## INTELLECTUAL PROPERTY ASSIGNMENT AND TECHNOLOGY TRANSFER AGREEMENT

This Intellectual Property Assignment and Technology Transfer Agreement (the "Agreement") is made and entered into in Montreal, Quebec, as of June 19, 2015 (the "Effective Date").

#### BETWEEN:

POLYVALOR, LIMITED PARTNERSHIP, a limited partnership duly constituted under the laws of Quebec, having its principal place of business at 3535 Queen Mary Road, Suite 220, Montreal (Quebec) H3V 1H8, acting through its general partner GESTION UNIVALOR, LIMITED PARTNERSHIP, a limited partnership duly constituted and having its principal place of business at the same address, itself acting through its general partner UNIVALOR INC., a corporation duly constituted and having its head office at the same address, represented herein by Jacques Simoneau, President and Chief Executive Officer, duly authorized for the purposes hereof, as he so declares;

(hereinafter referred to as "Polyvalor")

#### AND:

ORTHO REGENERATIVE TECHNOLOGIES INC., a corporation duly constituted under the *Canada Business Corporations Act*, RSC (1985) c. C-44, having its headquarters at 16667 Hymus Boulevard, Kirkland (Quebec), H9H 4R9, represented by Steve Saviuk, President, duly authorized for the purposes hereof, as he so declares;

(hereinafter referred to as "Ortho RTI")

(hereinafter referred to individually as the "Party" and, collectively, as the "Parties")

#### AND IN WHICH INTERVENES:

duly authorized for the purposes hereof, as he so declares;

(hereinafter referred to as "Polytechnique")

#### PREAMBLE

WHEREAS Polyvalor is, or will become, the owner of the Assigned Intellectual Property (as defined below) relating to the Technologies (as defined below) that have been, and continue to be, developed by and under the direction of the Researchers (as defined below);

WHEREAS Ortho RTI currently seeks to develop and commercialize a range of products, processes and services in the areas of "Polymer Devices (in the FDA sense of Device — that excludes Drug Delivery and Nucleic Acid Delivery Products) for Orthopaedic Tissue Repair (Meniscus, Cartilage, Bone, Ligaments) and intra-articular injections of platelet-rich plasma chitosan formulations"; and

WHEREAS Polyvalor wishes to sell, assign and transfer all rights, titles and interests it owns, or will own, in and to the Assigned Intellectual Property (as defined below) relating to the Technologies, to Ortho RTI, and Ortho RTI wishes to acquire from Polyvalor all rights, titles and interests in and to such Assigned Intellectual Property, pursuant to the terms and conditions set out in this Agreement.

## NOW THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

#### 1. DEFINITIONS

In the present Agreement as well as all other documents which reference or relate to this Agreement, unless the context provides otherwise, the words, terms and expressions shall have the following meanings:

- "Affiliate" shall mean any enterprise Controlled by another Person, or Controlling another Person. Shall also be considered an "Affiliate", any "related person" to another Person, pursuant to the meaning of "related person" in subsection 251(2) of the *Income Tax Act* (Canada);
- 1.2 "Agreement" shall mean the Agreement and its Appendices;
- "Assigned Intellectual Property" shall mean the Intellectual Property relating to the Technologies, namely the Patents, the Technical Data and the New R&D IP, except the Excluded Assets;
- 1.4 "Commercial Exploitation" shall mean the manufacturing, marketing, promotion, distribution and sale of the Products, Processes and Services in the Territory;
- 1.5 "Confidential Information" shall have the meaning given to that term in Section 7.1 hereof:
- 1.6 "Control" shall mean, for the purposes of this Agreement, the control or possession by a Person, directly or indirectly, of more than fifty percent (50 %) of the equity share capital of a legal entity having the right to vote to elect a majority of directors of the legal entity concerned;

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"Current Patents" shall mean the patent applications described in Appendix A hereof, as well as any other patent applications related to those patent applications which may be filed around the world and any patent that is issued in connection with the aforementioned applications, including any requests for reissues, continuation applications, continuation-in-part applications, divisional applications, supplementary applications, extension requests, re-examination requests, reinstatement requests, reissues or any other combination of the above that may arise;

- 1.8 "Excluded Assets" shall mean the excluded assets listed in Appendix D hereof;
- 1.9 "Fair Market Value" shall mean the amount that a Person who is under no obligation to buy would pay to a Person who is under no obligation to sell when those two Persons are dealing at arm's length;
- 1.10 "Fiscal Year" shall mean any financial year of Ortho RTI ending on June 30 of each year;
- 1.11 "Gross Sales" shall mean any and all revenues or compensation received by Ortho RTI or its Affiliates from the Commercial Exploitation, whether paid in legal tender or in any other form of benefit, advantage or concession, including but not limited to (i) all invoice price actually received for Products, Processes or Services sold by Ortho RTI or its Affiliates, (ii) any consideration including equity share capital and revenues received by Ortho RTI or its Affiliates in relation with the assignment of this Agreement or Ortho RTI's rights hereunder, (iii) any income received by Ortho RTI or its Affiliates under or in consideration of any license(s) granted for the Commercial Exploitation and includes but is not limited to initial license fees, milestone payments, minimum royalties, royalties on the Commercial Exploitation, and (iv) any consideration received by Ortho RTI or its Affiliates for the assignment of the Assigned Intellectual Property (or any part thereof). If compensation is received in a form other than legal tender, the Gross Sales will be deemed to be equivalent to the Fair Market Value in legal tender of such benefit, advantage or concession. In the event that Ortho RTI transacts with an Affiliate or a Person which is not at arm's length, the Gross Sales related to that transaction must be, at a minimum, equivalent to the Fair Market Value and if they are not, will be deemed to be equivalent to the Fair Market Value.
- 1.12 "Knowledge" means to the best knowledge of Polytechnique and Polyvalor as of the Effective Date, after having conducted a reasonable verification with the Researchers, who are the persons having the best knowledge of the Assigned Intellectual Property;
- 1.13 "Instalment Payments" shall have the meaning given to that term in Section 3,1.7;
- "Intellectual Property" means any and all intellectual property, whether or not patentable or otherwise protectable under any intellectual property legislation, including without limitation, works, inventions (whether patentable or not), discoveries, scientific formulae, data, information, reports, records of experiments, works, results, analysis, research tools, software, models, research and development information, technical information, prototypes, specifications, patterns, drawings, algorithms, products, compositions, processes and protocols, methods, tests, devices, computer programs, and bacterial, viral, plant, human, or animal material that has new genetic or other characteristics, and includes any and all related rights, patents, patent rights, patent applications, trademarks and copyrights;

"Inventors" shall mean for Technology 1: Wei Ouyang, Anik Chevrier, Marc Lavertu and Michael D. Buschmann and Caroline D. Hoemann; for Technology 2: Wei Ouyang, Anik Chevrier and Michael D. Buschmann; for Technology 3: Caroline D. Hoemann, Michael D. Buschmann and Daniel Veilleux; for Technology 4: Anik Chevrier, Michael D. Buschmann, Daniel Veilleux, Marc Lavertu and Caroline D. Hoemann, who are, or were, at the time of filing the Current Patents, employees of, or students enrolled at, Polytechnique;

- 1.16 "Laboratory Notes" shall have the meaning given to that term in Section 2.5;
- "Net Sales" shall mean the Gross Sales less applicable sales, transfer or excise taxes (including any tax such as value added or similar tax or governmental charge), commissions to representatives, agents or distributors, credits, rebates, discounts and retroactive price adjustments and refunds to customers for returns of Product, Process or Service (the "Deductible Amounts"), provided however that such Deductible Amounts shall not exceed amounts usually acceptable for a company in the same or a similar field of activities and at the same stage of development as Ortho RTI;
- "New Patents" shall mean all future patent applications covering, describing or claiming the New R&D IP, as well as any other patent applications related to those patent applications which may be filed around the world and any patent that is issued in connection with the aforementioned applications, including any requests for reissues, continuation applications, continuation-in-part applications, divisional applications, supplementary applications, extension requests, re-examination requests, reinstatement requests, reissues or any other combination of the above that may arise;
- "New R&D IP" shall mean any Intellectual Property in any form whatsoever, whether of a commercial nature or not related to the Technologies, created, invented or developed by, or under the direction of, the Researchers during the term of the R&D Agreements in conducting or completing the research projects described in the R&D Agreements. The New R&D IP shall include the New Technical Data;
- 1.20 "New Technical Data" shall mean the New Technical Data listed in Appendix C hereof that the Researchers plan to, or will, develop during the term of, and in accordance with, the R&D Agreements;
- 1.21 "Patents" shall mean the Current Patents and the New Patents;
- 1.22 "Person" shall mean, inter alia, an individual, a business, a corporation, a company, a partnership, an association, a consortium, a trust, a municipality, a city, a joint venture, a government, an organisation, an office or commission of the government or regulatory body as well as any other entity;
- 1.23 "Probationary Period" shall mean the period commencing on the Effective Date and ending when Ortho RTI: (i) will have completed the financing stipulated in Sections 5.1 and 5.3 in the time constraints of Round 1 and Round 2, respectively, (ii) will have paid the total amounts stipulated in paragraphs 3.1.1 to 3.1.4, inclusively, (iii) will have issued the shares to Polyvalor as stipulated in paragraph 3.1.5, and (iv) will have paid

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- Polytechnique the total amount arising from the R&D Agreements as stipulated in paragraph 3.1.7;
- 1.24 "Process" shall mean any method, or any process of production or manufacture (i) incorporating, prepared with, developed with, using or covered by all, or substantial part, of the Technical Data and/or the New R&D IP, or (ii) the incorporation, preparation, use, selling, making or development of which would infringe a claim of a Patent;"
- 1.25 "Products" shall mean any substance, mixture, material, seed or other product, including chemical and biological products (i) using, embodying, prepared with, manufactured with, developed with, covered by or exploiting, in whole or in substantial part, the Technical Data and/or the New R&D IP, or (ii) the using, incorporation, preparation, manufacturing, development, selling or making of which would infringe a claim of a Patent;"
- 1.26 "R&D Agreements" shall mean the R&D Agreements between Ortho RTI and Polytechnique specified in paragraph 3.1.7 and the research and development activities described in the MD-60 Study specified in paragraph 3.1.3;
- 1.27 "Researchers" shall mean Michael D. Buschmann and Caroline D. Hoemann, who are Polytechnique's employees subject to the *Policy Regarding Technological Intellectual Property* dated September 23, 2010 attached hereto as Appendix H;
- 1.28 "Round 1" shall mean October 31", 2015;
- 1.29 "Round 2" shall mean March 31"; 2016;
- 1,30 "Semester" shall mean a period of six (6) months calculated from Round 2;
- 1.31 "Services" shall mean all services embodying, prepared with, rendered with, using or covered, by the Patents, the Technical Data and/or the New R&D IP;
- 1.32 "Shareholders Agreement" shall mean the shareholders agreement executed by Polyvalor on the Effective Date of this Agreement with Ortho RTI as an intervening party;
- 1.33 "Technical Data" shall mean the technical data and protocols for manufacturing methods as described in Appendix B attached hereto and developed by the Researchers prior and up to the Effective Date of this Agreement;
- 1.34 "Technologies" shall mean collectively:
  - 1.34.1 the technology entitled DIV-372/VAL-780: Homogeneous blood/chitosan implant prepared by novel formation of physiological chitosan-NaCl solution/blood mixtures for tissue repair (the "Technology 1"),
  - 1.34.2 the technology entitled DIV-402/VAL-782: Clot-activated polymer composition for repairing tissue of subject, where the polymer composition adheres to the tissue and promotes cell proliferation, comprises platelet-rich plasma (PRP), a chitosan, a salt and a clot activator (Formulation de chitosane combiné à du PRP) (the "Technology 2"),

- the technology entitled DIV-518/VAL-1058: Freeze-dried chitosan scaffolds that spontaneously form a hydrated micro-particle dispersion after contact with blood or blood-derived fluids and stimulate anabolic wound repair processes including angiogenesis, cell chemotaxis, tissue remodeling, and viscoelastic articular repair cartilage matrix deposition (the "Technology 3"), and
- 1.34.4 the technology entitled DIV-517/VAL-1139: Freeze-dried Polymer Compositions for Mixing with Platelet Rich Plasma and Whole Blood to Form Implants for Tissue Repair or Compositions for Therapeutic Intra-articular Injections (the "Technology 4");
- 1.35 "Territory" means worldwide.

#### ASSIGNMENT

- 2.1 In consideration of Ortho RTP's commitment to meet the terms and conditions set forth in this Agreement, Polyvalor hereby assigns and transfers, and agrees to assign and transfer, to Ortho RTI all of its rights, titles and interests in and on:
- 2.1.1 the Current Patents and the Technical Data, which assignment is effective as of the Effective Date; and
- 2.1.2 the New R&D IP and the New Patents, which assignment is effective upon the creation, development or conception of the New R&D IP.
- 2.2 The Parties agree and acknowledge that the Excluded Assets are not being assigned to, and acquired by, Ortho RTI under this Agreement.
- 2.3 Effective upon the occurrence of the assignment described in Section 2.1, Ortho RTI hereby grants to Polytechnique and the Researchers a free and perpetual non-exclusive, non-commercial, non-sub-licensable, irrevocable, non-assignable license to use the Assigned Intellectual Property, including the Laboratory Notes, for purposes of research and teaching only, but not for any commercial use whatsoever.
- 2.4 During the Probationary Period, Ortho RTI may not assign, transfer, mortgage, pledge, self or otherwise dispose of the Assigned Intellectual Property, without the prior written consent of Polyvalor, who will have discretion to refuse or accept such a request. Notwithstanding the foregoing, the Parties agree that Ortho RTI may pledge, hypothecate or grant a security interest on the Assigned Intellectual Property in favor of a lender or creditor in any financing or secured transaction, provided that (i) Ortho RTI obtains Polyvalor's written consent which will not be unreasonably withheld prior to such transaction, and (ii) Polyvalor intervenes in the agreement between Ortho RTI and the lender or creditor granting to such lender or creditor the pledge, hypothec or security interest on the Assigned Intellectual Property, which agreement shall address the assignment back in favour of Polyvalor of the Assigned Intellectual Property as set forth in Section 6.2 of this Agreement at Polyvalor's satisfaction.

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2.5 During the Probationary Period, Ortho RTI may grant licenses or any other rights to a Person in, or on, the Assigned Intellectual Property, provided that for any license, at least thirty (30) days prior to the execution of the license agreement, Ortho RTI forwards to Polyvalor a draft copy of the license agreement for Polyvalor's consideration and approval within thirty (30) days from notice, otherwise it will be deemed to have been approved. Such license shall not be inconsistent with the terms of this Agreement and, to the extent reasonably feasible or applicable, it shall include a provision stating that the license may be succeeded directly by Polyvalor. In no event, shall Polyvalor be under any obligation to take-over a license which was not approved by Polyvalor in compliance with this Section 2.4.

2.6 Ortho RTI agrees that, during the term of the R&D Agreements and thereafter, all notes and all laboratory notebooks that constitute the documented Assigned Intellectual Property (the "Laboratory Notes") may be used by Polytechnique and/or the Researchers and Inventors, respectively, in accordance with Section 2.3. Ortho RTI, at its sole discretion as acquirer and legal owner of such Assigned Intellectual Property and Laboratory Notes as of the Effective Date and thereafter, may have access to the Laboratory Notes for on-site consultation or make copies thereof, upon reasonable notice and acting in a reasonable manner. Polytechnique and/or the Researchers and Inventors will cooperate and provide reasonable assistance to Ortho RTI, at Ortho RTI's costs.

#### 3. CONSIDERATION

- 3.1. This assignment is conveyed in consideration of:
  - 3.1.1 The payment(i) of a non-refundable fee of One Hundred Fifty Thousand Dollars (\$ 150,000.00) plus applicable taxes payable by Ortho RTI to Polyvalor on the Effective Date, (ii) of a non-refundable fee of Thirty-Five Thousand Dollars (\$ 35,000.00) plus applicable taxes payable by Ortho RTI to Polyvalor on October 31st, 2015 and (iii) of a non-refundable fee of Thirty-Six Thousand Four Hundred Ten Dollars and Twenty-Eight Cents (\$ 36,410.28) plus applicable taxes payable by Ortho RTI to Polyvalor on October 31st, 2016;
  - 3.1.2. The payment, on the Effective Date, of a non-refundable fee of Eight Thousand Dollars (\$ 8,000.00) plus applicable taxes payable by Ortho RTI to Polyvaior for reimbursement of the prosecution fees of the Patents related to the Technology 2;
  - 3.1.3. The payment by Ortho RTI to Polytechnique, on the Effective Date, of a non-refundable amount of One Hundred Eighteen Thousand Three Hundred Sixty Seven Dollars Twenty Cents (\$ 118,367.20) for the activities conducted during the study entitled "MD-60 · Meniscus repair with chitosan-PRP implants: Pilot study in a sheep model" (the "MD-60 Study"), which report is included in Appendix E attached hereto, as well as the work conducted by Caroline Hoemann's team in the context of the patents related to Technologies 3 and 4;
  - 3.1.4. The payment of a non-refundable fee of One Hundred Thousand Dollars (\$ 100,000.00) plus applicable taxes payable by Ortho RTI to Polytechnique, on or before October 31st, 2015;

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- 3.1.5. The payment by Ortho RTI to Polyvalor, on the Effective Date, of a non-refundable amount of Seventy-Five Thousand Seven Hundred Fifty-Seven Dollars Fifty-Six Cents (\$75 757,56) plus applicable taxes;
- 3.1.6. The issuance, on the Effective Date, by Ortho RTI to Polyvalor of Eight Hundred Thirty-Three Thousand Three Hundred Thirty-Four (833,334) fully paid and non-assessable common shares of Ortho RTI's capital stock equal to a six point seven percent (6,7%) equity stake of Ortho RTI's capital stock calculated on a fully diluted basis and at a value of CND\$ 0.0909 per share, for an aggregate value for the subscription being established at Seventy-Five Thousand Seven Hundred Fifty-Seven Dollars Fifty-Six Cents (\$75,757.56), which amount shall be payable by cheque by Polyvalor to Ortho RTI within a delay of fourteen (14) days following the Effective Date of this Agreement;
- 3.1.7. The execution of three R&D agreements by Ortho RTI and Polytechnique, on or before the Effective Date, for a financing totaling a non-refundable amount of Two Million One Hundred Thousand Dollars (\$ 2.1M), which includes the general expenses of Polytechnique up to a maximum of forty percent (40 %) of Polytechnique's direct expenses that are distributed as follows:
  - (a) A first R&D agreement for a non-refundable amount of Six Hundred Thirty Thousand Dollars (\$ 630,000,00) will be devoted to the development of Technology 3, under the general direction of Professor Caroline D. Hoemann (the "Caroline's R&D Agreement"), over a period of three (3) years, and it will include thirty-six (36) monthly installments of Seventeen Thousand Five Hundred Dollars (\$ 17,500.00), whereby Ortho RTI shall, on the Effective Date, (i) pay to Polytechnique the first instalment and (ii) provide to Polytechnique two post-dated cheques for the second and third instalments.

Caroline's R&D Agreement will be the subject of a detailed business plan, a Gantt chart, a schedule of specific deliverables, progress reports every 4 months and a detailed budget;

- (b) A second R&D agreement for a non-refundable amount of Eight Hundred Forty Thousand Dollars (\$ 840,000.00) will be devoted to the execution of the Project entitled "Development of freeze-dried chitosan products for injectable knee treatments", under the general direction of Professor Michael D. Buschmann, over a period of three (3) years, and it will include thirty-six (36) monthly installments of Twenty three Thousand and Three Hundred Thirty-Three Dollars and Thirty-Three Cents (\$ 23,333.33), whereby Ortho RTI shall, on the Effective Date, (i) pay to Polytechnique the first instalment and (ii) provide to Polytechnique two post-dated cheques for the second and third instalments.
- (c) A third R&D agreement for a non-refundable amount of Six Hundred Thirty Thousand Dollars (\$ 630,000.00) will be devoted to the execution of the Project entitled "Development of freeze-dried chitosan products for shoulder treatments", under the general direction of Professor Michael D. Buschmann, over a period of three (3) years, and it will include thirty-six (36) monthly installments of Seventeen Thousand Five Hundred Dollars (\$ 17,500.00), whereby Ortho RTI shall, on the

Effective Date, (i) pay to Polytechnique the first instalment and (ii) provide to Polytechnique two post-dated cheques for the second and third instalments.

The second R&D Agreement and third R&D Agreement described in paragraphs 3.1.7(b) and (c) are collectively referred to as the "Michael's R&D Agreements".

Michael's R&D Agreements will be the subject of a detailed business plan, a Gantt chart, a schedule of specific deliverables (including manufacturing procedures), progress reports every 4 months and a detailed budget.

Caroline's R&D Agreement and Michael's R&D Agreements are collectively, the "R&D Agreements".

- 3.1.8.Non-refundable payments by Ortho RTI to Polyvalor equal to one and a half percent (1.5 %) of Net Sales (hereinafter referred to as the "Instalment Payments").
- 3.2. For clarity purposes, all federal and provincial sales taxes applicable in respect of the transactions contemplated in this Agreement, including relating to the issuance of shares to Polyvalor, will be payable by Ortho RTI in addition to any consideration due to Polyvalor and/or Polytechnique under this Agreement.

#### 4. PAYMENT, REPORTS AND RECORDS

- 4.1 Within thirty (30) days following the end of each Semester, Ortho RTI will directly pay to Polyvalor the Instalment Payments received during the previous Semester and will provide Polyvalor with a concise written report indicating (i) the number of Products and Processes sold and the Services rendered during the previous Semester, (ii) the total Gross Sales and Net Sales made during the previous Semester, (iii) the Deductible Amounts, (iv) the date, price, type and currency of each of the corresponding Gross Sales made during the Semester in question, and (v) the details of the licenses or other rights granted, if applicable, during the previous Semester. If no Gross Sale is received during a given Semester, a written report must nevertheless be provided to Polyvalor on the date provided for its confirmation.
- 4.2 No later than ninety (90) days after the end of Ortho RTI's Fiscal Year, Ortho RTI will produce and deliver to Polyvalor a concise written report indicating (i) the number of Products and Processes sold and the Services rendered during the previous year, (ii) the total Gross Sales and Net Sales made during the previous year, (iii) the Deductible Amounts, (iv) the date, price, type and currency of each of the corresponding Gross Sales made during the previous year, and (v) the details of the licenses or other rights granted, if applicable, during the previous year.
- In the event that Ortho RTI fails to perform any of the payments provided in this Agreement, due to any reason whatsoever, compound interest at an annual rate of twelve percent (12 %) will be applied on any unpaid balance at the end of each month.
- In order to facilitate the calculation of the Instalment Payments and the verifications provided in this Agreement, Ortho RTI undertakes to keep and to instruct any licensee, Affiliate or beneficiary to conserve, if applicable, all files, documents, books, reports,

records and information reasonably required by Polyvalor relating to such payments (the "Documentation"), and undertakes to preserve and make the Documentation available to Polyvalor for a period of seven (7) years following the production of any report relying on the data they contain, and of any payment based on such data. During this period, the Documentation shall be made available for review and copying at reasonable times during regular business hours, subject to a ten (10) day prior written notice by Polyvalor and subject to any reasonable confidentiality obligations of Ortho RTI. Polyvalor may appoint any reasonably qualified representative of its choice to review and make copies of the Documentation, in order to ensure the accuracy of the calculation of the Instalment Payments paid or owed by Ortho RTI to Polyvalor. This verification by such representative will be conducted at the expense of Polyvalor unless errors, with the exception of good faith errors of Ortho RTI, representing a difference of more than ten percent (10 %) between the amount paid and the amount owed by Ortho RTI, are demonstrated after such verification. In that case, Ortho RTI will be liable for all reasonable expenses incurred in connection with the inspection and verification, and will reimburse Polyvalor within thirty (30) days of submission of the invoices. Ortho RTI undertakes to cover any payment shortfall upon receipt of the verification report.

4.5 The Instalment Payments and other amounts payable pursuant to this Agreement must be made in lawful money of Canada. Currency exchange rates, if any, will be determined on the day of payment. However, in the event that a payment remains due after its due date, the conversion to Canadian currency will be done at the most advantageous rate for Polyvalor during the period between the due date of the payment and the date the payment is made.

## 5. MILESTONES OF DILIGENCE AND DEVELOPMENT

- 5.1. Ortho RTI agrees that it will have secured a first round of financing of Seven Hundred and Forty Thousand Dollars (\$ 740,000.00), as of the Effective Date, which will consist of Five Hundred Thousand Dollars (\$ 500,000.00) in equity (44% share) and Two Hundred and Forty Thousand Dollars (\$ 240,000.00) credit line which can be drawn on an "as needed basis". Any amount outstanding on such credit line will bear interest at 8% per annum and will be repayable by Ortho RTI pursuant to the terms and conditions of the Repayment Agreement entered into between Ortho RTI and the lender, namely Manitex Capital Inc., concurrently with this Agreement.
- 5.2. Ortho RTI must obtain and conclude cumulative rounds of financing for a minimum amount of One Million and Five Hundred Thousand Dollars (\$ 1,500,000) (which amount shall include the financing of \$ 500,000.00 and, if disbursed, the amount of \$240,000.00 contemplated in Section 5.1) no later than Round 1, which amount will be used to meet the obligations described in paragraphs 3.1.1 to 3.1.7 herein and to further develop the Technologies, in accordance with the terms and conditions of the R&D Agreements.
- 5.3. Ortho RTI must obtain and conclude cumulative rounds of financing, no later than Round 2, for a minimum amount of Two Million Six Hundred Thousand Dollars (\$ 2.6 M) (which amount shall include the financing of \$ 1,500,000 contemplated in Section 5.2), which amount will be used to further develop the Technologies, in accordance with the terms and conditions of the R&D Agreements.

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5.4. In the event that the financing described in Sections 5.1 to Section 5.3 is not obtained, the Parties agree that Ortho RTI will have a period of three (3) months from each of the date of Round 1 in accordance with the financing described in Section 5.1, and the date of Round 2 in accordance with the financing described in Section 5.3, to find alternative financing solutions under the supervision of an investment committee consisting of one representative of Polytechnique, one representative of Polyvalor, the Researchers and the President of Ortho RTI. The decisions regarding alternative financing solutions will have to be taken by a majority of the members of such investment committee. If a majority of the investment committee do not agree on an alternative financing solution within the aforementioned three (3) month period, Ortho RTI will be immediately be deemed to be in default of this Agreement and no further notice will be required, including the notice requirement in paragraph 6.1. The Parties acknowledge that no member or his representative can be held responsible in any way in respect of the position he has taken in the investment committee.

- 5.5. Ortho RTI must create and maintain, at its own expense, for at least the duration of the R&D Agreements, a scientific committee, as set out in Appendix F attached hereto.
- 5.6. Polytechnique and Ortho RTI will create and maintain, at the expense of Ortho RTI, for the duration of the R&D Agreements and for a period of one (1) year following the termination of the R&D Agreements, an advisory committee, as set out in Appendix G attached hereto.
- 5.7. Ortho RTI is responsible, at its own expense, for all steps taken in relation to regulatory formalities with respect to the technological and clinical developments of the Assigned Intellectual Property and the Commercial Exploitation. The collaboration of Polytechnique, including Researchers, in these steps will be specifically described and budgeted in the R&D Agreements.

#### 6. DEFAULTS

- 6.1. Ortho RTI will be in default of this Agreement in each of the following cases:
  - 6.1.1 If any obligations or undertakings of Ortho RTI provided herein are not fulfilled or respected by the time it is due pursuant to this Agreement, and Ortho RTI has not remedied the situation within sixty (60) days from receiving a written notice to that effect unless there is a shorter delay expressly provided herein;
  - 6.1.2. If one or more of Ortho RTI's representations and warranties is materially inaccurate or misleading; or
  - 6.1.3.If Ortho RTI becomes insolvent or is about to file or files a proposal or an assignment of its property to the benefit of its creditors under the Bankruptcy and Insolvency Act (Canada) or any similar law, or if a sequestration order is about to be rendered or is rendered against the property of Ortho RTI due to its insolvency, or if a consolidation order or any similar order is about to be rendered or is rendered regarding the amounts owed by Ortho RTI, or if an order is about to be issued or is issued or a resolution is about to be adopted or is adopted to liquidate Ortho RTI.

- 6.2. In the event that one of the defaults described in paragraphs 6.1 or 6.1.1 occurs during the Probationary Period or, with respect to paragraph 6.1.2, the default occurs during or after the Probationary Period, the Parties recognize that this Agreement could be unilaterally terminated by Polyvalor, and that any and all amounts owed pursuant to this Agreement will become immediately payable, and that the Assigned Intellectual Property will immediately and automatically revert back and be assigned to Polyvalor in consideration for a total nominal amount of \$ 1.00, with a full release by Ortho RTI in favor of Polyvalor, the whole without any additional formalities and requirements, Ortho RTI accepting such assignment.
- 6.3. In the event that this Agreement is terminated pursuant to Section 6.1.3, Ortho RTI shall immediately stop using the Technologies and the Assigned Intellectual Property and cease Commercial Exploitation in the Territory. In addition, Ortho RTI shall return to Polyvalor, at Ortho RTI's costs, without keeping a copy, the information and materials relating to the Technologies and the Assigned Intellectual Property.
- 6.4. Termination of this Agreement according to Section 6.1.3 of this Agreement shall not in any way impede the right of Polyvalor to claim any other rights it may have against Ortho RTL including but without limiting the generality of the foregoing, the right to claim any unpaid Instalment Payments as of the effective date of termination and/or damages, if applicable.
- 6.5. Termination of this Agreement according to Section 6.1.3 of this Agreement shall not release Ortho RTI from any obligation or liability to Polyvalor, which shall have matured prior to termination, nor shall termination rescind or require repayment of any payment or consideration made or given by Ortho RTI to Polyvalor. Sections 6, 7, 10, 11 and 12 shall survive termination of this Agreement. On the effective date of such termination pursuant to Section 6.1.3 of this Agreement, Polyvalor will cease to be a shareholder of Ortho RTI.

#### 7. CONFIDENTIALITY

- 7.1. The Parties may communicate to each other any information, which can reasonably be considered to be confidential, proprietary or secret information, whether transmitted electronically, orally or in written form, relating to the Technologies, the Assigned Intellectual Property (the "Confidential Information"). When such Confidential Information is communicated verbally, the party transmitting it shall confirm to the other party, in writing and within a reasonable time, the confidentiality of the Confidential Information. The absence of marking or legend indicating that the Confidential Information is to be treated as confidential shall not limit or diminish the obligation of any Party to treat such information as Confidential Information.
- 7.2. Each Party undertakes to take all necessary measures to protect the confidentiality of the Confidential Information and to prevent any and all disclosure of Confidential Information other than the disclosure permitted pursuant to this Agreement. Any Person requesting access to the Confidential Information will be required to sign a confidentiality agreement suitably acceptable to the owner of the Confidential Information.
- 7.3. This obligation of confidentiality shall not apply to information:

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7.3.1.that is part of the public domain or publicly known without being in violation of the provisions of Section 7 hereof;

- 7.3.2. obtained from third parties who are not required to ensure the confidentiality thereof, to the extent that said information was not obtained in violation of the provisions of Section 7 hereof;
- 7.3.3.that must be disclosed by a Party to any public authority regulating securities or the stock exchange, to the extent necessary;
- 7.3.4.that must be disclosed by a Party as a result of any judicial or governmental decision ordering such Party to provide such information.
- 7.4. Where the disclosure of the Confidential Information is required pursuant to paragraphs 7.3.2 or 7.3.3, each Party shall use all reasonable efforts to minimize the extent of such disclosure and to obtain an undertaking from the recipient to maintain the confidentiality of such Confidential Information.
- 7.5. For greater clarity, it is understood that Ortho RTI, Polyvalor or Polytechnique may not, directly or indirectly, without prior written consent of the other Parties, as appropriate, disclose the terms of this Agreement or use, resort to, infer, state the names and business names belonging to Ortho RTI, Polyvalor and Polytechnique, in any document, publication, advertisement, note and other documents destined to be publicly released, unless legally required to do so. In the latter case, Ortho RTI, Polyvalor or Polytechnique, as appropriate, shall take all reasonable measures to notify the others in advance of the disclosure. Notwithstanding the foregoing, either Party may issue a press release concerning the Agreement concluded between the Parties and publish such press release on its website information and in its annual reports, provided that the press release does not disclose any specific regarding the Agreement's business terms.

#### 8. NEW R&D IP

Subject to the terms and conditions of this Agreement, and pursuant to paragraph 2.1.1 hereof, Polytechnique hereby agrees to assign, and will assign, to Polyvalor and Polyvalor hereby agrees to assign, and will assign, to Ortho RTI the New R&D IP upon its creation. The Parties will include such an intellectual property assignment clause relating to the New R&D IP in favour of Ortho RTI in the R&D Agreements, and the Parties will execute any necessary confirmatory or recordable assignment to effect the assignment of such New R&D IP in favour of Ortho RTI.

#### 9. PATENTS

9.1. As of the Effective Date, filing, prosecuting, defending and maintaining the Patents, and all related fees and costs will be the sole responsibility of Ortho RTI. It is understood that despite the assignment of the Assigned Intellectual Property, including the Patents, to Polyvalor pursuant to Section 6.1.3 hereof, Polyvalor will not be required to reimburse Ortho RTI any fees and costs paid or incurred by Ortho RTI up to such termination date of this Agreement.

9.2. In the context of filing, prosecuting, defending and maintaining the Patents during the Probationary Period, Ortho RTI shall fulfill its responsibilities with diligence to create and/or maintain in a reasonable manner the optimal value for the Patents. Ortho RTI shall notify Polyvalor, within a reasonable time and in writing, of any decision to be taken in relation to the Patents. During the Probationary Period, following receipt of such notice from Ortho RTI, Polyvalor will give Ortho RTI comments that will be considered by Ortho RTI prior to any decision making.

- 9.3. During the Probationary Period, Ortho RTI will ensure that Polyvalor is copied on all correspondence of the patent agents related to filing of the patent applications and maintaining the Patents.
- 9.4. Polyvalor and Polytechnique may provide, at the expense of Ortho RTI, including costs related to professional fees including those of the Researchers, any assistance that is reasonably necessary in the context of administrative or judicial proceedings aiming to oppose or attack third party patents or patent applications in connection with the Patents, and to defend the Patents. The Researchers undertake to provide, without charge, their reasonable assistance to Ortho RTI in the context of preparing any patent application relating to New Patents.

# 10. REPRESENTATIONS AND LIMITED WARRANTIES OF POLYTECHNIQUE AND POLYVALOR

- 10.1. Polyvalor is a limited partnership duly constituted pursuant to the Civil Code of Québec. Polyvalor has the capacity and power to possess and dispose of its property and discharge its liabilities which may result from this Agreement, if any. Polyvalor holds all the authorizations required by the federal, provincial or other authorities to engage in its activities.
- Except for the limited warranties and representations given in Section 10.3 by 10.2. Polytechnique and Polyvalor and those given by the Researchers in Schedule 10.2 herein, Polyvalor, Polytechnique and the Researchers make no representation and give no warranties of any kind, express, implied or statutory, regarding the quality of the Laboratory Notes, the level of development of the Assigned Intellectual Property, and they do not give any warranty as to the success of the Commercial Exploitation, or success in having the Patents issued. Polyvalor, Polytechnique and the Researchers make no representation and give no warranty of any kind, express or implied, that the use or exploitation of the Assigned Intellectual Property, the Products, the Processes or the Services does not constitute a violation of the rights of a third party. Polyvalor, Polytechnique and the Researchers make no representation and give no warranty of any kind, express or implied, relating to the Assigned Intellectual Property, the Products, the Processes or the Services and to the usefulness, quality or merchantability of the Assigned Intellectual Property, the Products, the Processes or the Services or of the possible effects arising from their use. Polyvalor, Polytechnique and the Researchers shall be in no way responsible for any warranties, representations, statements, or other commitments made by Ortho RTI to the benefit of whomever, in relation to the Assigned Intellectual Property, the Products, the Processes or the Services. Ortho RTI acknowledges that it acquires the Assigned Intellectual Property at its own risk and peril.

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10.3. Polytechnique and Polyvalor hereby represent, warrant and guarantee the following to Ortho RTI:

- 10.3.1. To their Knowledge, Polyvalor owns the Patents and the Technical Data and it has the right to assign and transfer the Patents and the Technical Data to Ortho RTI. To their Knowledge, no consent of any Person is required to enable Polyvalor to transfer to Ortho RTI all rights, titles and interests in and in respect of the Patents and the Technical Data;
- 10.3.2. With the exception of the license granted to Polytechnique and the Researchers in virtue of Section 2.2 hereof, to their Knowledge, no license, permission, authorization or other right of any kind has been granted in favor of any third party whatsoever on the Patents and the Technical Data, and Polyvalor and Polytechnique have not otherwise licensed, mortgaged, encumbered or disposed of, in whole or in part, the Patents and the Technical Data. To their Knowledge, neither Polyvalor nor Polytechnique violates any other agreement to which they are parties by assigning the rights in the Patents and the Technical Data as set out in this Agreement;
- 10.3.3. Polytechnique undertakes to take the necessary measures to ensure that the Researchers, and any collaborator invited to participate in the creative process of the New R&D IP, be informed in advance of this Agreement and that they sign an agreement undertaking to assign any rights that they may have in respect of the New R&D IP to Polytechnique, which will thereafter assign such rights to Polyvalor.

#### 11. INDEMNITY AND LIABILITY

- 11.1. Polyvator, Polytechnique and the Researchers assume no obligation or liability in connection with the Laboratory Notes, the Assigned Intellectual Property, the Products, the Processes and the Services, except for the limited warranties and representations given in Section 10.3 herein and Schedule 10.2.
- 11.2. Except for any claim, legal proceeding or liability arising from a breach of the limited warranties and representations given in Section 10.3 herein and Schedule 10.2, and subject to Section 11.3, Ortho RTI will indemnify, defend and hold harmless and hereby agrees to indemnify, defend and hold harmless Polyvalor and its directors, officers, partners, employees and representatives, Polytechnique and its directors, officers, employees, students and representatives, and the Researchers, and to release them of any claim or legal proceeding, and of the judgments relating thereto covering losses, damages, costs and expenses (including reasonable fees of counsel and lawyers) that they could be liable for and that would result from or manifest itself after or in connection with the exploitation of the Assigned Intellectual Property the Products, the Processes and the Services by Ortho RTI, its licensees, sub-licensees, Affiliates or any other third parties.
- 11.3. No Party, in any way and at any time, including after the termination of this Agreement, shall be liable for any special, indirect, consequential or incidental damages of any nature whatsoever (including without limitation, loss of profits, interruption of business operations, loss of business information or any other pecuniary losses), regardless of the

cause and whether arising in contract, or otherwise, even if advised of the possibility of such liabilities, in respect of their rights and duties under this Agreement.

11.4. Ortho RTI hereby accepts to maintain at all times a reasonable and comprehensive general liability insurance including product liability, contractual liability and personal injury, and an insurance against claims relating to the development of the Assigned Intellectual Property, and the Commercial exploitation of the Products, the Processes and the Services sufficient for the purpose of covering the indemnity of Ortho RTI for the benefit of Polyvalor and Polytechnique and to prove its existence upon Polyvalor's request thereof.

## 12. REPREPRESENTATIONS AND WARRANTIES OF ORTHO RTI

- 12.1. Ortho RTI represents and guarantees the following to Polyvalor:
  - 12.1.1. that it is, at the date of signature of this Agreement, a corporation duly incorporated and organized under the Canada Business Corporations Act;
  - 12.1.2. that it holds all the corporate powers and authority required to enter into this Agreement:
  - 12.1.3. that it is in compliance, in all important aspects, with all laws, regulations, directives, policies, guidelines, orders, judgments, decrees or standards for its property, activities and operations;
  - 12.1.4. that it is a not a party to any civil, administrative or criminal proceeding, it has not received any formal notice of default and has not been threatened by any lawsuit. To its knowledge, and after conducting a diligent verification, there is no cause of action in which it may be implicated and no judgment has been rendered against it;
  - 12.1.5. that, as of the date of this Agreement, it is not aware of any event which can adversely affect its business or income;
  - that it holds all licenses, permits and any other approval required to operate its enterprise, in the ordinary course of business, everywhere it operates, and it has no reason to believe that these licenses, permits and approvals will not be renewed at their respective expiry dates;
  - 12.1.7. As of the date of this Agreement, that the approval of this Agreement, the execution and delivery of this Agreement and the performance by Ortho RTI of its obligations hereunder and the completion of the transactions contemplated herein will not result (i) in a violation of, default under, or breach of, require any consent to be obtained under or give rise to any termination rights by a third party, any payment obligation by Ortho RTI or any rights of a third party, the exercise of which would result in any breach or default under any provision of any laws, or (ii) the creation or imposition of any encumbrance upon the securities or assets of Ortho RTI, or otherwise restrict, hinder, impair or limit the ability of Ortho RTI to carry on its business.
  - 12.2. Ortho RTI undertakes the following in favor of Polyvalor and Polytechnique and shall:

take all reasonable steps and measures required to ensure the optimal development of the Assigned Intellectual Property and optimal Commercial Exploitation, subject to reasonably satisfactory performance of Polytechnique, as well as delivery of results, under the R&D Agreements;

12.2.2. maintain its juridical personality and take the necessary steps to this end.

#### 13. NOTICES

13.1 Any notice, consent or other communication under this Agreement shall be given in writing and delivered by hand or by bailiff or sent by fax, and addressed as follows:

To: Polyvalor:

3535 Queen Mary Road, Suite 220 Montreal (Quebec) H3V 1H8 Facsimile: (514) 340-3204;

To the attention of: Incques Simoneau, Chief Executive Officer

To: Ortho RTI

16667 Hymus Boulevard Kirkland (Quebec) H9H 4R9 Facsimile: (514) 240-4371

To the attention of: Steve Saviuk, President

To: Polytechnique

2900 Édouard-Montpetit Boulevard Montréal (Quebec) H3T 1J4 Facsimile: (514) 340-5871;

To the attention of: Mr. Jean-Pierre Labelle, Director of the Office of research / Center for Technological Development – BRCDT.

13.2 Such notice, consent or other communication will be deemed to have been given and received on the day it is actually delivered or sent (or if that day is not a business day, on the following business day), unless it is delivered or sent after 4:30 p.m., in which case it will be deemed to have been given and received on the next business day. A Party may, from time to time, designate another address in accordance with this Section 13.

#### 14. APPLICABLE LAW

The Parties agree that the laws applicable in the Province of Quebec, and the Canadian federal laws applicable therein, shall apply to this Agreement and will determine the interpretation thereof.

#### 15. ENTIRE AGREEMENT

The Parties acknowledge that this Agreement, including the R&D Agreements and the corporate agreements executed as of the Effective Date of this Agreement between the Parties represent the sole and complete understanding between them with respect to the subject matter hereof. Ortho RTI acknowledges that no promise or representation made to it and no verbal or other agreement has happened between the Parties with respect to the specific subject matter hereof, such that this Agreement replaces and terminates any earlier agreement, representation, negotiation or proposal concerning the subject matter hereof.

#### 16. MISCELLANEOUS

- 16.1 The preamble and the Appendices are an integral part of this Agreement.
- 16.2 The Parties undertake to take any necessary step and to sign any document necessary to give full effect to this Agreement.
- 16.3 This Agreement shall not be interpreted as creating a partnership, company or a mandate between the Parties.
- The waiver by one Party of its rights relating to the violation of any provision hereof by the other Party does not represent a waiver of its rights relating to the further violation of that provision or the violation of any other provision. No provision of this Agreement shall be considered to have been the subject of a waiver by one of the Parties unless such waiver was formulated in writing.
- 16.5 The titles of the Sections of this Agreement have only been put to facilitate the reading of this Agreement, and may not be used to interpret it.
- 16.6 The terms and provisions of this Agreement shall be interpreted separately and the invalidity of one term or provision shall not affect the validity of any other term and provision.
- 16.7 This Agreement may not be modified or amended except by way of further written agreement signed by each of the Parties hereof.
- For the purposes hereof, the Parties irrevocably submit all disputes arising out of or relating to this Agreement to Quebec courts, judicial district of Montreal.
- 16.9 If applicable, the rights and obligations of the Parties pursuant to this Agreement shall be binding on their respective successors and assigns.
- Except as otherwise expressly set out herein, the Parties may not assign this Agreement or any right or obligation under this Agreement without the prior written consent of all Parties. Without limiting the generality of the foregoing, after the Probationary Period, Ortho RTI may assign this Agreement or any rights or obligations under this Agreement to any Affiliate, a purchaser of all or substantially all of Ortho RTI's assets or shares, or to a successor in interest of Ortho RTI, or as part of a corporate reorganization, consolidation or merger, without having obtained the prior written consent of Polyvalor, provided that such Affiliate, purchaser or successor agrees to be bound by all the terms of this Agreement.

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16.11 This Agreement may be signed in any number of counterparts, each of which is deemed to be an original and all of which when taken together are deemed to constitute one and the same instrument. Each counterpart may be delivered by fax or email and a faxed or emailed copy is as effective as an original.

[The remainder of this page intentionally left blank. The next page is the signature page] IN WITNESS HEREOF, the Parties have signed this agreement at the time and place indicated in the header.

POLYVALOR, A LIMITED PARTNERSHIP,

acting through its general partner Gestion Univalor, a limited partnership, itself acting through

its general partner Univalor Inc.

By:

Jakones Simoneau

President and Chief Executive Officer

ORTHO BEGENERATIVE TECHNOLOGIES INC

By:

Steve Saviuk President

#### INTERVENOR

The undersigned, CORPORATION DE L'ÉCOLE POLYTECHNIQUE DE MONTRÉAL, having read this Agreement, hereby agrees to act in accordance with the terms and conditions contained in this Agreement.

CORPORATION DE L'ÉCOLE POLYTECHNIQUE DE MONTRÉAL

By:

Name: Title:

Jean-Pierre Labello Directeur, Bureau de la recherche et Centre de développement technologique École Polylechnique de Montréal

#### **SCHEDULE 10.2**

#### Representations and undertaking by the Researchers

We, undersigned, Dr. Michael D. Buschmann and Dr. Caroline D. Hoemann, researchers at Corporation de l'École Polytechnique de Montréal, hereby declare that:

- 1- We have read this Intellectual Property Assignment and Technology Transfer;
- 2- To our best knowledge, as of the Effective Date of this Agreement and based on what we understand are Ortho RTI's objectives and plans as of the Effective Date regarding the development of the Technologies and the Commercial Exploitation;
  - a. that Ortho RTI will not require the Excluded Assets (Appendix D) for the development of the Technologies or the Commercial Exploitation;
  - that Ortho RTI will not require a chitosan-based solution that is mixed with whole blood for tissue repair and that includes an inorganic salt such as NaCl for the development of the Technologies or the Commercial Exploitation;
- 3- We shall abide by all provisions contained in this Intellectual Property Assignment and Technology (Transfer that concernus.

Michael D. Buschmann

#### SCHEDULE 10.2

## Representations and undertaking by the Researchers

We, undersigned, Dr. Michael D. Buschmann and Dr. Caroline D. Hoemann, researchers at Corporation de l'École Polytechnique de Montréal, hereby declare that:

- 1- We have read this Intellectual Property Assignment and Technology Transfer;
- 2- To our best knowledge, as of the Effective Date of this Agreement and based on what we understand are Ortho RTI's objectives and plans as of the Effective Date regarding the development of the Technologies and the Commercial Exploitation:

a. that Ortho RTI will not require the Excluded Assets (Appendix D) for the development of the

Technologies or the Commercial Exploitation;

- b. that Ortho RTI will not require a chitosan-based solution that is mixed with whole blood for tissue repair and that includes an inorganic salt such as NaCl for the development of the Technologies or the Commercial Exploitation;
- 3- We shall abide by all provisions contained in this Intellectual Property Assignment and Technology Transfer that concern us

Michael D. Buschmann

10831011.1

EP

Europe

Corporation de l'École Polytechnique de Montréal\*

#### APPENDIX A

		PA	TENTS		
	nogeneous bloo	d/chitosan implant prepa ures for tissue repair	red by novel i	formation of	physiological chitosan-
Country	App. No.	Recorded applicant	Status	Expiry	Next due date
Canada	CA 2,814,783	Corporation de l'École Polytechnique de Montréal*	Pending	November 18, 2030	Payment of annuities November 18, 2015
US	US 13/510,661	Polyvalor, Limited Partnership	Pending	November 18, 2030	Restriction Requirement – Final due date Sept 9, 2013
Europe	EP 10831000.4	Corporation de l'École Polytechnique de Montréal*	Pending	November 18, 2030	Payment of annuities November 18, 2015
		al chitosan training (with i	BGP and NaC	I) combined v	vith platelet-rich plasma
Country	App. No.	Recorded applicant	Status	Expiry	Next due date
Canada	CA 2,814,784	Corporation de l'École Polytechnique de Montréal*	Pending	November 19, 2030	Payment of annuities November 19, 2015
					Deadline for filing a Request for examination November 19, 2015
US	US 13/510,663	Polyvalor, Limited Partnership	Pending	November 19, 2030	Notice of appeal filed on December 2, 2014.

Pending

November

30, 2030

Amendment & RCE filed on December 22, 2014

Payment of annuities November 30, 2015

repair Country	App. No.	Recorded applicant	Status	Expiry	Next due date
International	PCT/ CA2015/050 130	Polyvalor, Limited Partnership	Pending	Latest: National phase in Cunada August 20, 2017	Amendment art. 19 August 20, 2015
VAL-1139-I	PM				
Title: Freez	e-dried polyme r composition	r compositions for mixin s for therapeutic intra-ar	g with platelet ticular injectio	rich plasma t ns	o form implants for tissue
International		Polyvalor, Limited	Pending	Latest: National phase in Canada August 20, 2017	Amendment art. 19 August 20, 2015

<sup>\*</sup> The assignment of patent rights from Corporation de l'École Polytechnique de Montréal to Polyvalor Limited Partnership has been executed but was not registered at the patent office on the Effective date.

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#### APPENDIX B

## TECHNICAL DATA

See the attached document.

#### **TECHNICAL DATA**

#### Composition

All retained (positive results) as well as discarded (negative results) chitosan-based solutions / compositions recipes, for example:

constituents (chitosan, lyoprotectant, etc.)
constituent concentration / ratio;
pH;
chitosan protonation, DDA %, and molecular weight;

which specifically applies to the following three technologies:

- (VAL-782) A chitosan-based solution that is for mixing with platelet rich plasma (PRP) for tissue repair and includes an inorganic salt such as NaCl and a clot activator such as CaCl<sub>2</sub>;
- (VAL-1139) A freeze-dried chitosan that is for rehydration in platelet rich plasma (PRP) for tissue repair or intra-articular injections and includes a lyoprotectant such as trehalose and a clot activator such as CaCl<sub>2</sub>;
- (VAL-1058) A freeze-dried chitosan that is for rehydration in vivo in a tissue defect to produce a microparticle dispersion in situ for tissue repair.

#### Preliminary Safety and efficacy studies

osmolality, and the like

- (VAL-1058) Study protocols and associated results (including positive and negative results) relative to restoration of joint function through subchondral delivery of therapeutics using a freeze-dried chitosan that is for rehydration in vivo in a tissue defect to produce a microparticle dispersion in situ for tissue repair as well as the design and manufacture of these freeze-dried chitosans that stimulate bone below the cartilage lesion to become porous and vascularized.
- Study protocols and associated results (including positive and negative results) obtained from a rabbit subcutaneous injection model where the injected material applied are the two technologies VAL-782 and VAL-1139.
- © (VAL-782) Study protocols and associated results (including positive and negative results) obtained from the characterization of chitosan/PRP clots prepared with chitosan solutions and PRP from rabbit, sheep and human PRP, and identification of an appropriate chitosan / PRP biohybrid formulation to use in the context of meniscus repair.
- (VAL-782) Study protocols and associated results (including positive and negative results) obtained from the manufacture of chitosan solutions for mixing with PRP to form clots at given mix ratio and chitosan concentration solution, and investigation of the retraction of PRP/chitosan clots prepared at such given ratio / concentration.
- Study protocols and associated results (including positive and negative results) obtained from the use of fluorescent labeling for assessing chitosan hybrid clot retraction, including testing different fixatives, different molecular weight chitosan, and identity of fluorescent label where the technologies VAL-782, VAL-1139, VAL-1058 were applied.

#### TECHNICAL DATA

- □ (VAL-1139) Study protocol and associated results (including positive and negative results) obtained from the development of freeze-dried chitosan formulations for chitosan/PRP-based implants, including testing different concentrations of excipients, how sugars affect chitosan dispersion in the clots, how chitosan molecular weight and lyoprotectants affect chitosan solubility and dispersion in PRP hybrid clots, developing freeze-dried chitosan cakes that reconstitute easily in PRP, developing paste-like freeze-dried chitosan/PRP implants are paste-like and have an osmolality close to physiological upon reconstitution.
- ci (VAL-1139) Study protocols and associated results (including positive and negative results) where a sheep meniscus repair model was used to test the technology noted above.
- □ (VAL-1139) Study protocol and associated results (including positive and negative results) where residency of a fluorescent freeze-dried chitosan-PRP implant was tested in a sheep meniscal defect model.
- (VAI.-1058) Study protocol and associated results (including positive and negative results) relative to freeze-dried chitosan implants with and without bulking agents in rabbit cartilage repair model, assessment of implant retention, subchondral bone remodelling, and macrophage recruitment to chitosan implant and effect of cryoprotectants, molecular weight of chitosan.
- (VAL-1058) Study protocol and associated results (including positive and negative results) relative to efficacy and safety of lyophilized chitosan subchondral implant in augmenting the therapeutic response marrow stimulation defects created in articular cartilage defect in sheep model, effect of chitosan concentration, % DDA, molecular mass, and protonation, as well as use of micro-CT scan measures.
- (VAL-1058) Study protocol and associated results (including positive and negative results) relative to histomorphometric and histological analyses of sheep cartilage repair tissue treated with lyophilized chitosan subchondral implant.
- (VAL-1139) Study protocols and associated results (including positive and negative results) relative to rabbit subcutaneous implantation of freeze-dried chitosan/PRP-based compositions, macroscopic and histological assessment of safety, biocompatibility, biodegradability and chemotactic effect, as well as effect of different exciplent concentration.
- (VAL-1139) Study protocol and associated results (including positive and negative results) relative to
  the assessment of cartilage repair by a freeze-dried chitosan/PRP mixture in a rabbit chronic
  cartilage defect model.
- 5tudy protocol and associated results (including positive and negative results) relative to biochemical analysis of meniscus and cartilage biopsies collected from animal meniscus repair models where the technologies VAL-782 and VAL-1139 were applied.
- O (VAL-1139) Study protocol and associated results (including positive and negative results) relative to selection of freeze-dried chitosan/PRP mixture for use in a sheep meniscus repair model, including preparation of compositions, in vitro characterization of the compositions and tissue collection as well as analysis thereof.

#### TECHNICAL DATA

#### Manufacturing Processes

Complete manufacturing protocols and associated results (including positive and negative results), for the chitosan-based solutions / compositions which apply to the three technologies noted above and protocols for mixing these with blood/PRP.

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#### APPENDIX C

## NEW TECHNICAL DATA

See the attached document.

#### **NEW TECHNICAL DATA**

### Viscosupplementation and Rotator Cuff Repair

- Documented study protocols and associated results (including positive and negative results) for viscosupplementation, including use of an animal model to generate such results, using chitosanbased solutions / compositions which specifically apply to any of the following three technologies:
  - (VAL-782) A chitosan-based solution that is for mixing with platelet rich plasma (PRP) for tissue repair and includes an inorganic salt such as NaCl and a clot activator such as CaCl<sub>2</sub>;
  - (VAL-1139) A freeze-dried chitosan that is for rehydration in platelet rich plasma (PRP) for tissue repair or intra-articular injections and includes a lyoprotectant such as trehalose and a clot activator such as CaCl<sub>2</sub>;
  - (VAL-1058) A freeze-dried chitosan (positive and negative results) that is for rehydration in vivo in a tissue defect to produce a microparticle dispersion in situ for tissue repair.
- Documented study protocols and associated results (including positive and negative results) which apply to rotator cuff repair, including use of an animal model to generate such results, using the chitosan-based solutions / compositions which apply to any of the above noted three technologies.

#### Manufacturing Processes

- Documented manufacturing protocols and associated results (including positive and negative results), for the chitosan-based solutions / compositions which apply to any of the above noted three technologies.
- Documented Quality Control protocols and associated results (including positive and negative results) for the chitosan-based solutions / compositions which apply to any of the above noted three technologies.
- Documented study protocols and associated results (including positive and negative results) for upscaling the manufacturing protocols of the chitosan-based solutions / compositions which apply to any of the above noted three technologies, such as: results on optimization of parameters affecting stability / biological activity, and the like.

#### Regulatory

- Documented study protocols and associated results (including positive and negative results) of studies carried out to assess in vivo efficacy / safety / posology (dosage) of the chitosan-based solutions / compositions which apply to any of the above noted three technologies for meniscus repair.
- Documented study protocols and associated results (including positive and negative results) of studies carried out to assess in vivo efficacy / safety / posology (dosage) of the chitosan-based solutions / compositions which apply to any of the above noted three technologies for viscosupplementation.

Documented study protocols and associated results (including positive and negative results) of studies carried out to assess in vivo efficacy / safety / posology (dosage) of the chitosan-based solutions / compositions which apply to any of the above noted three technologies for rotator cuff repair.

#### Financed MD-60 Study

ci Recipes for freeze-dried cake composition which were reconstituted in autologous PRP for use in a meniscus repair model in sheep, and results generated in the sheep model using these compositions, namely results of: implant retention, menisci macroscopic / microscopic assessment, macroscopic and microscopic assessment of synovial pathology, electromechanical properties and macroscopic / microscopic assessment of articular cartilage surfaces, and biochemical content of meniscal and articular surface tissues.

2		