at reasonable times to review such records.
- 10.5.5 Notwithstanding Clause 10.6, upon termination of this Agreement by IMPATIENTS pursuant to Clause 10.3 or by CELSION pursuant to Clause 10.4, Clause 7 shall not be applicable.

10.6 Survival.

Subject to the terms of this article 10, Article 1, Clause 4.4.1, and Articles 7-11 shall survive termination of this Agreement.

**Article 11 – Miscellaneous**

11.1 Entire Agreement.

This Agreement, together with the Confidentiality Agreement dated 26 August 2014 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 publish the existence of this Agreement, provided that the other Party shall have an opportunity to review press releases for at least five (5) working 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 Mediation Clause.

All disputes arising in connection with the present Agreement, or further contracts resulting therefrom, shall be settled by binding arbitration in accordance with the Arbitration Rules of the Netherlands Arbitration Institute. The arbitral tribunal shall be composed of three arbitrators. Each Party shall select an arbitrator of its choice, with a third arbitrator selected by the two arbitrators chosen by the Parties. The place of arbitration shall be Amsterdam and the procedure shall be conducted in the English language.

11.8 Choice of Law.

This Agreement shall be governed by and interpreted under the laws of The Netherlands.

11.9 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.

11.10 Assignment; Assumption.

Subject to 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.

11.11 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.

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11.12 Severability.

If any provision of this Agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, 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. Should any provision of this Agreement conflict with applicable legislation, then such provision shall be modified by the Parties in order to comply with said legislation. This modification shall not affect the other provisions of this Agreement.

11.13 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 CELSION:**

Celsion Corporation:  
Attn: Michael H. Tardugno  
Chairman, President, CEO  
997 Lenox Drive, Suite 100  
Lawrenceville, New Jersey, 08648  
U.S.A.  
Email: mtardugno@celsion.com

**For IMPATIENTS:**

Impatients N.V.:  
Attn.: Govert Schouten  
Pilotenstraat 45  
1059 CH  
Amsterdam  
The Netherlands  
Email: \*\*\*\*\*

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11.14 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 CELSION:**

**For IMPATIENTS:**

/s/ Michael H. Tardugno

/s/ Ronald H.P. Brus

Michael H. Tardugo

Ronald H.P. Brus

Chairman, President, CEO

CEO

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**Exhibit 1 – EAP Plan**

**LTLD (Lyso-Thermosensitive Liposomal Doxorubicin) EAP Execution Plan Version 1.0 9<sup>th</sup> March 2015**

\*\*\*\*\*

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## 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 a \*\*\*\*\*. The roles for the JSC chairperson and secretary shall rotate every year.

#### 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 every six (6) months in year one and annually thereafter) review and serve as a forum for discussing the EAP, and review and approve amendments thereto;
- (b) oversee the conduct of EAP activities;
- (c) establish any discounts regarding third parties
- (d) serve as a forum for discussing and coordinating strategies for obtaining Early Access Approvals and Regulatory Approvals for the Product in the Territory;
- (e) 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
- (f) 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.
- (g) either Party may request a meeting of the JSC at any time, which will be held in a timely fashion.

#### 1.3 Disbandment.

Upon Marketing Authorisation of the Product in Germany, United Kingdom, France, Spain and Italy, 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. Additionally, in the event of a Change of Control of CELSION, IMPATIENTS shall have the right at any time and for any reason, effective upon written notice, to disband the JSC.

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1.4 Subcommittees.

From time to time, the JSC may establish and delegate duties to sub-committees or directed teams (“Subcommittee(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.

2 General Provisions Applicable to committees.

2.1 Meetings and Minutes.

The committees shall meet quarterly, or in each case as otherwise agreed to by the Parties, with the location of such meetings alternating between locations designated by CELSION 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. If the senior officers are not able to agree on the resolution of any such issue within thirty (30) days after such issue was first referred to them, then, such dispute shall be finally and definitively resolved by: (a) the senior officer of IMPATIENTS to the extent the Dispute relates to the performance of the EAP (other than any matter requiring amendment of the Agreement which shall require mutual agreement of the Parties) and (b) by the senior officer of CELSION for all other disputes. In the event of (a), CELSION shall have the right to terminate this Agreement for convenience if it provides IMPATIENTS with two (2) months' written notification during the thirty (30) day period following Celsion's receipt of notice of IMPATIENTS' final and definitive resolution. In the event of (b), IMPATIENTS shall have the right to terminate this Agreement for convenience if it provides CELSION with two (2) months' written notification during the thirty (30) period following IMPATIENTS' receipt of notice of Celsion's final and definitive resolution.

### 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.

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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) CELSION providing to IMPATIENTS written notice of its intention to disband and no longer participate in such committee, *provided* that CELSION shall not give such written notice prior to Early Access Approvals in the Major Markets of the Territory. Notwithstanding anything herein to the contrary, once CELSION has provided such written notice, such committee shall be terminated and shall have no further rights or obligations under this Agreement, and thereafter any requirement of CELSION to provide Information or other materials to such committee shall be deemed a requirement to provide such Information or other materials to IMPATIENTS and IMPATIENTS shall have the right to solely decide, without consultation with CELSION, all matters that are subject to the review or approval by such committee hereunder.

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.

1.1. IMPATIENTS acknowledges CELSION's exclusive right, title, and interest in and to the Product Trademark ThermoDox and acknowledges that (i) neither this Agreement, nor its use of the Product Trademarks hereunder, shall be construed to accord to 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 CELSION.

1.2. Should it be necessary to record IMPATIENTS as a registered licensee of the Product Trademarks in any jurisdiction, CELSION shall do so at IMPATIENTS's expense, and IMPATIENTS will cooperate with CELSION 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 3.

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 CELSION or otherwise related to CELSION.

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 CELSION and to cooperate fully, at CELSION's expense, in the enforcement of CELSION's rights against such a third party. Nothing contained in this Section shall be construed as to require CELSION to enforce any rights against a third party or to restrict CELSION'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**

1. Product Price to be invoiced by IMPATIENTS to third parties excluding VAT:

Price: \*\*\*\*\*.

Price is established by CELSION, at its sole discretion, and may be changed by Celsion.

2. The royalty referred to in clause 7.1.2 shall be calculated as follows:

\*\*\*\*\*

3. The royalty referred to in clause 7.1.3 shall be calculated as follows:

\*\*\*\*\*

THE COMPANY HAS REQUESTED AN ORDER FROM THE COMMISSION PURSUANT TO RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*".

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## Exhibit 5 - Quality Agreement

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THE COMPANY HAS REQUESTED AN ORDER FROM THE COMMISSION PURSUANT TO RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*".

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## Exhibit 6 - Pharmacovigilance Agreement

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THE COMPANY HAS REQUESTED AN ORDER FROM THE COMMISSION PURSUANT TO RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*".

**CELSION CORPORATION  
CERTIFICATION**

I, Michael H. Tardugno, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Celsion Corporation; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

June 19, 2015

**Celsion Corporation**

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By: /s/ Michael H. Tardugno

Michael H. Tardugno  
Chairman, President and  
Chief Executive Officer  
(Principal Executive Officer)

**CELSION CORPORATION  
CERTIFICATION**

I, Jeffrey W. Church, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Celsion Corporation; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

June 19, 2015

**Celsion Corporation**

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By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and  
Chief Financial Officer  
(Principal Financial Officer)