

PreMD Inc.  
Form 6-K  
July 31, 2007

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16 OF THE

SECURITIES EXCHANGE ACT OF 1934

For the month of July, 2007

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### PreMD Inc.

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Commission File Number 1-31360

615-4211 Yonge Street

Toronto, Ontario M2P 2A9

CANADA

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

## Edgar Filing: PreMD Inc. - Form 6-K

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's home country), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If  is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

PreMD Inc. entered into the attached License Development and Supply Agreement between AstraZeneca Pharmaceuticals LP and PreMD Inc. on July 13, 2007. This Report on Form 6-K shall be deemed to be incorporated by reference into PreMD's Registration Statement on Form F-3, Registration No. 333-144593, as amended and declared effective on July 27, 2007 by the United States Securities Exchange Commission, and the related prospectus filed pursuant to Rule 424(b)(3) under the United States Securities Act of 1933, as amended, dated July 30, 2007, and shall be part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

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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.

**PreMD Inc.**

By: /s/ Ronald G. Hosking  
Ronald G. Hosking  
Vice President and Chief Financial Officer

Date: July 31, 2007

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
99.1	License Development and Supply Agreement between AstraZeneca Pharmaceuticals LP and PreMD Inc.***
99.2	FORM 51-102F3 - Material Change Report.

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\*\*\* Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Exhibit 99.1**

FINAL EXECUTION COPY

REDACTED VERSION

**LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT**

BETWEEN

**ASTRAZENECA PHARMACEUTICALS LP**

AND

**PREMD INC.**

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

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**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

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**LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT**

This LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT dated as of July 13, 2007 (this **Agreement** ) by and between PreMD Inc., a corporation incorporated under the laws of Canada and having its principal place of business at 4211 Yonge Street, Suite 615, Toronto, Ontario, M2P 2A9, Canada ( **PreMD** ), and AstraZeneca Pharmaceuticals LP, a limited partnership formed under the laws of Delaware and having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19858 ( **AstraZeneca** ). AstraZeneca and PreMD may also be referred to collectively as **Parties** and individually as a **Party**.

Whereas:

A. AstraZeneca desires to acquire, and PreMD wishes to grant, the exclusive license to Product in the Territory.

B. AstraZeneca and PreMD may wish to further develop Product.

C. PreMD desires to have manufactured and supply to AstraZeneca Product, and AstraZeneca desires to have PreMD have manufactured and supply to AstraZeneca Product.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound agree as follows:

**ARTICLE I**

**DEFINITIONS**

As used in this Agreement, the following terms shall have the following respective meanings:

1.1 All currency used in this Agreement shall be denominated in U.S. Dollars, unless specifically identified otherwise.

1.2 **Actual Knowledge** means, with respect to any fact or matter, the actual knowledge of the applicable Party.

1.3 **Adverse Device Effect** means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, including any effect that was not previously identified in nature, severity, or degree of incidence in the investigational plan or investigational device exemption (IDE) application, or any unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects, in connection with a Clinical Trial or other product development activities.

1.4 **Affiliate(s)** means, with respect to a Person, any Person that controls, is controlled by or is under common control with such first Person. For purposes of this definition and Section 3.2 only, **control** means (i) to possess, directly or indirectly, the power to direct the

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management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or (ii) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other ownership interest of such Person. For greater certainty, any Affiliate of AstraZeneca PLC shall be deemed to be an Affiliate of AstraZeneca for the purposes of this Agreement.

1.5 **Alternate Supplier** has the meaning set forth in Section 6.1.2.

1.6 **Applicable Laws** means all applicable laws, statutes, rules, regulations and guidelines that may apply to the sale of Product in a particular jurisdiction within the Territory or the promotion, marketing, manufacturing, packaging, labeling, importation, exportation, warehousing or distribution of Product that is to be sold in such jurisdiction within the Territory or the performance of either Party's obligations under this Agreement, and including the FDCA, all GLP, QSR, GMP, and GCP, all applicable requirements of CLIA and all applicable standards or guidelines promulgated by applicable Regulators.

1.7 **AstraZeneca Information** has the meaning set forth in Section 15.1.1.

1.8 **AstraZeneca Trademarks** has the meaning set forth in Section 14.12.

1.9 **Best Knowledge** or **Knowingly** means, with respect to any fact or matter, the actual knowledge of the applicable Party, or knowledge that should have been known by the applicable Party subject to commercially reasonable diligence.

1.10 **Calendar Quarter** means each successive period of three (3) calendar months commencing on January, 1<sup>st</sup> April, 1<sup>st</sup> July and 1<sup>st</sup> October.

1.11 **Calendar Year** means the period of time commencing on 1 January and ending on the following December 31.

1.12 **CLIA** means the United States Clinical Laboratory Improvements Act of 1988, as amended, and all regulations, guidances and rules promulgated thereunder.

1.13 **Clinical Trial** means a trial performed on humans or on human specimens using Product or Non-Field Product, as applicable; provided, however, that a Clinical Trial shall not include product development activities that are not intended to demonstrate either the safety or clinical effectiveness of Product or Non-Field Product.

1.14 **Commercial Sale** means an arm's length transaction and shipment by AstraZeneca or any of its Affiliates or Sublicensees of Product to an independent Third Party in the Territory.

1.15 **Competing Product** means a product that is used to measure, diagnose, monitor or predict skin Sterol in humans on areas of the body with no sebaceous glands (i.e., the palms of the hand and the soles of the feet).

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- 1.16 **CPR** has the meaning set forth in Section 19.6.
- 1.17 **Diligent Efforts** means the level of efforts required to carry out obligations or tasks in a sustained manner consistent with the efforts a similarly situated biotechnology research and development company or pharmaceutical company, as the case may be, devotes to a product of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing. For greater certainty, no Party shall be required to expend efforts or allocate resources if it would not be commercially reasonable to do so.
- 1.18 **Disclosure** has the meaning set forth in Section 15.8.
- 1.19 **Disclosure Requirements** has the meaning set forth in Section 15.8.
- 1.20 **Dispute** has the meaning set forth in Section 19.6.
- 1.21 **Dollar** means the legal currency of the United States.
- 1.22 **Effective Date** means the date first written above.
- 1.23 **Exploit** means to make, have made, import, use, sell, or offer for sale, including without limitation to research, develop, register, modify, enhance, improve, hold/keep (whether for disposal or otherwise), formulate, optimize, have used, distribute, promote, license, sublicense, market or have sold or otherwise dispose or offer to dispose of, a product or process.
- 1.24 **Exploitation** means the act of Exploiting a product or process.
- 1.25 **Extended Period** has the meaning set forth in Section 3.4.1.
- 1.26 **FDA** means the United States Food and Drug Administration and successor bodies.
- 1.27 **FDA Approval** means, in respect of a particular Product, all necessary Regulatory Approvals granted by the FDA for the manufacture, preparation, processing, assembly, packaging, labeling, importation, sale, and distribution of Product in the U.S.
- 1.28 **FDCA** means the United States Federal Food, Drug, and Cosmetic Act, as amended, and all regulations, guidances, and rules promulgated thereunder.
- 1.29 **Field** means all fields of measuring, diagnosing, monitoring and predicting skin Sterol in humans on areas of the body with no sebaceous glands (i.e., the palms of the hand and the soles of the feet). Unless otherwise specified, the Field shall include the Life Insurance Laboratory Field.
- 1.30 **5-Day Report** has the meaning set forth in Section 5.6.
- 1.31 **510(k) Notification** means a pre-market notification submitted pursuant to Section 510(k) of the FDCA.

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1.32 **First Commercial Sale** means, with respect to any Product, the first Commercial Sale of such Product.

1.33 **Good Clinical Practice** or **GCP** means the then current standards for clinical trials for medical devices, as set forth in the FDCA, as amended from time to time, including the United States Code of Federal Regulations, as amended from time to time, and such standards of good clinical practice as are required by other governmental organizations and agencies of jurisdictions within the Territory in which Product is intended to be sold, to the extent such standards do not contravene the United States GCP.

1.34 **Good Laboratory Practice** or **GLP** means the then current standards for laboratory activities for medical devices, as set forth in the FDCA, as amended from time to time, including the United States Code of Federal Regulations, as amended from time to time, and such standards of good laboratory practice as are required by other governmental organizations and agencies of jurisdictions within the Territory in which Product is intended to be sold, to the extent such standards do not contravene the United States GLP.

1.35 **GMP** or **good manufacturing practices** means the then-current standards for the manufacture of medical devices, as set forth in the FDCA, as amended from time to time, including the United States Code of Federal Regulations, as amended from time to time.

1.36 **Gross Profit** means, with respect to the Reader, the gross invoiced amount on sales of the Reader by AstraZeneca and its Affiliates and Sublicensees to Third Parties (including distributors) after deduction of:

- (i) Manufacturer's Cost;
- (ii) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed;
- (iii) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca or its Affiliates or Sublicensees in good faith;
- (iv) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program in the United States or equivalent governmental program in any other country;
- (v) any invoiced amounts which are not collected by AstraZeneca or its Affiliates or Sublicensees, including bad debts;
- (vi) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Reader;

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(vii) any other similar and customary deductions that are consistent with generally accepted accounting principles; and

(viii) any costs associated with transportation, distribution, special packaging and related insurance charges except to the extent that such charges are to be paid by or on behalf of the recipient.

Deductions pursuant to subsection (v) above shall be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable, but shall be added back in any future Calendar Quarter to the extent subsequently recouped in such Calendar Quarter.

1.37 **Improvement** means any change, improvement, development, or modification of Product, any apparatus, component or material associated therewith, or the method or process of making or using Product.

1.38 **Indirect Taxes** means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.39 **Intellectual Property** has the meaning set forth in Section 2.6.

1.40 **ISO** means certification for the then current standards as they apply to the design, development, manufacture and supply of Medical Devices and In Vitro Medical Devices (currently ISO 13485:2003) as established by the International Organization for Standardization.

1.41 **Joint Development Committee** or **JDC** means the committee established pursuant to Article II hereof.

1.42 **Joint Intellectual Property** has the meaning set forth in Section 2.6.3.

1.43 **Licensed Know-How** means the **PreMD Trademarks** together with any and all information or special knowledge not generally known to the public on the part of PreMD, its Affiliates and, to the extent developed for the benefit of PreMD or any of its Affiliates and to the extent to which PreMD or such Affiliates has the right to grant to AstraZeneca under such third party contractor agreements, third party contractors, all of which is either in existence as of the Effective Date or which is developed during the Term of this Agreement, including inventions, discoveries, reports, protocols, processes, apparatus, techniques, methods, models, screens, assays, products, regulatory submissions, and technical information, together with all experience, data, formulas, procedures and results, and including all chemical, pharmacological, toxicological, clinical, analytical, quality control, and safety data (including data from use of Product), and any other materials or compositions relating to or being useful in the manufacture, use, sale or Registration of Product, including the information listed on Appendix A, which PreMD shall update as necessary to reflect material changes to the foregoing. Licensed Know-How shall also include the **PreMD Improvement Intellectual Property** as set forth in Section 2.6.4 hereof to the extent not disclosed in any patent or patent application of the Licensed Patents and any Product Copyrights. All Licensed Know-How shall constitute confidential information of PreMD in accordance with Article XV.

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.44 **Licensed Patents** means:

- (i) any and all patents and patent applications relating to any Product or any component thereof that is owned, controlled, or licensed by PreMD or any of its Affiliates and includes the patents and patent applications set forth in and as described in Appendix B, a copy of which is attached hereto and made a part hereof, as amended in accordance with the provisions of Section 2.8 hereof from time to time;
- (ii) any and all extensions, renewals, revivals, reinstatements, continuations, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations, patents of importation, supplementary protection certificates of any of the foregoing in (i) or those set forth in (iv) or (v);
- (iii) any and all patents which are granted on any of (i), (ii), (iv) or (v) and any residual rights in any of the patents and applications that may be, or may have been, deemed abandoned or expired by any governmental agency for any reason;
- (iv) any and all patents and patent applications owned, controlled, or licensed by PreMD or any of its Affiliates with the right to sublicense which contain claims, the practice of which would infringe the claims of a patent or patent application included in (i), (ii), (iii), (iv) or (v); and
- (v) any and all patents and patent applications owned, controlled, or licensed by PreMD or any of its Affiliates with the right to sublicense which are directed to Improvements, including but not limited to **PreMD Improvement Intellectual Property** as set forth in Section 2.6.4 herein, which shall be set forth in and as described in Appendix C, which shall be amended in accordance with the provisions of Section 2.8 hereof from time to time.

1.45 **Licensed Technology** means the Licensed Patents and the Licensed Know-How.

1.46 **Life Insurance Laboratory Field** means the field of diagnosing and predicting skin Sterol for the sole purpose of determining the insurability of a life insurance applicant.

1.47 **Lock-Up** has the meaning set forth in Section 3.4.2.

1.48 **Manufacturer s Cost** means the total out-of-pocket costs paid by PreMD to its suppliers, contractors, and/or subcontractors for Product that is supplied to AstraZeneca in connection with the manufacture, importation, shipment or delivery of Product to AstraZeneca as contemplated herein, less the following amounts: (i) discounts, rebates, or trade allowances actually allowed or granted to PreMD in connection with Product (other than discounts associated with early or prompt payment) and (ii) credits or allowances actually granted to PreMD upon claims (including, without limitation, claims for destroyed goods) or returns in connection with Product, regardless of the Party requesting the return. For greater certainty, in

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the case of non-recurring capital expenditures incurred by PreMD, such costs shall be amortized, included in the calculation of Manufacturer's Cost, and paid by AstraZeneca, over the twelve (12) month period following such expenditure based upon the then-estimated purchases of Product (other than the Reader) by AstraZeneca hereunder.

1.49 **Medical Device Report Reportable Event** or **MDR Reportable Event** shall mean an event that reasonably suggests that a marketed device (i) may have caused or contributed to a death or serious injury, or (ii) has malfunctioned and the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as described in FDA's Medical Device Reporting regulations in 21 C.F.R. Part 803, as may be amended from time to time.

1.50 **Modified Technology** has the meaning set forth in Section 2.5.2.

1.51 **Net Sales** means, with respect to Product, the gross invoiced amount on sales of Product by AstraZeneca and its Affiliates and Sublicensees to Third Parties (including distributors) after deduction of:

- (i) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed;
- (ii) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca or its Affiliates or Sublicensees in good faith;
- (iii) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program in the United States or equivalent governmental program in any other country;
- (iv) any invoiced amounts which are not collected by AstraZeneca or its Affiliates or Sublicensees, including bad debts;
- (v) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Product; and
- (vi) any other similar and customary deductions that are consistent with generally accepted accounting principles.

Deductions pursuant to subsection (iv) above shall be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable, but shall be added back in any future Calendar Quarter to the extent subsequently recouped in such Calendar Quarter.

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1.51.1 Notwithstanding the foregoing, the provision of Product for free of cost to health care professionals as samples in a manner and in quantities consistent with customary industry practice shall not be deemed to amount to a Net Sale of such Product.

1.51.2 For the purposes of the determination of Net Sales for a particular sale, such sale shall be deemed to be billed at the date of shipment of Product to a Third Party.

1.52 **Non-Field Product** means systems, apparatus, processes, components, or finished devices for measuring skin Sterol other than in the Field.

1.53 **Person** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.54 **Pre-Market Approval Application** means an application for pre-market approval submitted pursuant to Section 515 of the FDCA.

1.55 **PreMD Improvement Intellectual Property** has the meaning set forth in Section 2.6.4.

1.56 **PreMD Trademarks** means the trademarks identified in Appendix D as well as any word, name, symbol, color, designation or device or any combination thereof for use in the course of trade, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol used by PreMD or any of its Affiliates in connection with Product.

1.57 **PREVU\* LT Product** means a Product to determine skin Sterol levels using a medical grade adhesive to non-invasively obtain a sample of skin which is then sent to a medical laboratory for processing, as shown by the drawings and summary in Appendix E.

1.58 **PREVU\* POC Product** means a Product that determines skin Sterol levels by measuring the color change of reagents placed on the palm of the hand with a Reader as contemplated by the summary in Appendix F.

1.59 **PREVU\* PT Product** means a Product incorporating a test to determine skin Sterol levels to be sold directly to consumers for home use as contemplated by the prototype drawings and summary in Appendix G.

1.60 **Product** means systems, apparatus, processes, components or finished devices for measuring skin Sterol in the Field, and include the PREVU\* PT Product, PREVU\* POC Product and PREVU\* LT Product.

1.61 **Product Copyrights** means all copyrightable subject matter included in Product labels and inserts, Product Promotional Materials, and Product training materials.

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

1.62 **Product Promotional Materials** means all written, printed or graphic material, other than Product labels and inserts, intended for use in promoting Product in the Territory, including without limitation visual aids, multimedia, website content, file cards, premium items, clinical study reports, reprints, drug or device information updates, packaging, photographs, electronic photography files and any other promotional support items.

1.63 **Product Quality Complaint** means any written, electronic or oral communication that (i) alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution; (ii) involves the possible failure of a device to meet any of the specifications for such device; (iii) involves any dissatisfaction with the design, package or labeling of a device or failure of the packaging or labeling to meet its specifications; or (iv) involves any complaint that may involve the Quality of such device.

1.64 **Project Costs** means any reasonable direct costs, whether internal or external, incurred solely for a research or development project, as agreed by the Parties in writing in advance of such project, it being understood that the Parties must also agree in writing in advance of such project as to the allocation of any internal costs (which shall consist solely of the compensation and benefit costs of PreMD's employees); provided, however, that any such internal costs as so agreed are to be allocated on a cost accounting basis consistent with Canadian generally accepted accounting principles; by way of example, if an employee of PreMD spent 40% of his/her time on such project and the remaining time on unrelated matters and the Parties had agreed to such allocation, 40% of the costs of such employee would be considered Project Costs for the purposes hereof.

1.65 **Purchase Price** has the meaning set forth in Section 8.1.

1.66 **Quality** means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

1.67 **Quality System Regulations** or **QSR** means the then current regulations and standards applicable to the design of medical devices, the organization, procedures and processes for implementing quality management, and good manufacturing practices, which regulations are currently promulgated in Part 820 of Title 21 of the United States Code of Federal Regulations.

1.68 **Reader** means a handheld spectrophotometer or similar device used to measure color change of reagents placed on the palm of the hand and to generate a numeric value for skin Sterol.

1.69 **Recall** has the meaning set forth in Section 13.1.

1.70 **Registration** means a filing with a governmental authority in the Territory for the purpose of obtaining legal and regulatory clearance for a 510(k) Notification submission or approval for a Pre-Market Approval Application to commence making, using, and/or selling a product.

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1.71 **Regulators** means any governmental department, commission, board, bureau, agency, court or other instrumentality within the Territory having jurisdiction over the manufacture, distribution, promotion, use and sale of Product or Non-Field Product, as the case may be, including the FDA.

1.72 **Regulatory Approval** means any and all clearances or approvals (including 510(k) Notifications, Pre-Market Approval Applications, supplements, amendments, label expansions, pre- and post-approvals), licenses, registrations or authorizations of any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use, promotion and sale of Product or Non-Field Product, as the case may be, in the Territory, including FDA Approval.

1.73 **ROW** means all the countries in the world except the U.S.

1.74 **ROW Partners** means the party or parties with whom PreMD may from time to time enter into agreements relating to Product and/or the Field in respect to all or a portion of the ROW.

1.75 **ROW Rights** has the meaning set forth in Section 3.4.

1.76 **Second Milestone** means FDA Approval of the PREVU\* POC Product with labeling substantially in the form below:

[\*\*\*], as measured by PREVU\* POC in patients [\*\*\*], or [\*\*\*], is intended to aid in the assessment of [\*\*\*] and in identification of the presence of [\*\*\*]. PREVU\* POC can be used in conjunction with [\*\*\*] and other [\*\*\*] for [\*\*\*] to aid physicians in determining [\*\*\*]. [\*\*\*]The safety and effectiveness of this device for [\*\*\*] for [\*\*\*] or as a [\*\*\*] or as a [\*\*\*] for other [\*\*\*] for [\*\*\*] have not been established.

1.77 **Second Milestone Completion Date** means the date of FDA Approval of the Second Milestone.

1.78 **Short Term** has the meaning set forth in Section 6.1.1.

1.79 **Specifications** means, in respect of a particular Product, the specifications for the Product and/or the imprinting and bulk packaging thereof including physical, quality analysis and assurance, test methodologies, bulk packaging, handling, shipping and other standards, instructions and procedures for the Product and its raw materials. All Specifications and any changes agreed to by the Parties from time to time shall be in writing. The current Specifications with respect to the PREVU\* POC Product (in its current embodiment set forth in Appendix F) are attached hereto as Appendix H.

1.80 **Sterol** means cholesterol.

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1.81 **Sublicensees** means, collectively, the Third Party Sublicensees and Affiliates of AstraZeneca to which AstraZeneca has granted a sublicense pursuant to Article III hereunder.

1.82 **Term** means the period from the Effective Date until this Agreement is terminated under Article XVII.

1.83 **Territory** means the United States and its territories and possessions.

1.84 **Third Milestone** means FDA Approval of the PREVU\* POC Product with labeling substantially in the form below:

[\*\*\*], as measured by PREVU\* POC, is [\*\*\*] at increased risk of [\*\*\*]PREVU\* POC can be used in conjunction with [\*\*\*], and other [\*\*\*] for [\*\*\*], to aid physicians in identifying [\*\*\*] increased risk of [\*\*\*], and to support physician-patient decisions regarding [\*\*\*]

1.85 **Third Milestone Completion Date** means the date of FDA Approval of the Third Milestone.

1.86 **Third Parties** means any Person other than a Party, an Affiliate of a Party, or a Third Party Sublicensee.

1.87 **Third Party Sublicensees** has the meaning set forth in Section 3.1.1.

1.88 **Title 11** has the meaning set forth in Section 19.13.

1.89 **United States** or **U.S.** means the United States of America (including Puerto Rico) and its territories and possessions.

## ARTICLE II

### DEVELOPMENT OF THE PRODUCT AND JOINT DEVELOPMENT COMMITTEE

2.1 During the Term of this Agreement,

(i) PreMD shall work with AstraZeneca as herein set out in a collaborative alliance to optimize Product in accordance with the terms set forth herein; and

(ii) PreMD shall use Diligent Efforts to gain Regulatory Approval for Commercial Sale of the PREVU\* POC Product having the labeling for the PREVU\* POC Product set forth in Section 1.76 and shall bear all costs in connection therewith; in accordance with all Applicable Laws and the terms set forth herein.

At AstraZeneca's expense and request, PreMD agrees to conform Product supplied to AstraZeneca, including but without limitation the software, to reflect the AstraZeneca Trademarks and commercially reasonable packaging, Product format and labeling Specifications.

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2.2 PreMD shall: (i) as soon as reasonably practicable after the Effective Date, furnish AstraZeneca with all copies of standard operating procedures (SOPs) relating to Licensed Technology presently in PreMD's possession that it is free to disclose; and (ii) provide AstraZeneca with access throughout the Term to such other information regarding manufacture of the Product and the Non-Field Product, as applicable, that it is free to disclose and as AstraZeneca may from time to time request. PreMD shall keep AstraZeneca reasonably informed during the Term of all material technical data, development, and improvements (including Improvements) within PreMD's Licensed Technology. There shall be no change, improvement (including any Improvement) or modification to Product, or any component thereof, implemented or made by PreMD after the Effective Date without the prior written notification to and approval of AstraZeneca. PreMD further agrees that no changes or modifications to the method or process of manufacture or production of the Product, or any component thereof or raw material therefor, or any manufacturer thereof, shall be made without prior written notification to and approval of AstraZeneca.

2.3 **Purpose; Formation of JDC.** Within thirty (30) days the execution and delivery of this Agreement, the Parties shall appoint their respective representatives to a committee to oversee, coordinate and provide strategic direction with respect to future development of Product (the **Joint Development Committee** or **JDC**). The JDC shall terminate on January 1, 2020.

2.3.1 **Membership of JDC.** Each Party shall initially appoint one (1) representative to the JDC. The JDC may change its size from time to time by mutual consent of its members; provided that the JDC shall at all times consist of an equal number of representatives of each of AstraZeneca and PreMD. Each Party may replace its JDC representatives at any time upon written notice to the other Party. The JDC may invite nonmembers to participate in the discussions and meetings of the JDC, provided that such participants shall have no voting authority at the JDC.

2.3.2 **Chairperson of JDC.** AstraZeneca shall name, from among its JDC representatives, a chairperson of the JDC. The chairperson shall be responsible for administering JDC meetings but shall have no additional powers or rights beyond those held by the other representatives on the JDC. The chairperson shall be responsible for preparing minutes of JDC meetings, which shall be circulated for review and approval by all members within thirty (30) days after each meeting.

2.3.3 **Decision-Making.** The JDC shall act by unanimous vote, with each Party's representative having one (1) vote. The Parties shall engage in good faith discussions to reach agreement on all issues presented. If the JDC becomes deadlocked on an issue, then the final decision on any issue will be made by the then current head of the U.S. cardiovascular franchise of AstraZeneca.

The provisions of this Section relating to the final decisions being made by the then current head of the U.S. cardiovascular franchise of AstraZeneca shall relate solely to matters of business and matters of allocation of resources but shall not, for greater certainty, relate to the interpretation of any of the provisions hereof, which matters of interpretation shall, in the absence of a consensual resolution, be dealt with as provided for in Section 19.6 hereof.

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2.3.4 Meetings of JDC. The JDC shall meet at least once per Calendar Quarter until the JDC terminates, unless the Parties mutually agree in writing to a different frequency or to disband the JDC on an earlier date. Each meeting of the JDC will be conducted by means of a conference telephone, videoconference, or similar communications equipment allowing all persons participating in the meeting to hear each other at the same time. Participation by such means shall constitute presence in person at the meeting. Any member of the JDC may call a special meeting of the JDC from time to time to address issues in connection with which a decision or review is reasonably required prior to the next regularly scheduled JDC meeting. Meetings of the JDC shall be effective only if a representative of each Party is present or participating. Each Party shall bear all expenses it incurs in regard to participating in JDC meetings.

2.3.5 Specific Responsibilities of the JDC. In addition to its general responsibility to oversee, coordinate and provide strategic direction with respect to development activities for the Product with respect to the Field and the Territory, the JDC shall in particular be responsible for the activities set forth in Section 2.4 below.

2.3.6 Limited Authority. The members of the JDC shall have the authority to provide consents or approvals as contemplated herein on behalf of their nominating Party, provided that any such consents or approvals shall be in writing and shall expressly refer to the fact that they constitute consents or approvals as contemplated by this Agreement. The JDC shall have no authority to amend this Agreement.

2.4 Responsibilities. The JDC shall be responsible for deciding whether any future Clinical Trials on Product will be performed: (i) for purposes of seeking any further Regulatory Approvals thereon in the U.S. (other than as set forth in Section 2.1(ii)), and (ii) for purposes of providing data to support AstraZeneca's marketing objectives relating to Product. Except as set forth in Section 2.5, the JDC shall determine which Party shall conduct clinical development activities with respect to the Field (excluding the Life Insurance Laboratory Field) and with respect to the Territory and AstraZeneca shall bear all costs related to such activities unless otherwise agreed by the Parties. For the avoidance of doubt and for purposes of this Section 2.4, (x) with respect to the Territory shall mean that the applicable Clinical Trial shall be for purposes of distributing, marketing, promoting and selling Product in the Territory, even if such Clinical Trial (or any part thereof) is conducted physically outside of the Territory; and (y) with respect to outside the Territory shall mean that the applicable Clinical Trial shall be for purposes of distributing, marketing, promoting and selling Product in a location other than the Territory, even if such Clinical Trial (or any part thereof) is conducted physically in the Territory. For example, if a Clinical Trial is for purposes of distributing, marketing, promoting and selling Product in the United Kingdom, but is conducted physically in the United States, such Clinical Trial shall be, for purposes of this Section 2.4, with respect to outside the Territory .

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2.4.1 PreMD shall not commence any Clinical Trial with respect to the Field (excluding the Life Insurance Laboratory Field) and with respect to the Territory without obtaining the JDC's prior written approval therefor. PreMD shall adopt and implement any AstraZeneca requirements with respect thereto.

2.4.2 If PreMD wishes to commence a Clinical Trial with respect to the Field and with respect to outside the Territory, (a) PreMD shall notify AstraZeneca of such proposed Clinical Trial and the scope, activities, direction and sequence thereof; (b) AstraZeneca shall have the opportunity to comment thereon; and (c) PreMD shall have the right not to accommodate AstraZeneca's comments and requests with respect thereto except to the extent AstraZeneca demonstrates that PreMD's decision not to accommodate any such comment or request was unreasonable. AstraZeneca shall provide comments and requests to PreMD within thirty (30) days of the date on which it has received information from PreMD that is sufficiently detailed for AstraZeneca to make an informed decision with respect thereto. In determining whether PreMD's decision not to accommodate AstraZeneca's comments or requests under this Section 2.4.2 was unreasonable, and whether any AstraZeneca comments or requests under Section 2.4.3 were unreasonable, consideration shall be given to how a similarly situated biotechnology research and development company, with financial and human resources similar to those of PreMD, would treat such comments or requests, as well as taking into account the reasonably foreseeable profit potential and the strategic value resulting from the implementation of such comments or requests both inside and outside the Territory, based upon the facts reasonably available to PreMD at the time (including any facts provided to PreMD by AstraZeneca) and any risks associated with not taking into account such comments or requests that have been called to PreMD's attention by AstraZeneca.

2.4.2.1 Subject to Section 2.4.2.2, AstraZeneca shall consider in good faith, on a case-by-case basis, any reasonable request by PreMD for AstraZeneca to waive AstraZeneca's rights under Section 2.4.2(c); provided, however, that nothing in this Section 2.4.2.1 shall obligate AstraZeneca to waive such rights.

2.4.2.2 AstraZeneca shall waive its rights under Section 2.4.2(c) if: (a) PreMD wishes to commence a Clinical Trial with respect to the Field and with respect to outside the Territory; (b) PreMD has granted ROW Rights to a Third Party; and (c) such Third Party is one of the following Persons or a direct or indirect wholly-owned subsidiary thereof:

[\*\*\*]

2.4.3 If PreMD wishes to commence a Clinical Trial with respect to the Life Insurance Laboratory Field and with respect to the Territory, (a) PreMD shall notify AstraZeneca of such proposed Clinical Trial and the scope, activities, direction and sequence thereof; (b) AstraZeneca shall have the opportunity to comment thereon; and (c) PreMD shall accommodate AstraZeneca's comments and requests with respect thereto except to the extent PreMD demonstrates that any such comment or request was unreasonable. AstraZeneca shall provide its requests to PreMD within thirty (30) days of the date on which it has received information from PreMD that is sufficiently detailed for AstraZeneca to make an informed decision with respect thereto.

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2.4.4 PreMD may commence in its discretion a Clinical Trial that is outside the Field (whether such Clinical Trial is inside or outside the Territory). PreMD shall notify AstraZeneca of any such proposed Clinical Trial and the scope, activities, direction and sequence thereof, provided that the compliance with the foregoing obligation shall not result in PreMD being in breach of any obligation which it has to any Third Party.

2.4.5 If AstraZeneca wishes to commence a Clinical Trial with respect to the Field and with respect to the Territory, (a) AstraZeneca shall notify PreMD of such proposed Clinical Trial and the scope, activities, direction and sequence thereof; and (b) PreMD (and any ROW Partner of PreMD) shall have the opportunity to comment thereon, it being understood that AstraZeneca shall have no obligation to accommodate PreMD's (or such ROW Partner's) comments and requests with respect thereto and that AstraZeneca may accept or reject such comments and requests in its sole discretion.

2.4.6 PreMD (and any ROW Partner of PreMD, with respect to Section 2.4.5) and AstraZeneca shall be provided with an opportunity to review all results of any Clinical Trials that may be conducted pursuant to this Section 2.4, provide comments to each other regarding the same, and (except for the Clinical Trials described in Section 2.4.4 and 2.4.5) accommodate the other Party's reasonable requests thereon.

2.5 Except with respect to Clinical Trials (which are addressed in Section 2.4), if PreMD wishes to conduct further development work for Product, whether inside or outside the Territory, in order to make a change, improvement or modification thereto, (a) PreMD shall notify AstraZeneca of such proposed activities and the scope, direction and sequence thereof; and (b) pursuant to Section 2.2, AstraZeneca shall promptly and within a reasonable period of time (not to exceed sixty (60) days) comment thereon and to determine whether AstraZeneca approves thereof. If AstraZeneca does not approve of such activities, (x) AstraZeneca shall have no obligations with respect thereto and (y) PreMD shall not further develop such Product for the Territory; provided, however, PreMD may further develop such Product (whether inside or outside of the Territory) for Exploitation outside the Territory.

2.5.1 If PreMD wishes to conduct such further development work for Product, whether inside or outside the Territory, and AstraZeneca has approved such proposed activities, pursuant to Section 2.2, and has agreed that PreMD shall conduct the proposed activities related thereto, AstraZeneca shall, unless otherwise requested by PreMD, reimburse PreMD for the Project Costs incurred by PreMD in connection therewith. Such costs shall be reimbursed within sixty (60) days of submission to AstraZeneca by PreMD of an invoice with respect thereto (it being understood that such invoices may be submitted periodically during the process of PreMD conducting such activities, and shall not be conditioned on any outcome or results therefrom).

2.5.2 If AstraZeneca wishes to conduct further development work for Product in order to make a change, improvement or modification thereto, AstraZeneca shall notify PreMD thereof. Within a reasonable period of time after PreMD receives such AstraZeneca notification, PreMD shall notify AstraZeneca whether or not PreMD elects to conduct the activities related to such AstraZeneca notification, either inside or outside the Territory.

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- (i) If PreMD elects to conduct such activities, the Parties shall work together to develop the terms that shall apply to such activities. If PreMD conducts such activities, AstraZeneca shall reimburse PreMD for PreMD's Project Costs as provided in Section 2.5.1.
  
- (ii) If PreMD elects not to conduct such activities, AstraZeneca may conduct such activities in the Territory, and any Intellectual Property that is conceived or reduced to practice in connection therewith (the **Modified Technology**) shall be subject to Section 2.6.2.

2.5.3 For the avoidance of doubt, upon completion of the activities proposed under Sections 2.5.1 or 2.5.2(i), if such development activities are successful, PreMD shall provide AstraZeneca with the Specifications for such Product as proposed to be so changed, improved or modified and AstraZeneca shall then have the right pursuant to Section 2.2 to determine, in its sole discretion, whether such Product shall be so changed, improved or modified. If AstraZeneca has conducted such activities pursuant to Section 2.5.2(ii), and, upon completion of such activities, determines that such Product should be changed, improved or modified as a result thereof, AstraZeneca shall provide PreMD with the Specifications for such Product as proposed to be so changed, improved or modified, and PreMD shall cooperate in all reasonable respects with (and at the expense of) AstraZeneca to endeavor to cause such change, improvement or modification to occur in the Territory, including with respect to PreMD's manufacturers, Regulatory Approvals and other necessary steps.

2.6 Any intellectual property rights, including without limitation, patents, patent applications, works of authorship, copyrights, whether registered or not, trade secrets, know-how, designs, technical data, inventions, data, processes, methods, techniques and technology (hereinafter referred to as **Intellectual Property**) owned or controlled by either Party prior to the Parties' entering into this Agreement shall remain the property of such Party, subject only to the rights and licenses granted herein.

2.6.1 Any Intellectual Property that is first conceived and first reduced to practice during the Term of this Agreement solely by personnel employed by or on behalf of PreMD or any of its Affiliates shall remain the property of PreMD or such Affiliate, subject to the rights and licenses granted herein.

2.6.2 Any Intellectual Property that is first conceived and first reduced to practice during the Term of this Agreement solely by personnel employed by or on behalf of AstraZeneca or any of its Affiliates shall remain the property of AstraZeneca or such Affiliate, subject to the rights and licenses granted herein.

2.6.3 Any Intellectual Property that is first conceived or first reduced to practice during the Term of this Agreement by personnel employed by or on behalf of AstraZeneca or any of its Affiliates and personnel employed by or on behalf of PreMD or any of its Affiliates

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(other than the Intellectual Property described in Section 2.6.1 and Section 2.6.2) shall remain the joint property of PreMD and AstraZeneca, subject to the rights and licenses granted herein ( **Joint Intellectual Property** ). Patents and patent applications are only Joint Intellectual Property if AstraZeneca or such Affiliate and PreMD or such Affiliate both have at least one of their respective personnel named as an inventor on the patent or application (such that AstraZeneca and PreMD each has an ownership interest therein), subject to the resolution of any dispute concerning the proper identification of the named inventors according to Section 19.6 of this Agreement. The Parties agree to keep the Joint Intellectual Property in confidence and not to publicly disclose the same except in accordance with Article XV. Notwithstanding the foregoing, none of AstraZeneca, PreMD or any of their respective Affiliates or Sublicensees shall Exploit any Joint Intellectual Property outside the scope of this Agreement without the consent of the other Party, and neither AstraZeneca nor PreMD nor such Affiliates shall assign, pledge, encumber or otherwise transfer any of its rights in any Joint Intellectual Property without the other Party's prior written consent. The Parties agree that any Intellectual Property owned or controlled by PreMD relating to the PREVU\* PT Product, PREVU\* LT Product or PREVU\* POC Product, which is conceived and reduced to practice on or before the Effective Date of this Agreement shall not constitute Joint Intellectual Property, but shall be deemed to be part of the Licensed Technology.

2.6.4 Any Intellectual Property which is owned or controlled or licensable, either in whole or in part, by PreMD or any of its Affiliates during the Term of this Agreement and acquired or developed after the Effective Date shall be added to the Licensed Technology to the extent that the Intellectual Property is relevant to the manufacture, use, sale or Registration of Product ( **PreMD Improvement Intellectual Property** ) (and, for greater certainty, the PreMD Improvement Intellectual Property shall not include the Intellectual Property identified on Appendix B as at the date hereof).

2.7 In the event that a published patent application or a granted patent results from the PreMD Improvement Intellectual Property, such patent application(s) and patent(s):

- (a) shall be included in the Licensed Patents so long as and to the extent that such patent application(s) and patent(s) are relevant to the manufacture, use, sale or Registration of Product, and
- (b) shall be added to Appendix C, which is attached hereto and made a part hereof, within thirty (30) days of filing or grant, whichever is applicable.

Otherwise, for purposes of this Agreement, such PreMD Improvement Intellectual Property relating to the manufacture, use, sale or registration of Product shall be regarded as Licensed Know-How.

2.8 PreMD shall update and amend the list of patent applications and patents within the Licensed Patents as set forth in Appendix B and Appendix C no less frequently than one (1) time per Calendar Year.

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**ARTICLE III**

**LICENSE GRANTS, EXCLUSIVITY, AND OTHER RIGHTS**

3.1 For the Term of this Agreement, subject to Section 3.2, PreMD hereby grants to AstraZeneca, the exclusive (including with regard to PreMD and its Affiliates) right and license, with the unrestricted right to grant sublicenses to AstraZeneca's Affiliates, in and to the Licensed Technology and to Exploit the Licensed Technology for Product (with the exception of the PREVU\* LT Product in the Life Insurance Laboratory Field) in the Field in the Territory.

3.1.1 Third Party Sublicenses: AstraZeneca may also grant sublicenses of such rights to Third Parties, subject to PreMD's prior written approval in respect of sublicenses relating to the Territory (the **Third Party Sublicensees**). PreMD's approval, which shall not be unreasonably withheld, will be deemed granted unless it provides written objection within twenty (20) days of AstraZeneca's written notification of its desire to grant a particular sublicense.

3.1.2 The rights and licenses contemplated herein may only be exercised by AstraZeneca and/or its Sublicensees as specifically contemplated in this Agreement.

3.1.3 Provided that PreMD fulfills AstraZeneca's supply and manufacture requirements as set forth in Articles VI and VII, AstraZeneca will not exercise its rights to make Product or have Product made.

3.1.4 Attached hereto as Appendix I is PreMD's marketing plan for the PREVU\* LT Product in the Life Insurance Laboratory Field in the Territory, as of the Effective Date. PreMD shall provide any amendment thereto as soon as practicable, but in any event within forty (40) days of amendment of such marketing plan. For the avoidance of doubt, PreMD is not obligated to provide the marketing plan of any Third Party with whom PreMD or any of its Affiliates may enter into an agreement with respect to the PREVU\* LT Product.

3.1.4.1 PreMD agrees, and shall cause its Affiliates to agree, that any sale of the PREVU\* LT Product in the Life Insurance Laboratory Field (and any marketing plan associated therewith) shall comply with Applicable Laws and the terms set forth herein applicable to the PREVU\* LT Product in the Life Insurance Laboratory Field. PreMD agrees that it shall cause it and its Affiliates to not, directly or indirectly, knowingly Exploit the PREVU\* LT Product outside the Life Insurance Laboratory Field in the Territory and to use Diligent Efforts to remedy any such prohibited Exploitation. PreMD shall cause sales of the PREVU\* LT Product by PreMD and its Affiliates to be subject, at a minimum, to the following restrictions, among other restrictions that PreMD shall observe to ensure compliance with the terms of this Agreement (in each case such restrictions being limited to the Life Insurance Laboratory Field in the Territory): (a) the PREVU\* LT Product shall [\*\*\*] (or to the divisions of [\*\*\*] which are focused on [\*\*]) and their relevant personnel including [\*\*\*] and [\*\*\*] and [\*\*\*] acting under the direction of the [\*\*\*]; (b) PreMD [\*\*\*] and [\*\*\*] to the PREVU\* LT Product [\*\*\*] only to [\*\*\*] in connection with [\*\*\*]; (c) PreMD [\*\*\*]; (d) only [\*\*\*] from

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\*\*\* with a \*\*\* bar-code (or labels identifying the device as a \*\*\*) will be \*\*\* and \*\*\* will only be \*\*\*; and (e) the package \*\*\* the PREVU\* LT Product \*\*\* that the \*\*\* is only to be \*\*\* and such \*\*\* will be placed prominently in the labels and labeling under a section headed \*\*\* will also be \*\*\* in the \*\*\* for \*\*\* to the \*\*\* for the PREVU\* LT Product, but if the \*\*\* as part of the \*\*\* for \*\*\*, it will be \*\*\* in the \*\*\* and \*\*\*.

3.1.4.2 PreMD agrees, and shall cause its Affiliates to agree, that all agreements entered into by PreMD or any of its Affiliates with a Third Party with respect to a collaboration in the Territory relating to the marketing and distribution of the PREVU\* LT Product in the Life Insurance Laboratory Field (excluding, for greater certainty, any Third Party which is purchasing such Product without an intent to resell) shall contain the following requirements (which requirements PreMD shall use Diligent Efforts to enforce): (a) such Third Party shall agree that any sale of the PREVU\* LT Product in the Life Insurance Laboratory Field shall comply with Applicable Laws and the terms set forth in this Agreement applicable to the PREVU\* LT Product in the Life Insurance Laboratory Field; (b) such Third Party shall not, directly or indirectly, knowingly Exploit the PREVU\* LT Product outside the Life Insurance Laboratory Field in the Territory and shall use Diligent Efforts to remedy any such prohibited Exploitation; (c) such Third Party shall cause sales of the PREVU\* LT Product to be subject, at a minimum, to the following restrictions, among other restrictions that such Third Party shall observe to ensure compliance with the terms of the agreement with PreMD or PreMD's Affiliate, as applicable: (i) the PREVU\* LT Product shall \*\*\* be provided to \*\*\* (or to the divisions of \*\*\* which are focused on \*\*\*) and their relevant personnel including \*\*\* and \*\*\* persons acting under the direction of the \*\*\*; (ii) PreMD \*\*\* the PREVU\* LT Product in the \*\*\* only to \*\*\* in connection with \*\*\* (iii) PreMD \*\*\*; (iv) only \*\*\* from \*\*\* with a \*\*\* bar-code (or labels identifying the device as a \*\*\*) will be t\*\*\* will only be \*\*\* and (v) the package \*\*\* the PREVU\* LT Product \*\*\* that the \*\*\* is only to be \*\*\* and such \*\*\* will be placed prominently in the labels and labeling under a section headed \*\*\*, and such \*\*\* will also be \*\*\* in the \*\*\* for \*\*\* to the \*\*\* for the PREVU\* LT Product, but if the \*\*\* as part of the \*\*\* for \*\*\*, it will be \*\*\* in the \*\*\* and \*\*\*; and (d) \*\*\* shall be the \*\*\* of such \*\*\* and \*\*\* such \*\*\* by \*\*\*, among other things, \*\*\* and may obtain \*\*\* of any such \*\*\*.

3.1.4.3 In the event that (a) PreMD fails, or fails to cause its Affiliates, to comply with the requirements set forth in Section 3.1.4.1; (b) PreMD fails, or fails to cause its Affiliates, to include in the agreements with Third Parties described in Section 3.1.4.2 the requirements described in Section 3.1.4.2; or (c) PreMD fails, or fails to cause its Affiliates, to use Diligent Efforts to enforce the requirements described in Section 3.1.4.2 that are included in such agreements with Third Parties, then AstraZeneca may, in its sole discretion and without waiver of any other remedies or rights it may have, set off against any amounts AstraZeneca is obliged to pay PreMD pursuant to Section 4.1 an amount equal to the profit on sale of Product that AstraZeneca would have made absent any such PreMD failure (the Set-Off Amount ). The Parties acknowledge and agree that any such lost profits shall be considered direct damages for purposes of this Agreement and thus not subject to the limitation on damages imposed by Section 11.6 of this Agreement. Within twenty (20) days after any such set-off, AstraZeneca shall provide to PreMD information sufficient to show how AstraZeneca calculated the Set-Off

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Amount, including (i) the basis for AstraZeneca's conclusion that PreMD failed to meet its obligations under Section 3.1.4 and (ii) a reasonably detailed calculation of the Set-Off Amount. After the earlier of (x) the receipt of such information by PreMD and (y) the thirtieth (30<sup>th</sup>) day after such set-off, PreMD may, pursuant to Section 19.6, dispute whether AstraZeneca properly exercised its set-off rights and/or the calculation of the Set-Off Amount. In the event of an arbitration under Section 19.6, AstraZeneca shall have the burden to prove, by a preponderance of the evidence, PreMD's failure that is the basis for AstraZeneca's set-off and the amount of the Set-Off Amount.

3.2 In the event of a Change of Control (as defined below) of PreMD by any Person after the Effective Date, the rights and licenses granted or referenced in Section 2.6.3, 2.6.4 or 3.1 shall apply to the extent the Intellectual Property of such Person and its Affiliates constitutes, as applicable, Joint Intellectual Property, PreMD Improvement Intellectual Property or Licensed Technology, unless, and to the extent, PreMD demonstrates that any such Intellectual Property was developed (a) independent of (i) confidential information of PreMD, or any subsidiary of PreMD existing before or after such Change of Control, or any of PreMD's Affiliates that were in existence immediately prior to such Change of Control and (ii) then existing patents or patent applications relating to Product; and (b) without the assistance of personnel employed by or on behalf of PreMD, or any subsidiary of PreMD existing before or after such Change of Control, or any of PreMD's Affiliates that were in existence immediately prior to such Change of Control. To the extent any such Intellectual Property meets the criteria set forth in (a) and (b) above, and to the extent any such Intellectual Property results in a product that is used to measure, diagnose, monitor or predict skin Sterol in humans on areas of the body with no sebaceous glands (i.e., the palms of the hands and the soles of the feet), such product shall be a Competing Product. For purposes of this Section 3.2, Change of Control with respect to PreMD shall mean an event in which any other Person or group of Persons acquires control of PreMD.

3.3 PreMD hereby grants to AstraZeneca, for the Term of this Agreement, the right to use, copy, display and otherwise make use of the assets specified in Appendix J (including the right to use, copy, display, modify and create derivative works of the content of the PREVU\* Website files). For clarification, the Parties agree that the foregoing right shall not permit AstraZeneca to modify the content that PreMD actually displays on any PreMD website.

3.4 During the [\*\*\*], the Parties shall enter into good faith negotiations regarding the grant by PreMD of an exclusive license in and to the Licensed Technology and to Exploit the Licensed Technology for Product (with the exception of the PREVU\* LT Product in the Life Insurance Laboratory Field) in the ROW (the **ROW Rights**).

3.4.1 In the event that Parties have not executed a definitive agreement with respect to the ROW Rights by [\*\*\*], AstraZeneca, in its sole discretion, shall have the right to pay to PreMD [\*\*\*] Dollars (\$[\*\*\*]) and, in consideration therefor, PreMD shall extend the time period in which the Parties may continue their negotiations of the terms of a definitive agreement with respect to the ROW Rights until [\*\*\*] (the period from [\*\*\*] to [\*\*\*] being referred to herein as the **Extended Period**).

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3.4.2 In consideration of Sections 3.4 and 3.4.1, PreMD shall not grant the ROW Rights to any other Person or solicit, offer or negotiate, or permit its Affiliates or representatives to solicit, offer or negotiate, from or with any other Person a grant of such ROW Rights (the **Lock-Up** ) (i) prior to the end of the third [\*\*\*] and (ii) during the Extended Period if AstraZeneca elects to exercise its right under Section 3.4.1.

3.4.3 If AstraZeneca determines that it does not wish to acquire the ROW Rights, AstraZeneca shall promptly notify PreMD, and the Lock-Up shall terminate upon receipt by PreMD of such notice.

3.4.4 If the Parties enter into a definitive agreement with respect to the ROW Rights, [\*\*\*].

3.5 AstraZeneca covenants that it and its Affiliates (a) shall not, directly or indirectly, knowingly Exploit Product (i) outside the Territory, (ii) to a Third Party in the Territory outside the Field, (iii) to a Third Party in the Territory in the Life Insurance Laboratory Field or (iv) to a Third Party in the Territory for Exploitation outside of the Territory, and (b) shall use Diligent Efforts to remedy any such prohibited Exploitation.

#### ARTICLE IV

##### PAYMENTS AND REPORTS

4.1 **Running Royalty Payments:** As consideration for the rights granted herein by PreMD to AstraZeneca, AstraZeneca hereby agrees to make the following royalty payments to PreMD.

4.1.1 Except as set forth in Sections 4.1.2 and 4.1.3, commencing in the Calendar Year of the First Commercial Sale of a Product in the Territory by AstraZeneca, its Affiliates and Sublicensees and each Calendar Year thereafter, AstraZeneca will pay to PreMD the greater of:

(a) a running royalty based upon any Net Sales of Product (excluding the Reader), at the rate of twenty percent (20%) of Net Sales (excluding the Reader); and

(b) [\*\*\*] (\$[\*\*]) per unit of Product sold (excluding the Reader); provided, however, that AstraZeneca shall pay PreMD a royalty at the rate of twenty-five percent (25%) of Net Sales (excluding the Reader) for that portion of aggregate Net Sales of all Product (excluding the Reader) that exceeds Thirty Million Dollars (\$30,000,000) during the Calendar Year of such First Commercial Sale and in any Calendar Year thereafter. For the avoidance of doubt, the twenty-five percent (25%) royalty rate shall be paid only in any Calendar Year in which the aggregate Net Sales of all Product (excluding the Reader) sold by AstraZeneca and its Affiliates and Sublicensees in the Territory exceeds Thirty Million Dollars (\$30,000,000).

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4.1.2 Commencing in the Calendar Year of the First Commercial Sale of the PREVU\* POC Product in the Territory by AstraZeneca and each Calendar Year thereafter, AstraZeneca will pay a running royalty to PreMD based upon any Gross Profit of Readers, at the rate of [\*\*\*] percent ([\*\*\*]%) of Gross Profit.

4.1.3 **Competition Adjustment:** In the event that: (i) a Competing Product has been granted approval or cleared by the FDA for sale or distribution in the U.S. and is sold in the Territory (i) by any Third Party or (ii) by an Affiliate of PreMD pursuant to the circumstances described in Section 3.2, then the royalty rates payable to PreMD, pursuant to Section 4.1.1, shall be reduced by [\*\*\*] percent ([\*\*\*]%); and (ii) more than one (1) such Competing Product is sold in the Territory, the royalty rates payable to PreMD, pursuant to Section 4.1.1, shall be reduced by [\*\*\*] percent ([\*\*\*]%). Such reduction in the royalty rates shall commence in the Calendar Quarter in which such Competing Product(s) are first sold. In the event such royalty rates are reduced pursuant to this Section 4.1.3, the payments required to be made by AstraZeneca pursuant to Sections 4.1.1(b) or 4.1.4 shall be reduced by [\*\*\*] percent ([\*\*\*]%).

4.1.4 Commencing in Calendar Year 2008 and in any Calendar Year thereafter, if the amounts paid pursuant to Sections 4.1.1 and 4.1.2 total less than [\*\*\*] Dollars (\$[\*\*\*]) in the aggregate, AstraZeneca shall make a payment within thirty (30) days of end of such Calendar Year, of an amount equal to the difference between [\*\*\*] Dollars (\$[\*\*\*]) and the amounts paid pursuant to such Sections for such Calendar Year.

4.2 Except as may be provided in the definition of Net Sales, no royalties due under this Article shall be payable on sales transactions as between AstraZeneca and any of its Sublicensees (unless such Sublicensee is not acquiring Product for the purposes of resale or redistribution), it being the intention of the Parties that the amount generated from the final vendee sale to a Third Party alone shall (except as otherwise provided in the definition of Net Sales) be used for the purposes of determining the royalty payments due hereunder. For greater certainty, only one royalty payment shall be payable on the sale of each Product, and the amount of such royalty will be provided in accordance with the rate set forth in Sections 4.1.1 and 4.1.2 and the sales date of the Product to a Third Party shall be deemed to be made in accordance with Section 1.51.2.

4.3 **One-Time Payment Based Upon Execution of this Agreement:** As promptly as practicable, but in any event, within ten (10) days of the execution of this Agreement, AstraZeneca will pay PreMD a one-time payment of Five Hundred Thousand Dollars (\$500,000).

4.4 **One-Time Milestone Payment Based Upon FDA Approval:** As promptly as practicable, but in any event, within thirty (30) days of the Second Milestone Completion Date, AstraZeneca will pay PreMD a one-time milestone payment of [\*\*\*] Dollars (\$[\*\*\*]).

4.5 **Milestone Payments Based Upon Net Sales:** AstraZeneca shall make the following one-time lump sum milestone payments to PreMD in the following amounts:

- (a) [\*\*\*] Dollars (\$[\*\*\*]) within thirty (30) days after the last day of the Calendar Quarter in which cumulative Net Sales of all Product (excluding the Reader) first exceeds [\*\*\*] Dollars (\$[\*\*\*]).

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- (b) [\*\*\*] Dollars (\$[\*\*\*) within thirty (30) days after the last day of the Calendar Quarter in which cumulative Net Sales of all Product (excluding the Reader) first exceeds [\*\*\*] Dollars (\$[\*\*\*)).
- (c) [\*\*\*] Dollars (\$[\*\*\*) within thirty (30) days after the last day of the Calendar Quarter in which cumulative Net Sales of all Product (excluding the Reader) first exceeds [\*\*\*] Dollars (\$[\*\*\*)).
- (d) [\*\*\*] Dollars (\$[\*\*\*) within thirty (30) days after the last day of the Calendar Quarter in which cumulative Net Sales of all Product (excluding the Reader) first exceeds [\*\*\*] Dollars (\$[\*\*\*)).

No payment in this Section will be made more than once irrespective of the number of times the milestone events set forth in this Section have been achieved.

**4.6 One-Time Milestone Payment Based Upon Outcomes Prediction Label:** As promptly as practicable, but in any event, within thirty (30) days of the Third Milestone Completion Date, AstraZeneca will pay PreMD a one-time milestone payment of [\*\*\*] Dollars (\$[\*\*\*)), reduced by the amount, if any, not to exceed [\*\*\*] Dollars (\$[\*\*\*)), which AstraZeneca has paid for the Clinical Trial that results in the FDA Approval for such Third Milestone.

4.7 AstraZeneca shall keep true and accurate records and books of account containing all data reasonably required for the computing of and verification of the Net Sales and payments to be made in accordance with this Article. Such records shall be retained for at least the period of time that documentation must be preserved in accordance with the requirements and guidelines of applicable government authorities (but in no event less than seven years) and shall be available during normal business hours and no more than once during each Calendar Year for inspection by an independent certified public accountant, certified general accountant or chartered accountant to whom AstraZeneca has no reasonable objection, on its behalf for the sole purpose of verifying the amount of payments to be made hereunder. The accountant shall disclose to PreMD only information relating to the accuracy of the royalty report and the royalty payments made according to this Agreement. The information received by the accountant shall be held confidential except for information necessary for disclosure to PreMD to establish the accuracy of the royalty reports. In the event that any such inspection shows an under-reporting and underpayment for any three-month period, then AstraZeneca shall pay such shortfall amount to PreMD within forty-five (45) days after the end of the Calendar Quarter in which AstraZeneca received notice of such shortfall. In the event that any such inspection shows an over-reporting and overpayment for any three-month period, then AstraZeneca shall reduce any then current royalty payments owed to PreMD by such amount. In the event that any such inspection shows an under-reporting and underpayment in excess of five percent for any three-month period, then PreMD shall also be entitled to be reimbursed for the reasonable cost of the inspection.

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4.8 All royalties shall be calculated and payable on a Calendar Quarter basis as of the end of the each Calendar Quarter, and royalties shall be paid within thirty (30) days following the end of such Calendar Quarter. Each such payment shall be accompanied by a written report (in the format attached as Appendix K) indicating the amount of Net Sales during such Calendar Quarter and a calculation of the royalties due and such other information as called for in the format attached as Appendix K. AstraZeneca shall deliver the written report for each such Calendar Quarter, regardless of whether any royalties are required to be paid in that Calendar Quarter, commencing in the first Calendar Quarter following the date of the First Commercial Sale of any Product by AstraZeneca. Each such report shall state, separately for AstraZeneca and each Affiliate and Sublicensee, the number, description, and aggregate Net Sales of each Product sold during the Calendar Quarter upon which a royalty is payable under this Agreement.

4.9 All payments due under this Agreement to PreMD shall be made by bank wire transfer in immediately available funds to accounts designated in writing by PreMD from time to time. All payments to PreMD or to AstraZeneca hereunder shall be in lawful currency of the United States. Any payment due hereunder that is not paid by ten (10) days after the payment's due date shall accrue interest, which must be paid by the Party with the payment obligation to the recipient Party, on a daily basis at a rate equal to the then-applicable prime rate as published in *The Wall Street Journal* on the first day of the month in which the payment is due (or the maximum amount permitted by law, if less) from the date first owed until paid.

4.10 In the event AstraZeneca grants sublicenses to an Affiliate or a Third Party Sublicensee to sell Product, or otherwise grants rights to, or enters into arrangements with, its Affiliates or a Third Party Sublicensee to sell Product, such sublicenses, rights and arrangements shall include an obligation for the Sublicensee to account for and report its sales of Product in accordance with the terms set forth in this Agreement as if such sales were Net Sales by AstraZeneca, and AstraZeneca shall pay to PreMD, with respect to such sales, royalties as if such sales of the Sublicensee were Net Sales of AstraZeneca.

## ARTICLE V

### GOVERNMENT AUTHORIZATIONS

5.1 **Regulatory Approval:** Except with respect to the PREVU\* LT Product in the Life Insurance Laboratory Field, PreMD shall use Diligent Efforts to obtain and maintain all necessary Regulatory Approvals of Product in the Territory, at PreMD's sole cost in accordance with the terms of this Agreement and all Applicable Laws, and PreMD shall own all such Regulatory Approvals.

5.2 **AstraZeneca Regulatory Approval:** Notwithstanding anything contained in Section 5.1 or elsewhere in this Agreement to the contrary, upon written notice to PreMD, if in AstraZeneca's reasonable judgment PreMD has not been effectively prosecuting or managing any then existing Registrations for Product or any then existing Regulatory Approvals for Product (including any then existing 510(k) Notification submissions or then existing Pre-Market Approval Applications), or effectively managing its relationship with Regulators, AstraZeneca

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shall have the right (but not the obligation) at any time to elect to prepare, file, and prosecute a new Registration to obtain Regulatory Approval for any then existing or new Product in the Territory, and shall have the right to use all data and information related to Product that is available to PreMD as AstraZeneca may reasonably require for all such regulatory filings of Product in the Territory. If AstraZeneca exercises such right, AstraZeneca shall use Diligent Efforts to obtain and maintain all necessary Regulatory Approvals of such Product in the Territory, at its sole cost in accordance with the terms of this Agreement and all Applicable Laws. For the avoidance of doubt, such right to elect to prepare, file and prosecute a Registration shall not apply to any then existing Registrations of PreMD s for Product or any then existing Regulatory Approvals of PreMD s for Product. Each Party agrees to provide a right of reference to data contained in regulatory filings related to Product for which it has obtained (or applied for) Regulatory Approval as the other Party may reasonably require for its regulatory filings. AstraZeneca shall bear all regulatory expenses related to AstraZeneca s submissions of any such Registration for such Product in the Territory, and AstraZeneca shall be the sole communicator with the Regulators for all regulatory issues concerning such Product. Notwithstanding the above, PreMD agrees to participate in communications with any Regulators upon the request of AstraZeneca. PreMD shall thereafter be precluded from preparing, filing, and/or otherwise prosecuting a Registration to obtain Regulatory Approval for such Product in the Territory either alone or with a Third Party, without the prior written consent of AstraZeneca. If AstraZeneca elects to file and prosecute in its name all relevant regulatory filings for such Product in the Territory, AstraZeneca shall be responsible for undertaking, and paying all costs associated with, any Clinical Trial required to be undertaken in order to obtain such Regulatory Approval for that Product in the Territory.

5.3 AstraZeneca shall have the right to participate with PreMD in communications with the governmental health authorities in the Territory for all issues relating to a Product. Each Party shall promptly provide copies to the other Party of all correspondence received from any governmental health authorities in the Territory relating to any Product and shall consult with the other Party prior to responding to any such correspondence and prior to initiating any other communications with any governmental health authorities in the Territory relating to any Product. Notwithstanding the foregoing, nothing contained herein shall limit or restrict a Party s right to respond to such authorities within the timeframe required and if the other Party does not provide input and comments on a timely basis, no breach shall arise hereunder in respect of the failure to consider the other Party s comments, provided that the other Party has received 24 hours notice of the intention of such Party to invoke the provisions of this sentence.

5.4 AstraZeneca shall have the responsibility of communicating with consumers and the health care profession regarding Product in the first instance, and some of these communications may relate to Product Quality Complaints related to Product. AstraZeneca shall establish a method by which it may receive such Complaints by telephone in respect of Product.

5.5 Except to the extent AstraZeneca is required to do so under Applicable Laws, PreMD shall be solely responsible for the preparation, submission and prosecution of any application, report, submission and response to any Regulators in connection with Product, including, to the extent required by Applicable Laws, reporting Adverse Device Effects, MDR

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Reportable Events, and Notices of Correction and Removal; provided that when feasible PreMD shall consult with AstraZeneca with respect to any such matter and give due consideration to any comments provided by AstraZeneca. PreMD shall notify AstraZeneca of all communications with any Regulators concerning Product within ten (10) days of receipt of any such communication and shall, to the extent permitted by Applicable Laws, attach copies of all such communications to the notice sent pursuant to this Section; provided, however, if AstraZeneca has, pursuant to Section 5.2, elected to prepare, file and prosecute a Registration with respect to Product, then the foregoing sentence shall be read as if AstraZeneca has the obligations to so notify PreMD, solely with respect to such Product.

PreMD shall be solely responsible for investigating all Product Quality Complaints, Adverse Device Effects, and MDR Reportable Events in respect of Product, in each case, to the extent required by Applicable Laws, except to the extent AstraZeneca is required to do so under Applicable Laws.

AstraZeneca shall cooperate with all of PreMD's reasonable requests and use its reasonable efforts to assist PreMD in connection with (i) preparing any and all such reports with Regulators, and (ii) investigating and responding to any Product Quality Complaint or Adverse Device Effect or MDR Reportable Event related to Product.

**5.6 Adverse Event and Product Quality Complaint Notification and Reporting:** AstraZeneca shall provide notice to PreMD within five (5) days from the time it becomes aware of any Product Quality Complaint or any Adverse Device Effect or any MDR Reportable Event associated with use of Product (whether or not the reported effect is determined to be attributable to such Product) and of any information in or coming into its possession or control concerning such Product Quality Complaint, Adverse Device Effect or MDR Reportable Event by contacting the PreMD Information Center at such telephone number as PreMD may from time to time designate or by completing the complaint registration forms provided by PreMD and submitting such form to PreMD. Such notice shall be confirmed in writing within three (3) days of the original notification.

AstraZeneca shall notify PreMD within one (1) Work Day, as defined in 21 C.F.R. § 803.3, of the time it becomes aware of any information that might necessitate the filing by PreMD of an MDR Reportable Event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, as required under 21 C.F.R. § 803.53 (a **5-Day Report** ), or a Notice of Correction and Removal as required under 21 C.F.R. § 806.10, as such regulations may be amended from time to time, by contacting the PreMD Information Center by telephone at such telephone number as PreMD may from time to time designate. Such notice shall be confirmed in writing within three (3) days of the original notification.

PreMD shall provide notice to AstraZeneca within five (5) days from the time it becomes aware of any Product Quality Complaint or any Adverse Device Effect or any MDR Reportable Event associated with use of Product or Non-Field Product (whether or not the reported effect is determined to be attributable to such Product or Non-Field Product) and of any information in or

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coming into its possession or control concerning such Product Quality Complaint, Adverse Device Effect or MDR Reportable Event by contacting the AstraZeneca Information Center at such telephone number as AstraZeneca may from time to time designate. Such notice shall be confirmed in writing within three (3) days of original notification. In the event AstraZeneca is conducting a Clinical Trial, developing information for a Registration, or holding a Regulatory Approval for a Product, then PreMD shall notify AstraZeneca within one (1) Work Day, as defined in 21 C.F.R. § 803.3, of the time PreMD becomes aware of any Adverse Device Effect or MDR Reportable Event with respect to such Product, confirmed in writing within three (3) days of the original notification. PreMD shall also notify AstraZeneca immediately of any formal communication received by PreMD from the FDA regarding any threatened or pending action that may affect the safety or efficacy claims of Product or Non-Field Product or the continued marketing of Product or Non-Field Product.

AstraZeneca shall immediately notify PreMD of any information AstraZeneca receives regarding any threatened or pending action by any Regulator that may affect the safety or efficacy claims of Product or the continued marketing and promotion of Product. Upon receipt of any such information, PreMD shall consult with AstraZeneca in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing herein shall restrict PreMD's ability to make a timely report of such matter to any Regulator or take other action that it deems to be appropriate or required by Applicable Laws.

PreMD shall inform AstraZeneca of any information, announcements, reports, submissions, communications, resolutions, actions, decisions or meetings, in each case involving any Regulator, regarding the Product or Non-Field Product.

## ARTICLE VI

### SUPPLY REQUIREMENTS

6.1 During the Term of this Agreement in the Territory, and subject to the provisions of this Article VI, PreMD shall have manufactured for and supply to AstraZeneca, all Product as may be required of PreMD by AstraZeneca, and AstraZeneca shall purchase all of its requirements for Product from PreMD, all of which shall be manufactured in accordance with their respective Specifications.

6.1.1 In the event that PreMD is unable to supply all Product as may be required by AstraZeneca from the manufacturing facilities as referred to in Section 7.4 because of either: (i) a force majeure as detailed in Section 19.5, which force majeure continues uninterrupted for a period in excess of ninety (90) days; or (ii) a failure to meet binding estimates for expected purchases of Product pursuant to the forecasts provided pursuant to Section 6.2 hereof for a consecutive two (2) month period, AstraZeneca may, pursuant to Section 3.1.3, exercise its right to make Product or have Product made, and PreMD hereby permits AstraZeneca and its Affiliates to exercise such right to make and have made Product anywhere in the world (notwithstanding the terms of Section 3.1) solely for sale in the Territory. In such event, PreMD shall then promptly provide AstraZeneca with all Product Specifications and quality and standard

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operating procedures that it has not yet otherwise received pursuant to Section 2.2, and shall further use Diligent Efforts to provide AstraZeneca with reasonable and necessary training to enable AstraZeneca and its Sublicensees, or a Third Party designee thereof, to manufacture the Product. PreMD shall cooperate and make Diligent Efforts necessary to facilitate the manufacture of that Product under this Section 6.1.1 by AstraZeneca or its Sublicensees with a view to allowing such to be lawfully manufactured, imported and distributed under the FDA Approval held by PreMD for Product. In the event that AstraZeneca enters into a supply agreement with a Third Party for the supply of Product in accordance with this Section 6.1.1, AstraZeneca shall use reasonable efforts to obtain a short term supply contract ( **Short Term** ) for the supply of such Product. This right to manufacture or have manufacture shall exist only for that period of time during which the force majeure and/or production limitations continue to exist and, in the event that AstraZeneca enters into a supply contract with a Third Party, throughout the Short Term, after which such right shall immediately terminate (and, for greater certainty, AstraZeneca shall be entitled to sell or otherwise distribute such levels of inventories of such Product). For greater certainty, the Parties acknowledge that such right shall not be operative in connection with any failure by PreMD to meet revised projections for formerly binding estimates provided pursuant to succeeding forecasts. Subject to Section 10.3, PreMD shall reimburse any extra costs paid to Third Parties that AstraZeneca shall incur as a result of PreMD's failure to supply AstraZeneca's required quantities of Product.

6.1.2 In the event that AstraZeneca believes that:

- (i) one or more components of any Product may be obtained at an appropriate quality level for a lower price than supplied through PreMD, or
- (ii) the supply of any Product or one or more components of any Product may be improved through sources other than through PreMD's suppliers;

and AstraZeneca identifies to PreMD a potential supplier (the **Alternate Supplier** ) anywhere in the world that is satisfactory to PreMD in the exercise of its reasonable discretion and that is able to manufacture Product or such components, as the case may be, in accordance with the Specifications and the appropriate ISO, QSR and GMP standards, then provided that the obtaining of such components would not have an effect on the Regulatory Approvals relating to the marketing of such Product (or, if they will affect such approvals, that such approvals may be obtained on reasonable terms if the Alternate Supplier supplies the Product and if AstraZeneca agrees to incur all costs associated with obtaining such approvals on such amended terms), PreMD shall enter into a supply agreement with the Alternate Supplier on terms and conditions satisfactory to PreMD and AstraZeneca.

6.1.2.1 AstraZeneca shall reimburse PreMD for all reasonable costs paid to Third Parties in connection with entering into supply arrangements with the Alternate Supplier and in connection with determining whether the Alternate Supplier will be able to manufacture the Product in accordance with the Specifications and that such arrangements will not affect any governmental or regulatory approvals obtained or required to be obtained to market such Product (and, if they will affect such approvals, whether such approvals may be obtained on reasonable

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terms if the Alternate Supplier supplies the Product). AstraZeneca shall further indemnify and hold PreMD harmless from all liabilities and obligations arising under such supply arrangements for Product or any component thereof with the Alternate Supplier relating to any payments which PreMD shall be required to make in connection therewith relating to obtaining such supply (including, without limitation, any up-front payments and any minimum quantities which must be purchased).

6.1.2.2 Notwithstanding anything contained in this Agreement, PreMD shall have no liability to AstraZeneca as a result of any breach or non-performance of an Alternate Supplier that provides Product unless (i) PreMD shall have expressly agreed in writing with AstraZeneca that the provisions of this Section 6.1.2.2 shall not apply and the indemnification provisions of Section 6.1.2.1 shall not apply; or (ii) PreMD has contracted with the Alternate Supplier on an exclusive basis for the supply of Product; or (iii) the breach or non-performance of the Alternate Supplier resulted from an act or omission by PreMD.

6.2 No earlier than [\*\*\*] and thereafter by the [\*\*\*] day of each succeeding calendar month, AstraZeneca shall provide PreMD with an estimate of and commitment for its expected purchases of each Product (and, if applicable, the particular components thereof, such as devices and reagents, in the event that they are to be purchased separately or in varying quantities) in each of the following twelve (12) months, which forecast shall be (i) non-binding in respect of each of the last nine (9) months of such twelve (12) month period; and (ii) binding in respect of each of the first three (3) months of such twelve (12) month period. Each succeeding forecast shall revise any preceding forecasts (but shall not amend any month in respect of which there was a binding commitment except with the consent of PreMD). To the extent that any succeeding forecast reflects revised increased projections for purchases for a month for which a binding estimate has already been given through a prior forecast, PreMD shall use Diligent Efforts to meet such increased demand but shall have no liability to AstraZeneca if it is unable for any reason to do so. The form of estimate and commitment of AstraZeneca with respect to Product is attached as Appendix L hereto. Notwithstanding anything contained herein, PreMD shall have no liability to AstraZeneca in respect of the failure to deliver Product in respect of which a binding commitment has not been made by AstraZeneca hereunder. All forecasts and commitments by AstraZeneca shall be subject to the provisions of Section 6.3 hereof.

6.3 AstraZeneca shall place, and PreMD shall use Diligent Efforts to fulfill, purchase orders for Product in the following manner:

6.3.1 AstraZeneca shall place purchase orders for Product with PreMD from time to time in accordance with the amounts committed under Section 6.2, but no later than the fifteenth (15<sup>th</sup>) day of the month in which such amount is committed under Section 6.2, specifying (i) the quantities of Product desired and (ii) the dates by which Product is to be available for pick-up by or on behalf of AstraZeneca from PreMD's manufacturer or supplier (it being understood that AstraZeneca shall be responsible for distributing such Product therefrom);

6.3.2 Within fifteen (15) days after the purchase order date, PreMD shall (i) make such quantities of Product available for shipment from PreMD's manufacturer or supplier;

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(ii) complete all applicable product approval and release requirements; and (iii) provide AstraZeneca with a copy of the certificate of analysis with respect to the applicable batch or lot associated with such purchase order, unless previously provided by PreMD; and

6.3.3 PreMD agrees to use Diligent Efforts to fulfill purchase orders, including such as may be in excess of the forecast amounts which are binding pursuant to Section 6.2, but shall have no obligation to accomplish such fulfillment beyond such binding forecast amounts. Should the purchase orders, in any given period, exceed the forecast amounts which are binding pursuant to Section 6.2, the Parties shall jointly undertake commercially reasonable activities to attempt to fulfill such requirements. AstraZeneca shall be responsible for making all commercially reasonable arrangements necessary associated with delivery of Product and/or the components thereof; provided, however, that such items must be picked up within the month in which the corresponding amounts are committed under Section 6.2.

6.4 Title shall pass to AstraZeneca at [\*\*\*] Product [\*\*\*] or [\*\*\*].

6.5 Subject to the foregoing provisions of this Article VI, PreMD shall use Diligent Efforts to satisfy all purchase orders of all ordered Product, so that such Product is available for shipment from PreMD's manufacturer or supplier no later than the shipment dates provided in AstraZeneca's purchase orders to the place(s) and in the manner directed by AstraZeneca.

6.6 As of the time when title to the Product is transferred to AstraZeneca, PreMD warrants that Product will conform to the Specifications.

6.7 PreMD and its selected manufacturer shall perform quality control tests and assays consistent with PreMD's ISO policies and procedures and as set forth in Appendix M, on all packaging, raw materials and finished Product or portions thereof, in accordance with the Specifications, and PreMD's and its selected manufacturer's customary procedures. PreMD and its selected manufacturer shall prepare and maintain, as hereinafter contemplated, batch records and a retained sample, (other than a retained sample of the Reader) properly stored, from each lot or batch of Product or portions thereof manufactured, sufficient to perform quality control tests specified in the Specifications at least twice; the obligation in the foregoing sentence shall apply:

(a) in respect of the Reader, for the duration of the then-projected useful life of the Reader; and

(b) in respect of all other components of the test kits, samples shall be maintained until the expiry date of the particular samples and batch records shall be maintained for [\*\*\*] years thereafter.

A copy of the certificate of analysis shall be provided to AstraZeneca when each batch or lot is available for shipment pursuant to Section 6.3.

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**ARTICLE VII**

**MANUFACTURE**

7.1 In the manufacture of Product for AstraZeneca, PreMD shall ensure compliance, by itself and its suppliers and subcontractors, with all Applicable Laws, including all applicable ISO, QSR and GMP requirements and guidances, and the Quality Agreement between AstraZeneca and PreMD attached hereto in Appendix N, as they pertain to Product, all applicable requirements of the FDA and the FDCA and all applicable Specifications. The Parties agree to comply with the terms of the Quality Agreement.

7.2 PreMD agrees to keep exact, true and complete records of the supply of Product to AstraZeneca, and PreMD agrees to require that its suppliers keep exact, true and complete records of the manufacture and supply of Product to AstraZeneca (and all costs associated therewith), which shall at all reasonable times, and upon reasonable notice be available for examination, audit and copying by AstraZeneca and its representatives. PreMD shall have Product manufactured by one or more manufacturers selected by PreMD and which is/are satisfactory to AstraZeneca, acting reasonably.

7.3 In the event AstraZeneca and PreMD mutually determine to amend the Specifications in any respect, PreMD shall use Diligent Efforts to implement such amendments through its suppliers (and, if considered commercially reasonable and if such suppliers are unwilling or unable to implement such amendments, then the Parties will mutually consider changing suppliers or further modifying the Specifications in a manner which may be implemented through the existing suppliers), or such other amendments as may be mutually agreed to by the Parties. If any such amendments are requested by AstraZeneca, AstraZeneca shall be responsible for reimbursing PreMD for all costs associated therewith. Except as contemplated in Section 9.1, amendments to the Specifications shall not be binding unless agreed to in writing by both Parties. In the event that AstraZeneca and PreMD are unable to agree on all amendments, the matter will be referred to the Joint Development Committee for resolution as set forth in Article II.

7.4 AstraZeneca shall have the right, at its own expense, to inspect at all reasonable times during normal business hours, and on reasonable prior notice to PreMD and the supplier, as applicable, the operations and facilities of PreMD and its suppliers in which Product is manufactured, packaged, inspected, tested, labeled, stored or shipped; provided, that PreMD or such supplier may refuse entry to areas where products of other customers are being manufactured, inspected or packaged, in order to fulfill its obligations of confidentiality to these customers. PreMD agrees to comply with AstraZeneca's reasonable requests and to ensure that its suppliers comply with AstraZeneca's reasonable requests to modify plant conditions, policies or practices, to conform said conditions, policies or practices to all applicable FDA regulatory requirements and all Specifications.

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7.4.1 As soon as practicable after the Effective Date, but not later than [\*\*\*], PreMD shall, using Diligent Efforts, [\*\*\*] the [\*\*\*], and [\*\*\*] related to Product [\*\*\*] at such [\*\*\*] in accordance with [\*\*\*] and the [\*\*\*].

7.5 PreMD and AstraZeneca agree to permit and fully cooperate with, and to require its suppliers to permit and fully cooperate with, any inspections by the applicable Regulators of the facilities used to manufacture or store Product or Non-Field Product, or any component thereof, to the extent that such inspections relate to Product or Non-Field Product. PreMD shall notify AstraZeneca immediately when PreMD becomes aware that such inspection is scheduled, shall allow representatives of AstraZeneca to be present at such inspection to the extent that PreMD is permitted to do so (AstraZeneca acknowledging that under PreMD's contractual arrangements existing at the Effective Date, PreMD is not permitted to do so) and shall report the results of any such inspection relating to the manufacture of Product or Non-Field Product, or any component thereof, to AstraZeneca to the extent the same are provided to PreMD. PreMD further agrees to comply with and to use Diligent Efforts to require its suppliers to comply with all required modifications as may be necessary to conform to all applicable regulatory requirements. AstraZeneca shall have the right to review any responses to Regulators related thereto.

7.6 PreMD shall, and shall require its suppliers to, conduct regular stability tests of chemical components and finished goods of Product (except the PREVU\* LT Product in the Life Insurance Laboratory Field) pursuant to the Stability Test Program (Appendix O) and all applicable ISO and applicable FDA regulatory requirements, and to provide written stability reports in compliance with such test program to AstraZeneca within two months of the conclusion of each Calendar Year. At such time as PreMD has obtained Regulatory Approval to market and sell the PREVU\* LT Product in the Territory outside the Life Insurance Laboratory Field, PreMD shall, and shall require its suppliers to, conduct regular stability tests of chemical components and finished goods of the PREVU\* LT Product pursuant to appropriate stability testing (which Appendix O shall then be amended to reflect) and all applicable ISO and applicable FDA regulatory requirements, and PreMD shall provide written stability reports in compliance with such test program to AstraZeneca of any batch of the PREVU\* LT Product or components that fail to meet any minimum standard as set out in the Specifications, the stability test program as set forth in such amended Appendix O or any applicable ISO, GMP or regulatory requirement. PreMD shall promptly notify AstraZeneca of any batch of Product or component thereof that fails to meet any minimum standard as set out in the Specifications, the Stability Test Program, or any applicable ISO, GMP or regulatory requirement. Unless previously agreed by both Parties, all Product, from the time it is available to be shipped in accordance with the purchase orders, shall have a remaining shelf life of not less than [\*\*\*] months.

## ARTICLE VIII

### PURCHASE PRICE

8.1 AstraZeneca shall purchase from PreMD and PreMD shall sell to AstraZeneca all Product as may be ordered by AstraZeneca at a price (the **Purchase Price**), payable in U.S.

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dollars, equal to Manufacturer's Cost. For greater certainty, in the case of the portion of Manufacturer's Cost which is as a result of non-recurring capital expenditures incurred by PreMD (which the Parties agree shall be amortized, included in the calculation of Manufacturer's Cost, and paid by AstraZeneca, over the twelve-month period following such expenditure based upon the then-estimated purchases of Product (other than the Reader) by AstraZeneca hereunder), then immediately following such twelve-month period, to the extent that the actual purchases of Product (other than the Reader) is less than such prior then-estimated purchases, there shall be a reconciliation and AstraZeneca shall pay any balance remaining unpaid in respect of such non-recurring capital expenditures).

8.2 The Purchase Price will be F.O.B. [\*\*\*] of [\*\*\*] or [\*\*\*], and will be inclusive of all imprinting and bulk packaging costs.

8.3 AstraZeneca shall pay all actual freight, insurance and government sales tax imposed on purchases of finished goods for resale, and import and export duties and other fees and costs incurred in connection with the importation, sale and shipment of Product to AstraZeneca's desired place of destination. Risk of loss shall belong to [\*\*\*] when [\*\*\*] are [\*\*\*] to the [\*\*\*] by [\*\*\*] for [\*\*\*] the [\*\*\*] of [\*\*\*] or [\*\*\*].

8.4 Payments to PreMD for the Purchase Price of Product shall be made by AstraZeneca within [\*\*\*] days after the date of shipment thereof from PreMD's manufacturer or supplier, except as to Product orders which do not conform to the Specifications.

8.5 PreMD and AstraZeneca shall cooperate in identifying and implementing raw material and manufacturing improvements that result in increased Product production efficiencies and capabilities, subject to ensuring that such improvements are in compliance with applicable regulatory and governmental approvals and permits. The Purchase Price for Product shall be adjusted accordingly to reflect any such cost savings/improvements and shall be effective upon the implementation of such improvements. For purposes of Section 8.7, if a Party has incurred costs pursuant to this Section 8.5, such Party shall provide written documentation reasonably satisfactory to the other Party that demonstrates that such costs have been incurred.

8.6 The Purchase Price for any given Product (other than the Reader) will be reviewed with PreMD's suppliers annually and any increase in pricing must be based upon written documentation of [\*\*\*] in [\*\*\*] or [\*\*\*] by [\*\*\*], and/or [\*\*\*] for Product or, in the case of [\*\*\*], a division of [\*\*\*], written documentation of [\*\*\*]. Changes in such pricing must be made with at least 60 days prior written notification. Current pricing arrangements with the supplier of the Reader are as outlined on Appendix P hereto. PreMD shall keep complete, true and accurate books of accounts and records in accordance with Canadian generally accepted accounting principles (GAAP) for the purpose of determining the amounts payable pursuant to this Agreement. Such books and records shall be kept at the principal place of business of PreMD for at least seven (7) years following the end of the Calendar Year to which they pertain. Such records shall be open for inspection during such seven (7) year period by an independent auditor chosen by AstraZeneca and reasonably acceptable to PreMD for the sole purpose of

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verifying the amounts payable by AstraZeneca hereunder. Such inspections may be made no more than once each Calendar Year, at reasonable times and on reasonable notice. The auditor shall disclose to AstraZeneca only information relating to the accuracy of the information to substantiate the amounts payable to AstraZeneca under this Agreement. The independent auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 8.6 shall be at the expense of AstraZeneca, unless a variation or error producing an underpayment in amounts payable by AstraZeneca exceeding [\*\*\*] percent ([\*\*\*]%) of the amount paid for any period covered by the inspection is established in the course of any such inspection, whereupon all costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by PreMD, together with interest on such unpaid amounts at the rate set forth in Section 4.9 above. The Parties will endeavour to minimize disruption of PreMD's normal business activities to the extent reasonably practicable during such audit.

8.7 In the event that the Purchase Price is reduced pursuant to Section 6.1.2 or 8.5, (a) the Party or Parties who paid to achieve such reduction shall receive the benefit of the Purchase Price reduction (proportionately, in the case of unequal contributions) until such time as such Party or Parties recovers any costs it has incurred pursuant to Sections 6.1.2, 6.1.2.1 or 8.5, and (b) thereafter, AstraZeneca and PreMD shall share equally in the benefit of any such Purchase Price reduction by increasing at such time the Purchase Price by fifty percent (50%) of such Purchase Price reduction. (For purposes of illustration only, if the Purchase Price were \$6.00 and AstraZeneca paid \$1 million for a project to lower the costs of Product by \$1.00 per unit, the Purchase Price would be reduced from \$6.00 to \$5.00 until such time as the \$1 million project costs were recovered. In other words, one million units would have to be sold to AstraZeneca at \$5.00 before the Purchase Price would increase, at which time the Purchase Price would increase to \$5.50.)

## ARTICLE IX

### PACKAGING AND LABELING

9.1 All Product supplied by PreMD to AstraZeneca shall be in the finished goods format as agreed by the Parties from time to time, including, but not limited to, package sizes, shapes and formats. AstraZeneca will work with PreMD to develop packaging and labeling that is suitable and in compliance with applicable government and regulatory regulations and requirements. AstraZeneca has the discretion to establish Specifications for packaging and labeling, provided that such Specifications would conform to the foregoing regulations and requirements. AstraZeneca shall be responsible for ensuring that such Specifications are in compliance with the foregoing regulations and requirements. Under no circumstances shall PreMD modify or change any packaging and labeling for Product without AstraZeneca's prior written consent.

9.2 PreMD agrees to mark, affix, label or otherwise use the AstraZeneca Trademarks and AstraZeneca's tradenames on Product and its bulk packaging in such manner as AstraZeneca may reasonably request and, in this regard, PreMD is hereby granted a non-

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exclusive license, sublicensable to all of PreMD's manufacturers and suppliers, to use the same for such purpose. PreMD shall not use any markings, logos, legends, labels or notices whatsoever on the Product or its packaging except as may be authorized in advance in writing by AstraZeneca. AstraZeneca shall reimburse PreMD for all costs associated with matters contemplated in this Section.

9.3 The Parties shall use commercially reasonable efforts to ensure that all advertising and promotional materials produced by or for AstraZeneca for Product will conform to the approved regulatory indications for use in the Territory.

## ARTICLE X

### INSPECTION

10.1 Acceptance of Product ordered by AstraZeneca shall be subject to prior inspection and approval by AstraZeneca's quality assurance personnel or such other technical representatives as AstraZeneca may select, with respect to whether each order of Product conforms to the applicable Specifications.

10.2 AstraZeneca shall, as promptly as practical, but not more than thirty (30) working days after actual receipt of a Product order, notify PreMD of its disapproval, if any, of samples of Product inspected and its non-acceptance of the Product order in the event AstraZeneca is of the opinion that a Product sample fails to conform to the Specifications. The foregoing time period is not intended to include Product that contains a latent defect that has not been caused by AstraZeneca.

10.3 PreMD shall, within thirty (30) days after it is determined that any Product does not conform to the applicable Specifications, replace any Product not conforming to the applicable Specifications (unless such defect is due to any negligent or wrongful act or omission by AstraZeneca or its agents or subcontractors). If AstraZeneca shall previously have paid for Product being replaced, then the replacement shall be at PreMD's cost and expense, including shipping costs. AstraZeneca's remedy for the delivery by PreMD of Product which does not conform to the Specifications and which has not caused damages to any Third Party is to require that PreMD replace such Product. If AstraZeneca shall not have previously paid for Product being replaced, then AstraZeneca shall be obliged to pay for the replacement Product, provided that it meets the Specifications, on the same terms and conditions as if originally delivered in accordance with the Specifications. PreMD shall be responsible for all costs related to the return or destruction of the non-conforming Product. Notwithstanding the foregoing, any non-conformance relating to the performance of Product in accordance with the Specifications shall be reported to PreMD within the time period set out in Section 10.2.

10.4 If AstraZeneca alleges that any Product does not conform to the applicable Specifications, it shall give written notice thereof to PreMD as herein contemplated, which notice shall contain such information as required by the Non-Conforming Notice attached as Appendix Q. AstraZeneca shall not return any such Product to PreMD or its manufacturer except

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as permitted hereunder. Upon receipt by PreMD of the Non-Conforming Notice or a substantially similar AstraZeneca form, PreMD shall deliver to AstraZeneca a returned goods authorization form attached as Appendix R or a substantially similar AstraZeneca form, executed by PreMD, containing instructions and directions as to the disposition of Product which AstraZeneca alleges does not conform to the applicable Specifications. At PreMD's option, such Product shall be returned to PreMD or destroyed by AstraZeneca, and such return or destruction shall be at PreMD's expense including shipping costs. If such Product is returned to PreMD, PreMD shall certify to AstraZeneca that (i) PreMD has destroyed such Product, (ii) PreMD has removed any AstraZeneca Trademarks and AstraZeneca's traddress thereon, or (iii) PreMD has returned such Product to the manufacturer. In the event PreMD has returned such Product to the manufacturer, PreMD shall use Diligent Efforts (without the need to make any payment or offer other consideration to the manufacturer) to obtain a certification from the manufacturer, that shall be supplied to AstraZeneca, that the manufacturer has (x) destroyed such Product or (y) removed any AstraZeneca Trademarks and AstraZeneca's traddress thereon, or (z) in the case of the Reader, repaired such Reader in accordance with the Specifications therefor.

10.5 AstraZeneca's right to inspect and right to replacement of Product not conforming to applicable Specifications shall not preclude AstraZeneca from exercising or enforcing any other rights or remedies it may have to redress any loss or damage resulting from PreMD's failure to timely supply Product conforming to the Specifications.

## ARTICLE XI

### WARRANTIES AND INDEMNITIES

11.1 PreMD represents, warrants and covenants to AstraZeneca that:

11.1.1 It has the unencumbered right to convey the rights granted by this Agreement.

11.1.2 All Product when supplied to AstraZeneca shall conform to and shall be produced in compliance with all Regulatory Approvals which have been obtained and conveyed to PreMD, which includes but is not limited to those from the FDA, the Specifications, and the Applicable Laws of the Territory. Product when supplied to AstraZeneca shall not be adulterated, misbranded within the meaning of the FDCA, or a device that may not be introduced into United States interstate commerce under sections 505, 510 or 515 of the FDCA.

11.1.3 To its Actual Knowledge as of the Effective Date, the manufacture, importation, use and sale of the PREVU\* POC and PREVU\* LT Product in their current Specifications do not infringe the patents of any Third Party.

11.1.4 It has full corporate power and authority to enter into this Agreement and to carry out the provisions thereof.

11.1.5 The intellectual property rights licensed to AstraZeneca hereunder are all intellectual property rights owned or controlled by PreMD or to which PreMD has a license that

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relate to the Licensed Technology and that PreMD has not withheld from AstraZeneca any such intellectual property rights for the manufacture, import, use, sale or offer for sale of Product in the Territory. The Licensed Patents represent all patents within PreMD's control relating to Product.

11.1.6 As of the Effective Date, PreMD has not granted any subsisting (i.e., unexpired and unexpired) license, right or interest in or to any Product or Licensed Patents to any Third Party relating to Product in the Territory, other than licenses for the purposes of manufacturing Product for supply to AstraZeneca in the Territory for use other than in the Life Insurance Laboratory Field and to PreMD (i) in the Territory in the Life Insurance Laboratory Field and (ii) for the ROW.

11.1.7 As of the Effective Date, PreMD has no subsisting (i.e., unexpired and unexpired) agreement, whether written or oral, that has assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to, the Licensed Patents, Licensed Know-How, regulatory documentation or Product (including without limitation by granting any covenant not to sue with respect thereto). PreMD will not enter into any such agreements or grant any such right, title or interest to any person or entity that is inconsistent with the rights and licenses granted to AstraZeneca under this Agreement.

11.1.8 During the Term of this Agreement, PreMD shall not encumber or diminish the rights granted to AstraZeneca hereunder with respect to the Licensed Technology, including by not (a) committing any acts or permitting the occurrence of any omissions that would cause the breach or termination of any agreement with any Third Party under which PreMD has rights that relate to the Licensed Technology, or (b) amending or otherwise modifying or permitting to be amended or modified, any such agreement if such amendment or modification would have the effect of encumbering or diminishing the rights granted to AstraZeneca hereunder with respect to the Licensed Technology. PreMD shall promptly provide AstraZeneca with notice of any alleged, threatened or actual breach of any such agreement. As of the Effective Date, none of PreMD, its Affiliates and, to their Actual Knowledge, any Third Party is in breach of any such agreement.

11.1.9 Except as disclosed on Appendix B, to PreMD's and its Affiliates' Best Knowledge, the Licensed Patents are in good standing and being prosecuted in the Territory in accordance with all applicable laws and regulations. Unless otherwise expressly stated in Appendix B of this Agreement, the Licensed Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

11.1.10 In respect of the pending United States patent applications included in the Licensed Patents, PreMD has presented all prior art that PreMD has determined is material to patentability of claims in the U.S. patent applications to the relevant Patent Examiner at the United States Patent and Trademark Office.

11.1.11 PreMD's trade secrets included in the Licensed Technology have been maintained in confidence and have been disclosed to Third Parties only under terms of confidentiality. To the Actual Knowledge of PreMD and its Affiliates no breach of such

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confidentiality has been committed. For the avoidance of doubt, other than as disclosed in a published patent application or issued patent, no information regarding PreMD's chemical formulae or PreMD's methods of manufacture have been disclosed to any Third Party except as disclosed on Appendix S.

11.1.12 As of the Effective Date, to PreMD's and its Affiliates' Actual Knowledge, there is no actual infringement or threatened infringement of the Licensed Patents or PreMD Trademarks by any Person.

11.1.13 To PreMD's and its Affiliates' Actual Knowledge, AstraZeneca's Exploitation of PreMD's regulatory documentation, Licensed Patents or Licensed Know-How hereunder will not infringe any patent or other intellectual property or proprietary right, other than those rights conveyed hereunder, of any Person.

11.1.14 The Licensed Patents and the Licensed Know-How existing as of the Effective Date are subsisting (i.e., unexpired and unexpired) and are not invalid or unenforceable, in whole or in part unless otherwise expressly stated in Appendix B of this Agreement. The conception, development and reduction to practice of the regulatory documentation, the Licensed Patents and Licensed Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person. There are no claims, judgments or settlements against or amounts with respect thereto owed by PreMD or any of its Affiliates relating to the regulatory documentation, the Licensed Patents or the Licensed Know-How. No claim or litigation has been brought or threatened by any Person alleging, and PreMD is not aware of any possible claim or threatened claim that (a) the Licensed Patents or the Licensed Know-How are invalid or unenforceable or (b) the regulatory documentation, the Licensed Patents or the Licensed Know-How or the disclosing, copying, making, assigning, licensing or Exploiting of the regulatory documentation, the Licensed Patents or the Licensed Know-How, or product and services embodying the regulatory documentation, or the PREVU\* POC Product and the PREVU\* LT Product in their current Specifications, violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Person.

11.1.15 PreMD has made (and will make) available to AstraZeneca all regulatory documentation, Licensed Know-How and other information in its possession or control regarding or related to Product and all such regulatory documentation, Licensed Know-How and other information are (and, if made available after the Effective Date, will be) true, complete and correct. As of the Effective Date, PreMD has prepared, maintained and retained all regulatory documentation that is required to be maintained or reported for the PREVU\* POC Product and the PREVU\* LT Product in their current Specifications pursuant to and in accordance with GLP, GCP, QSR, GMP, medical device reporting requirements and Applicable Laws and to its Actual Knowledge, all such information is true, complete and correct and is what it purports to be.

11.1.16 To its Actual Knowledge, PreMD has not been debarred and is not subject to debarment pursuant to Section 306 of the FDCA. After the Effective Date, PreMD

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will not knowingly use in any capacity in connection with any Clinical Trial or any other product development activities, any Person who has been debarred pursuant to Section 306 of the FDCA, or who is the subject of a conviction described in such section or who has been determined a disqualified clinical investigator pursuant to 21 C.F.R. § 312.70 or 21 C.F.R. § 812.119. After the Effective Date, PreMD will not knowingly use in any capacity pursuant to any contract or agreement entered into by PreMD after the Effective Date in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FDCA, or who is the subject of a conviction described in such section. PreMD agrees to inform AstraZeneca in writing immediately if it, or if to PreMD's Actual Knowledge any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or is designated as a disqualified clinical investigator, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to PreMD's or its Affiliates Actual Knowledge, is threatened, relating to the debarment or conviction of PreMD or any Person performing services hereunder.

11.1.17 PreMD, and to its Actual Knowledge, each of its clinical investigators for any Clinical Trial or other product development activities for Product, have been and are complying, and will comply after the Effective Date, in all material respects with all Applicable Laws applicable to their respective activities in the conduct, sponsorship, monitoring, and reporting of Clinical Trials or any other product development activities, including requirements for informed consent of study subjects, institutional review board approval, GCP requirements, financial disclosure requirements, and recordkeeping and reporting requirements.

11.1.18 PreMD has been advised by counsel with respect to the negotiation and drafting of this Agreement. Such counsel was able, free of conflict of interests, to provide PreMD the advice and assistance necessary for PreMD to understand and make the decision to agree to all the terms of this Agreement.

11.2 PreMD agrees to indemnify and hold AstraZeneca and its Affiliates, distributors, Sublicensees and its and their respective directors, officers and employees harmless against any action, claims, damages, injuries, losses, costs and expenses (including reasonable attorney's fees and disbursements (both those incurred in connection with the defense or prosecution of the claim for indemnification and those incurred in connection with the enforcement of this provision)) arising from or alleged or claimed to arise from (i) any intentionally wrongful act or omission or negligence of PreMD or its Affiliates, employees or agents in performing services specified in this Agreement; (ii) bodily injury, death or property damage sustained by any person resulting from use of the Product manufactured or supplied by PreMD unless such arises solely from a negligent or intentionally wrongful act or omission by AstraZeneca or its Affiliates, distributors or Sublicensees; or (iii) any material breach by PreMD of its obligations or warranties under this Agreement. PreMD shall name AstraZeneca as an additional insured on its product liability insurance with respect to the liabilities assumed by PreMD in this Agreement.

11.3 AstraZeneca agrees to indemnify and hold PreMD and its Affiliates harmless against any actions, claims, damages, injuries, losses, costs and expenses (including reasonable attorney's fees and disbursements (both those incurred in connection with the defense or

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prosecution of the claim for indemnification and those incurred in connection with the enforcement of this provision)) arising from or alleged or claimed to arise from (i) any material breach by AstraZeneca of its obligations or warranties under this Agreement; or (ii) any intentionally wrongful act or omission or sole negligence of AstraZeneca or its Affiliates, employees or agents in performing services specified in this Agreement.

11.4 A Party seeking indemnification hereunder agrees to give prompt written notice to the indemnifying Party after the receipt of any written notice of the commencement of any action, suit, proceeding or investigation or threat thereof made in writing for which such Party will claim indemnification pursuant to this Agreement provided that the failure to so notify will relieve the indemnifying Party from liability to the extent it has been materially prejudiced by such failure.

11.5 PreMD recognizes that AstraZeneca and its Affiliates have been actively involved in the research, development, marketing and sale of products and services in the field of cardiovascular health and in the investigation of entries into such field. AstraZeneca and its Affiliates intend to continue with such activities and make no representation or warranty that it will be able to successfully market any Product under this Agreement or that the Product will be the exclusive means by which AstraZeneca and its Affiliates may participate in this field. PreMD agrees that AstraZeneca's payment of milestones and royalties as provided for in Article IV, and the other covenants of AstraZeneca contained in this Agreement, are full consideration for the licenses granted herein. Furthermore, all business decisions including, without limitation, the sale, price and promotion of Product in the Territory and the decision whether to sell a particular Product shall be within the sole discretion of AstraZeneca. PreMD and AstraZeneca further agree that the provisions provided for under Section 17.3 herein are in lieu of any obligation of any specific level or standard of efforts to be used by AstraZeneca in the marketing of Product.

11.6 EXCEPT FOR THE EXPRESS WARRANTIES OR REPRESENTATIONS CONTAINED IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, CONDITIONS OR REPRESENTATIONS, EXPRESS, IMPLIED OR STATUTORY, TO THE OTHER PARTY HERETO, WITH RESPECT TO ANY PRODUCT, SERVICES, CONTENT OR OTHER MATERIALS PROVIDED BY SUCH PARTY HEREUNDER RELATING TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN IN RESPECT OF SUCH USES AND PURPOSES AS ARE PERMITTED UNDER APPLICABLE REGULATORY LICENSES. EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES, AND EXCEPT WITH RESPECT TO CLAIMS BROUGHT BY THIRD PARTIES FOR WHICH INDEMNIFICATION IS SOUGHT UNDER SECTION 11.2 OR 11.3, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR SPECIAL DAMAGES ARISING FROM OR IN ANY WAY OUT OF THIS AGREEMENT OR THE SERVICES TO BE PROVIDED HEREUNDER, HOWEVER CAUSED, WHETHER ARISING UNDER A THEORY OF CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE) OR OTHERWISE, WHETHER OR NOT SUCH PARTY HAS

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BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. FURTHERMORE, THIS SECTION 11.6 SHALL NOT HAVE ANY EFFECT ON ANY [\*\*\*] THAT [\*\*\*] AS A [\*\*\*] UNDER [\*\*\*].

11.7 The provisions and obligations of this Article XI shall survive any termination of this Agreement.

## ARTICLE XII

### INSURANCE

12.1 PreMD shall obtain and maintain at all times during the term of this Agreement and for a period of two (2) years thereafter Comprehensive General Liability Insurance, including Products Liability, with limits of liability of not less than the US equivalent of [\*\*\*] Dollars (\$[\*\*\*]) each occurrence and [\*\*\*] Dollars (\$[\*\*\*]) policy aggregate, increasing to [\*\*\*] Dollars (\$[\*\*\*]) policy aggregate effective January 1, 2010. The policy(ies) described above shall name AstraZeneca as an additional insured. The coverage afforded under these policies of insurance shall be primary to any liability insurance carried by AstraZeneca which insurance(s) shall be excess and non-contributory for claims and losses arising out of the performance of this Agreement. The limits specified above may be evidenced by a combination of primary and excess/umbrella insurance policies.

12.1.1 All such insurances shall be written with a company or companies licensed to do business in the Province of Ontario having a financial rating of not less than A- in the most current edition of Bests Key Rating Guide.

12.1.2 PreMD shall provide AstraZeneca with a Certificate of Insurance evidencing the above requirements at the Effective Date and at each renewal period thereafter.

## ARTICLE XIII

### PRODUCT RECALLS

13.1 In the event of a recall, corrective action, or other removal of a Product, or any lots thereof (collectively **Recall** ), by any Regulators or if a Recall is considered by AstraZeneca to be advisable, such Recall shall be promptly implemented and administered by AstraZeneca in a manner which is appropriate and reasonable under the circumstances and in conformity with accepted trade practices, including the issuing of advisory notices to end-users. PreMD shall cooperate with AstraZeneca in activities related to implementing the Recall and shall use Diligent Efforts to obtain the cooperation of its suppliers. AstraZeneca shall keep accurate records of the distribution and sales of Product to enable appropriate procedures to be implemented in the event a recall of Product is required. The costs of any such Recall shall be borne by the Party or Parties in an amount corresponding to the extent that such Party or Parties were responsible for causing the need for such event. Notwithstanding the above, PreMD shall be responsible for all costs associated with the Recall of any Product that failed to meet the Specifications, or which contained a latent defect not apparent during the inspection as set forth in Article X.

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



13.2 The provisions and obligations of this Article XIII shall survive any termination of this Agreement.

#### ARTICLE XIV

##### PATENTS AND TRADEMARKS

14.1 PreMD agrees to prosecute or cause to be prosecuted the applications for patents included in the Licensed Patents, maintain such Licensed Patents, and defend, at its option, against any action by any Third Party for invalidation or revocation of any Licensed Patent at PreMD's sole cost and expense. PreMD shall notify AstraZeneca in the event PreMD (A) decides to abandon or discontinue the prosecution in the Territory of any patent application included in the Licensed Patents; (B) decides not to pay the maintenance fee in the Territory due on any patent application or patent included in the Licensed Patents; or (C) decides not to defend against any action by any Third Party for invalidation or revocation of any patent application or patent included in the Licensed Patents insofar as such Licensed Patents relate to the Territory. Such notice to AstraZeneca shall be sufficiently in advance of any abandonment, discontinuance, maintenance fee due date, or response date so as to give AstraZeneca reasonable time to consider and exercise the following option:

14.1.1 AstraZeneca shall have the option, exercisable upon written notice to PreMD, to assume full responsibility for the prosecution of the affected application in the Territory, to pay the maintenance fees due on the patent application or patent in the Territory, or to defend against such Third Party action insofar as such action relates to the Territory. In such circumstances, PreMD agrees to assign to AstraZeneca any such subject patent or patent application. The external reasonable out-of-pocket cost of assuming prosecution or paying maintenance fees shall be deductible from future royalties payable to PreMD from Net Sales in the Territory. In the event AstraZeneca exercises its option to defend against any such Third Party action, AstraZeneca shall use Diligent Efforts to defend against such action and shall obtain the written consent of PreMD prior to ceasing to defend, settling or otherwise compromising any such action.

14.2 Notwithstanding the provisions of Section 14.1, AstraZeneca shall have the sole right, through counsel of its choosing, to obtain, prosecute (including without limitation any interferences, reissue proceedings and re-examinations) and maintain at AstraZeneca's expense any and all Joint Intellectual Property patents in the Territory. PreMD shall have the right to request that AstraZeneca obtain, prosecute and maintain a Joint Intellectual Property patent in the Territory. If AstraZeneca declines, or otherwise fails, to initiate any such requested action with respect to a Joint Intellectual Property patent within sixty (60) days (or, if after initiating any requested action, AstraZeneca at any time thereafter fails to diligently pursue such action), in each case PreMD shall have the right to take such action with respect to such Joint Intellectual Property patent. AstraZeneca and PreMD shall, and shall cause their respective Affiliates, as

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applicable, to assist and cooperate with one another in filing, prosecuting and maintaining the Joint Intellectual Property patents. The Party prosecuting a patent application shall provide the other Party with copies of all Joint Intellectual Property patent applications and correspondence to and from patent offices. The prosecuting Party shall endeavor to provide the other Party with a reasonable period of time in which to review and comment upon draft patent applications and draft Office Action responses prior to submission to patent offices and shall consider any comments on draft patent applications and draft Office Action responses offered by the other Party.

14.3 [intentionally omitted]

14.4 (i) If PreMD or AstraZeneca become aware of any infringement in the Territory by a Third Party or Sublicensee of any Licensed Patents, that Party shall promptly notify the other Party in writing to that effect. AstraZeneca shall be entitled, in its sole discretion, through counsel of its choosing, to take any measures (including filing patent infringement actions) it deems appropriate to stop such infringing activities by such Third Party or Sublicensee in any part of the Territory or to grant to the infringing Third Party or Sublicensee adequate rights and licenses necessary for continuing such activities in the Territory. Any license or other grant of rights in the Licensed Patents is subject to the approval provisions of Section 3.1.1 of this Agreement. Upon reasonable request by AstraZeneca, PreMD shall give AstraZeneca all reasonable information and assistance, including allowing AstraZeneca access to PreMD's files and documents and to PreMD's personnel who may have possession of relevant information. If requested by AstraZeneca, PreMD agrees to be named as a party or coparty to any such legal action, and to initiate or join such action with all of PreMD's out-of-pocket costs and expenses to be paid by AstraZeneca. PreMD shall use Diligent Efforts to obtain any consents required by Third Parties owning Licensed Patents licensed to PreMD in order for AstraZeneca to remove such infringement.

(ii) In the event AstraZeneca fails within ninety (90) days following notice of such infringement, or earlier notifies PreMD in writing of its intent not, to take commercially appropriate steps to remove any infringement of any Licensed Patents that is likely to have a material adverse effect on the sale of Product, and AstraZeneca has not granted the infringing Third Party or Sublicensee rights and licenses to continue its otherwise infringing activities, PreMD shall have the right to do so at its expense; provided, however, that if AstraZeneca has commenced negotiations with an alleged infringer for discontinuance of such infringement within such ninety (90) day period, AstraZeneca shall have an additional ninety (90) days to conclude its negotiations before PreMD may bring suit for such infringement. Following such period(s) and the continued infringement by such Third Party or Sublicensee, PreMD shall be entitled, in its sole discretion, through counsel of its choosing, to take any measures (including filing patent infringement actions) it deems appropriate to stop such infringing activities by such Third Party or Sublicensee in any part of the Territory. Upon reasonable request by PreMD, AstraZeneca shall give PreMD all reasonable information and assistance in connection with such suit for infringement, including allowing PreMD access to AstraZeneca's files and documents and to AstraZeneca's personnel who may have possession of relevant information. If requested by PreMD, AstraZeneca agrees to be named as a party or coparty to any such legal action, and to initiate or join such action with all of AstraZeneca's out-of-pocket costs and expenses to be paid by PreMD.

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14.5 In the event that a Third Party or Sublicensee asserts, as a defense or as a counterclaim in any infringement action under Section 14.4, that any Licensed Patent or Joint Intellectual Property patent is invalid or unenforceable, then the Party pursuing such infringement action shall promptly give written notice to the other Party. The Parties shall cooperate in the defense of any such counterclaim, including by providing reasonable information and assistance and obtaining consents as set out in Section 14.4. Carriage of the litigation and costs regarding Joint Intellectual Property shall be determined on the same basis as set out in Section 14.4.

14.6 Similarly, if a Third Party or Sublicensee asserts, in a declaratory judgment action or similar action or claim filed by such Third Party or Sublicensee, that any Licensed Patent or Joint Intellectual Property patent is invalid or unenforceable, then the Party first becoming aware of such action or claim shall promptly give written notice to the other Party. The Parties shall cooperate in the defense of any such action or claim, including by providing reasonable information and assistance and obtaining consents as set out in Section 14.4. Carriage of the litigation and costs regarding Joint Intellectual Property shall be determined on the same basis as set out in Section 14.4.

14.7 Any amounts recovered by either Party pursuant to Section 14.4, whether by settlement or judgment, shall be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder being retained by AstraZeneca, to the extent attributable to lost sales of Product, shall be deemed Net Sales for which AstraZeneca shall pay PreMD any royalties that may be owed with respect to such Net Sales under Section 4.1. Any monetary settlement paid in the settlement of an action by an alleged infringer of the Licensed Patents to AstraZeneca shall be deemed Net Sales even if the alleged infringer does not admit to liability for infringement. The Party pursuing any action under Section 14.4 will bear all payments awarded against or agreed to be paid by such Party pursuant to such action, including without limitation any costs or expenses incurred that exceed the amounts recovered by such Party, provided that AstraZeneca shall have the right to offset fifty percent (50%) of such amounts (including without limitation such costs and expenses) against the milestone payments and royalties payable under Article IV; and provided further that no royalty payment when due, regardless of the amount or number of credits available to AstraZeneca in accordance with this Agreement, shall be reduced by more than fifty percent (50%) in any Calendar Quarter. Credits not exhausted in any Calendar Quarter may be carried into future Calendar Quarters, subject to the foregoing sentence.

14.8 In the event PreMD or AstraZeneca learn that the making, using or selling of a Product infringes, will infringe or is alleged by a Third Party to infringe, in the Territory, a Third Party patent, the Party becoming aware of same shall promptly notify the other. The Joint Development Committee shall thereafter attempt to agree upon a course of action which may include: (a) modifying the Product or its use and manufacture so as to be non-infringing; or (b) obtaining a license or assignment from said Third Party.

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14.9 In the event PreMD or AstraZeneca cannot agree on modifying the Product pursuant to Section 14.8 (and whether or not PreMD or AstraZeneca have received notice from a Third Party alleging that the making, importing, using or selling of Product infringes or will infringe, in the Territory, a Third Party patent), AstraZeneca shall in the first instance have the right to negotiate with said Third Party for such license or assignment in a territory including the Territory. Any license or assignment must be approved by PreMD prior to execution should it require a payment by PreMD or a set-off of an amount due to PreMD under this Agreement. In the event that such negotiation results in a consummated agreement, then (i) all costs associated with any lump sum payment and/or royalties to be paid thereunder shall, when paid, be shared equally by PreMD and AstraZeneca, and (ii) such licensed patents shall be included in the definition of Licensed Patents only to the extent that such licensed patents relate to the Field. In the event that such negotiations do not result in a consummated agreement, AstraZeneca shall have the first right, but not the obligation, through counsel of its choosing, to assume direction and control of the defense of claims arising therefrom (including without limitation the right to settle such claims provided that PreMD approves any settlement prior to execution should such settlement seek to affect PreMD's rights or impose any obligations on PreMD). If AstraZeneca notifies PreMD in writing that it does not wish to assume such direction and control, PreMD shall have the right, but not the obligation, at its sole cost and expense, to defend against such claims (including the right to settle such claims provided that AstraZeneca approves any settlement prior to execution should such settlement seek to affect AstraZeneca's rights or impose any obligations on AstraZeneca). The Parties shall cooperate in such action or claim, including by providing reasonable information and assistance and obtaining consents as set out in Section 14.4. Any such settlement shall provide that both AstraZeneca and PreMD shall be the beneficiaries of such settlement and shall be entitled to rely upon the terms thereof.

14.10 The following amounts shall be offset against the milestone payments and royalties payable under Article IV:

- (a) [\*\*\*] percent ([\*\*\*]%) of all reasonable costs, including without limitation Indirect Taxes if applicable, and expenses incurred by AstraZeneca in defending or otherwise dealing with a suit under Sections 14.4 or 14.9;
- (b) [\*\*\*] percent ([\*\*\*]%) of all damages or costs awarded against AstraZeneca under Sections 14.4 or 14.9; and
- (c) [\*\*\*] percent ([\*\*\*]%) of all payments or royalties that AstraZeneca is ordered to or agrees to pay to a Third Party in accordance with this Article XIV in order to secure the right to continue making, using or selling Product, provided always that if PreMD is in breach of any of the representations and warranties in Article XI, the percentages in this Section 14.10 shall be increased to [\*\*\*] percent ([\*\*\*]%). For the avoidance of doubt, where Indirect Taxes apply to milestones, royalties or costs, the Parties shall invoice these sums according to Applicable Law. Any

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payments or offsets made under this Section 14.10 shall be without prejudice to any other remedies AstraZeneca may have under this Agreement or otherwise. Any amounts recovered by AstraZeneca in connection with any action, claim or suit under this Article XIV shall be allocated between the Parties as provided in Section 14.7.

14.11 AstraZeneca and its Affiliates may advertise, promote, market and sell Product in the Territory under any trademark(s), tradename(s) and tradedress of their own choosing provided that they have rights at law to use such trademark(s), tradename(s) and tradedress. PreMD shall not acquire any right, title or interest whatsoever in or to any such trademark(s), tradename(s) or tradedress by virtue of such use by AstraZeneca and its Affiliates. So long as AstraZeneca or its Affiliates shall have any interest in and to any such trademarks, tradenames or tradedress, whether as proprietor, owner, licensee, or licensor in any country of the world, PreMD shall not adopt, use, apply for registration, register, own or acquire any such trademarks, tradenames or tradedress, or any mark, name or tradedress confusingly similar thereto, in any state or country of the world.

14.12 AstraZeneca shall be responsible for selecting any name, logotype, or trademark(s) for Product (collectively, **AstraZeneca Trademark(s)**) in the Territory. AstraZeneca will be responsible, at its own discretion and expense, for securing registration of such AstraZeneca Trademark(s) in the Territory, and shall own and control such AstraZeneca Trademark(s). AstraZeneca shall further be responsible for filing, maintaining, and protecting any such AstraZeneca Trademark(s). For greater certainty, PreMD shall continue to own and control the PREVU\* trademarks and variations thereof.

14.13 AstraZeneca shall, in its sole discretion, have the right to promote and sell Product under the AstraZeneca Trademark(s) selected by AstraZeneca, which AstraZeneca Trademark(s) shall be and remain the property of AstraZeneca.

## ARTICLE XV

### CONFIDENTIALITY

15.1 Disclosures of any information, data, plans and business information, whether orally or in writing or any other form, and whether designated as Confidential or not, by one Party to the other, and whether made prior to or subsequent to the Effective Date, shall be deemed to be confidential, shall be safeguarded by the recipient, shall not be disclosed to Third Parties and shall be made available only to recipient's Affiliates, employees or independent contractors who agree to keep the information in confidence and who have a need to know the information for the purposes specified under this Agreement, subject to the provisions of this Article XV.

15.1.1 PreMD recognizes that by reason of AstraZeneca's status as an exclusive licensee pursuant to the grants under Section 3.1, AstraZeneca has an interest in PreMD's retention in confidence of certain information of PreMD. Accordingly, until the termination of

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AstraZeneca's exclusive position with respect to a Product (or any improvement or modification thereon) under Article XVII, PreMD and its Affiliates and their respective officers, directors, employees and agents shall, and PreMD shall obtain a covenant from each of its sublicensees to, keep completely confidential, and not publish or otherwise disclose, and not use directly or indirectly for any purpose that would cause such publication or disclosure, any such information relating to (a) any Product or any improvement or modification thereon, or (b) the Exploitation of such Product, including any development, sales or marketing plans therefor (the **AstraZeneca Information**), except to the extent (i) the AstraZeneca Information is in the public domain through no fault of PreMD, its Affiliates and sublicensees or any of their respective officers, directors, employees or agents, (ii) such disclosure or use would be permitted under Sections 15.3 or 15.4 or (iii) such disclosure or use is otherwise expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of this Agreement. For clarification, the disclosure by PreMD to AstraZeneca or by AstraZeneca to PreMD of AstraZeneca Information shall not cause such information to cease to be subject to the confidentiality provisions of this Section 15.1. Notwithstanding the foregoing, and for greater certainty, PreMD shall use Diligent Efforts to enforce the obligations of its sublicensees with respect to this Article XV; provided, however, PreMD shall have no liability to AstraZeneca for any breaches by its sublicensees with respect to this Article XV except to the extent that PreMD is able to recover from such sublicensees as a result of such breaches, which amounts PreMD undertakes to use Diligent Efforts to collect; provided, further, however, that nothing contained herein shall limit the ability of AstraZeneca or PreMD to seek injunctive relief against any such sublicensees or one another arising from such breaches.

15.2 All such information deemed to be confidential by a Party and disclosed from one Party to the other shall remain the property of the disclosing Party. All such written confidential information shall be returned to the disclosing Party within thirty (30) days of receipt of a written request by the disclosing Party. However, each Party's counsel may retain one copy of these documents for archival purposes to be used to monitor compliance herewith and in respect of any litigation relating to the provisions of this Agreement including the provisions of this Article. All such information, whether written or oral or in any other form, shall only be used for the purposes contemplated in this Agreement and for no other purpose.

15.3 These mutual obligations of confidentiality shall not apply to any information that:

- (i) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation by the recipient to the disclosing Party; or
- (ii) was already known to the recipient as evidenced by prior written documents in its possession; or
- (iii) is disclosed to the recipient by a Third Party who is not in default of any confidentiality obligation to the disclosing Party hereunder;  
or

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(iv) is developed by or on behalf of the receiving Party, without reliance on confidential information received hereunder; or

(v) has been approved in writing for publication by each of the Parties.

15.4 Notwithstanding the restrictions of Section 15.1 hereinabove, PreMD and AstraZeneca may disclose such portions of the confidential information that:

- (i) are provided to Third Parties under appropriate terms and conditions including confidentiality provisions equivalent to those in this Agreement for consulting, manufacturing development, manufacturing, external testing and marketing trials with respect to Product; or
- (ii) are used in applications for patents, trademarks, tradenames, tradedress, or copyrights under, and as specifically permitted under, the terms of this Agreement; or
- (iii) are otherwise required to be disclosed in compliance with Applicable Laws or order by a court or other regulatory body having competent jurisdiction; provided, however, that the recipient shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash any such order or obtain a protective order requiring that the confidential information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the confidential information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in response to such court or governmental order.

In making such disclosures under this Section 15.4, the disclosing Party shall obligate the recipient to secrecy, if possible.

15.5 Notwithstanding the restrictions of Section 15.1 hereinabove, AstraZeneca and PreMD may disclose confidential information to their employees, consultants, advisors and subcontractors who are engaged directly or indirectly in the manufacture, use or sale of the Product who have first been instructed to maintain such confidential information in confidence. For the avoidance of doubt, however, AstraZeneca and PreMD shall be free to disclose the existence of this Agreement and the nature of the licenses granted hereunder to its Affiliates and prospective Sublicensees with an appropriate obligation of confidentiality and non-use.

15.6 The conditions and restrictions of this Article XV shall remain in force during the term of this Agreement and for eight (8) years thereafter, surviving the termination of this Agreement.

15.7 Subject to all legal requirements and the overriding discretion and requirements of the agencies hereinafter referred to, the Parties shall agree in advance with each other on the

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terms of this Agreement that the Parties shall seek to be redacted in any filings with the United States Securities and Exchange Commission, the Ontario Securities Commission or any similar agency in any other province or territory of Canada, or any successor agencies thereto, or any other governmental or regulatory authority that the Parties are required to report, to the extent that any such filing may be required.

15.8 (a) Except as may otherwise be required by Applicable Law or by any applicable securities commission or any stock exchange upon which its securities are listed or any securities quotation system on which such securities are traded (the **Disclosure Requirements** ), PreMD shall not issue any press release or make any other public announcement or otherwise disclose or announce this Agreement, the existence thereof, or the terms, conditions or subject matter hereof (including Product), or the name of AstraZeneca or any of its Sublicensees (the **Disclosure** ), without the prior written approval of AstraZeneca including approval of the specific text of such release, announcement or statement. Any determination that disclosure by PreMD pursuant to this Section is required by the Disclosure Requirements shall not be inconsistent with PreMD's past practices with respect to such disclosures unless such inconsistency is intended to respond to changes to the Disclosure Requirements or is otherwise required in order to conform to the Disclosure Requirements. Notwithstanding anything to the contrary in this Section 15.8, PreMD shall provide AstraZeneca with a copy of any proposed disclosure pursuant to Disclosure Requirements and shall accommodate AstraZeneca's reasonable requests for changes thereto to the extent consistent with such Disclosure Requirements and provided that compliance by PreMD shall not result in breach of such Disclosure Requirements.

(b) Notwithstanding Subsection 15.8(a), if PreMD would like AstraZeneca to consider whether PreMD may make a Disclosure (other than a Disclosure required by the Disclosure Requirements), then PreMD shall provide AstraZeneca with a copy of such proposed Disclosure at least seven (7) days prior to its proposed issuance or submission; and, to the extent practical, shall discuss the need for such proposed Disclosure with AstraZeneca. AstraZeneca, in its sole discretion, may require that modifications be made to the announcement or disclosure prior to publication, and AstraZeneca, in its sole discretion, shall further determine whether or not such proposed Disclosure, either as originally presented by or as modified by AstraZeneca, may be publicly announced or disclosed.

(c) Notwithstanding the above, PreMD shall have the right to disclose, in private or public offering documents or in verbal discussions with current or potential investors, the fact that PreMD has signed a license agreement with AstraZeneca regarding a device to diagnose, predict and monitor skin Sterol.

(d) Notwithstanding the above, PreMD may issue a press release limited to the specific announcement of the issuance of any patent within the Licensed Patents without AstraZeneca's prior written approval of the text of such press release.

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**ARTICLE XVI**

**CONTRACTUAL RELATIONSHIP**

16.1 The relationship of the Parties under this Agreement is that of independent contractors and not as agents of each other or partners or joint venturers, and neither Party shall have the power to bind the other in any way with respect to any obligation to any Third Party unless a specific power of attorney is provided for such purpose. Each Party shall be solely and exclusively responsible for its own employees and operations.

**ARTICLE XVII**

**TERM AND TERMINATION**

17.1 This Agreement shall become effective as of the Effective Date.

17.2 Notwithstanding anything contained elsewhere in this Agreement to the contrary, AstraZeneca may (in its sole discretion) terminate this Agreement in its entirety, upon [\*\*\*] days prior written notice to PreMD.

17.2.1 In the event of termination of this Agreement by AstraZeneca pursuant to Section 17.2, AstraZeneca shall: (i) transfer to PreMD, free of charge, the ownership of any Registrations for Product in the Territory that are owned by AstraZeneca at the time of such termination, and all the data used to support the same; (ii) provide such other reasonable transition support as PreMD may reasonably request; and (iii) grant to PreMD a royalty-free, perpetual, irrevocable license to Exploit Product under the Modified Technology in the Field in the Territory.

17.2.2 In the event of termination of this Agreement by AstraZeneca pursuant to Section 17.2, PreMD shall immediately cease using the AstraZeneca Trademarks and any other trademarks, tradenames, tradedress, service marks or devices applied to or used in association with the Product that are the property of AstraZeneca, except for the purposes of selling its remaining stocks of Product bearing the AstraZeneca Trademarks in accordance with Section 17.2.3.

17.2.3 PreMD shall have a period of ninety (90) days from the effective date of termination of this Agreement pursuant to Section 17.2 during which it may sell in the Territory its stocks of Product remaining at the effective date of such termination bearing the AstraZeneca Trademarks on the terms and conditions set forth herein and in a manner substantially similar to the manner in which AstraZeneca was selling Product prior to the termination of this Agreement in the Territory, provided, however, that PreMD agrees to indemnify and hold AstraZeneca and its Affiliates, distributors, Sublicensees and its and their respective directors, officers and employees harmless against any actions, claims, damages, injuries, losses, costs and expenses (including reasonable attorney's fees and disbursements (both those incurred in connection with the defense or prosecution of the claim for indemnification and those incurred in connection with the enforcement of this provision)) arising from or alleged or claimed to arise from any sale of such remaining stock of Product.

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17.3 Commencing in Calendar Year 2010 and in any Calendar Year thereafter, if AstraZeneca is required to make a payment under Section 4.1.4, then PreMD may terminate this Agreement upon written notice at any time during the sixty (60) day period commencing with the last day of the period in which such payment was required to be made by AstraZeneca under said Section 4.1.4.

17.4 PreMD may terminate this Agreement immediately upon written notice in the event:

17.4.1 AstraZeneca fails to make any payment due and owing and fails to cure such nonpayment within sixty (60) days after written notice thereof; or

17.4.2 AstraZeneca commits a breach of any material provision of this Agreement and (i) AstraZeneca fails to cure such breach within sixty (60) days after notice thereof if such breach is curable; or (ii) if the breach is not curable within such 60 day period, then AstraZeneca fails to take significant steps to present a plan to cure such breach (which plan shall be acceptable to PreMD, acting reasonably) within such sixty (60) day period or fails to thereafter use commercially reasonable efforts to implement such plan.

17.5 AstraZeneca may terminate this Agreement immediately upon written notice in the event PreMD commits a breach of any material provision of this Agreement which is not cured within sixty (60) days after written notice thereof.

17.5.1 In the event of termination of this Agreement by AstraZeneca pursuant to Section 17.5, PreMD shall immediately cease using the AstraZeneca Trademarks and any other trademarks, tradenames, tradedress, service marks or devices applied to or used in association with Product which are the property of AstraZeneca.

17.6 The rights of termination set forth in Sections 17.4 and 17.5 hereinabove, however, cannot be exercised by PreMD or AstraZeneca, as the case may be, if at any time during said sixty (60) day period, AstraZeneca or PreMD, as the case may be, advises the other Party in writing that it challenges the alleged payment owed or the alleged breach. In such event, the Parties will negotiate in good faith to resolve the dispute concerning the alleged payment owed or the alleged breach and, if the Parties are unable to resolve such dispute then such termination may only be effective upon a determination by the mediator or arbitrator, as applicable, pursuant to Section 19.6.

17.7 Either Party may terminate this Agreement if the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, or files a voluntary petition of bankruptcy in any court of competent jurisdiction, or shall make or execute an assignment of substantially all its assets for the benefit of creditors. However, the Parties agree that PreMD has transferred exclusive, proprietary rights and interest in the Licensed Technology in the Territory to AstraZeneca under this Agreement.

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17.8 Termination of this Agreement for any reason shall not release either Party from any obligation theretofore accrued.

17.9 The failure on the part of either Party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right, or any other right conferred hereunder, nor operate to bar the exercise or enforcement thereof at any time thereafter.

17.10 Upon termination of this Agreement for any reason,

17.10.1 PreMD shall fill all binding orders of AstraZeneca for Product which were placed prior to the date of notice of termination given by PreMD pursuant to this Agreement (or placed prior to the effective date of the termination if notice is given by AstraZeneca hereunder), unless otherwise instructed by AstraZeneca; and

17.10.2 AstraZeneca shall have the right to sell any Product in its inventory within the ninety (90) day period following termination of this Agreement, provided AstraZeneca pays to PreMD the applicable royalty, if any.

17.10.3 AstraZeneca shall assign to PreMD any Registrations that it has as a result of the exercise by AstraZeneca of its rights under Section 5.2.

This Section 17.10 shall survive termination of this Agreement.

17.11 Notwithstanding any such termination of this Agreement, the following provisions shall continue to apply: Articles I, XI XIII, XV XVII, XIX, and XX, Article XIV (insofar as it relates to Joint Intellectual Property) and Sections 2.6, 2.7, 5.5, 5.6 and 8.6.

## ARTICLE XVIII

### EXCHANGE OF INFORMATION

18.1 **Meetings.** At least once per Calendar Quarter throughout the Term of this Agreement, unless the Parties mutually agree in writing to a different frequency or to dispense with the requirements of this Article, an appropriate representative of each of the Parties shall meet to exchange the information contemplated herein (in addition to such other number of representatives of a Party as such Party may determine appropriate). Each such meeting will be conducted in person or by means of a conference telephone, videoconference, or similar communications equipment allowing all persons participating in the meeting to hear each other at the same time. Each Party shall bear all expenses it incurs in regard to participating in such meetings. Either Party may call a special meeting from time to time to address issues in connection with matters of the nature set out below in Section 18.2. The meetings will be held at locations alternately selected by AstraZeneca and by PreMD.

18.2 At each such meeting, (i) the Parties shall cause the Persons present and representing such Party to share and discuss with the other Persons updates on operational and

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intellectual property issues and (ii) AstraZeneca is to provide PreMD with information relating to its then-current marketing plan and shall provide PreMD with any relevant market and customer feedback on Product and strategic direction for Product in the Territory.

## ARTICLE XIX

### MISCELLANEOUS PROVISIONS

19.1 The rights and obligations of PreMD and AstraZeneca under this Agreement are personal thereto and neither Party shall have the right to sublicense (except with AstraZeneca's right to sublicense all or part of its rights and obligations under this Agreement to its Affiliates), assign, transfer or delegate, in whole or in part, any of its rights or obligations hereunder to any Third Party without the prior written consent of the other Party, except that either Party may assign this Agreement to any Affiliate provided that the assignor guarantees all of the covenants and obligations of such Affiliate arising pursuant to such assignment.

19.2 The illegality, invalidity, or otherwise voidability or unenforceability of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement. In the event that any part, section, clause, paragraph or subparagraph of this Agreement shall be held to be indefinite, invalid, illegal or otherwise voidable or unenforceable, the entire agreement shall not fail on account thereof, and the balance of this Agreement shall continue in full force and effect. The Parties shall replace such illegal or invalid provisions with a valid and enforceable provision which most closely approaches the idea, intent, and purpose of this Agreement, and in particular, the provision to be replaced.

19.3 Any notice required or permitted under this Agreement shall be deemed to have been sufficiently provided and effectively made (i) as of the delivery date if hand-delivered in person or by a reputable courier service, (ii) as of the delivery date if delivered by facsimile transmission (provided that if the transmission occurs on a day other than a day on which the main branches of chartered banks are open for business in The City of New York or after 5:00 p.m. on any day, then the facsimile transmission shall be deemed to be delivered on the next day on which such branches are open for business in The City of New York), or (iii) as of the fifth day following the mailing date if mailed by registered mail, postage-prepaid, and addressed to the receiving Party at the following respective address:

#### **To AstraZeneca Pharmaceuticals LP**

Address: 1800 Concord Pike  
Wilmington, DE 19858  
Facsimile: (302) 885-3919  
Attention: Vice President, Healthcare Innovation

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

With a copy to:

Address: AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
Wilmington, DE 19858  
Facsimile: (302) 886-4693  
Attention: General Counsel

**To PreMD:**

Address: Suite 615  
4211 Yonge Street  
Toronto, Ontario  
Canada M2P 2A9  
Facsimile: (416) 222-4533  
Attention: Chief Executive Officer

or such other address which the receiving Party has given notice pursuant to the terms of this Section 19.3.

19.4 This Agreement represents the entire understanding between AstraZeneca and PreMD, and supersedes all other understandings and agreements, express or implied, not specifically referenced and incorporated herein, concerning Product. Any modification of this Agreement to be effective must be in writing, specifically refer to this Agreement, and be signed by both Parties.

19.5 Any delays in or failures of performance by a Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected, including but not limited to: acts of terrorism, acts of God, embargoes, governmental restrictions, materials shortages, strikes or other concerted acts of workers, fire, flood, explosion, earthquake, hurricanes, storms, tornadoes, riots, wars, civil disorder, terrorism, failure of public utilities or common carriers, labor disturbances, rebellion or sabotage. The Party suffering such occurrence shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue, and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence; provided, however, that the Party suffering such occurrence uses commercially reasonable efforts to mitigate any damages incurred by the other Party. The Party giving such notice shall, thereupon, be excused from such of its obligations under this Agreement as it is, thereby, disabled from performing, except for the obligation to pay any amounts due and owing. The other Party may likewise suspend the performance of all or part of its obligations, except for the obligation to pay any amounts due and owing, to the extent that such suspension is commercially reasonable.

19.6 **Dispute Resolution.** In the event of any controversy or claim relating to, arising out of or in any way connected to any provision of this Agreement (a **Dispute**), either Party may, by notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated employees are as follows:

For PreMD: Chief Executive Officer, or his/her designee

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For AstraZeneca: Vice President, Healthcare Innovation, or his/her designee

If the Dispute has not been resolved by negotiation within thirty (30) days of the disputing Party's notice, the Parties shall endeavor to settle the Dispute by mediation under the Mediation Procedure of the International Institute for Conflict Prevention & Resolution (CPR) then in effect. Unless otherwise agreed, the Parties will select a mediator from the CPR Panel of Distinguished Neutrals and, failing agreement, such mediator shall be selected by CPR. All of the foregoing negotiations and proceedings shall be confidential and shall be treated as compromise and settlement negotiations for the purpose of applicable rules of evidence and any additional confidentiality protections provided by applicable law.

If mediation as contemplated above does not resolve the Dispute, such Dispute shall be finally resolved by final and binding arbitration in accordance with the Rules for Non-Administered Arbitration of CPR then pertaining, except where those rules conflict with this provision, in which case this provision controls. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16 to the exclusion of state laws inconsistent therewith. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Arbitration shall exclusively and solely be held in New York, New York. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitration shall be conducted before a single arbitrator mutually chosen by the Parties from the CPR's Panel of Distinguished Neutrals, but if the Parties have not agreed upon a single arbitrator within fifteen (15) days after notice of the institution of the arbitration proceeding, then the arbitration shall be conducted by an arbitrator selected by CPR. Within 45 days of initiation of the arbitration, the Parties shall reach agreement upon and thereafter follow procedures, including limits on discovery, assuring that the arbitration will be concluded and an award rendered within no more than eight months from selection of the arbitrator, or failing agreement, procedures meeting such time limits will be designated by the arbitrator and adhered to by the Parties. The arbitrator shall apply the substantive law of New York, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. Prior to the commencement of any arbitration, the Parties may apply to any court having jurisdiction for emergency relief to avoid irreparable harm. Except to the extent entry of judgment and any subsequent enforcement may require disclosure, all matters relating to the arbitration, including the award, shall be held in confidence by the Parties.

**19.7 Governing Law.** All matters affecting the interpretation, validity, and performance of this Agreement shall be governed by the laws of the State of New York, U.S.A., without regard to its choice or conflict of law principles other than Section 5-1401 of the New York General Obligations Law.

19.8 This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

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19.9 Each Party shall use commercially reasonable efforts to maintain in full force and effect all necessary licenses, permits and other authorizations required by Applicable Law to carry on its duties and obligations under this Agreement. Each Party shall comply with all Applicable Laws. Each Party shall cooperate with the other to provide such letters, documentation and other information on a timely basis as the other Party may reasonably require to fulfill its reporting and other obligations under Applicable Laws to applicable Regulators. Except for such amounts as are expressly required to be paid by a Party to the other under this Agreement, each Party shall be solely responsible for any costs incurred by it to comply with its obligations under Applicable Laws. Each Party shall conduct its activities hereunder in an ethical and professional manner.

19.10 This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

19.11 This Agreement is made subject to any restrictions concerning the export of products or technical information which may be imposed upon or related to any Party from time to time. Each Party agrees that it will not knowingly export, directly or indirectly, any technical information or any products to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity. The Parties agree to use Diligent Efforts to obtain all such consents and approvals prior to export of the Product.

19.12 Whenever this Agreement requires that a consent, approval, authorization or similar type of permission be obtained from a Party, then such consent, approval, authorization or similar type of permission shall not, unless otherwise expressly provided, be unreasonably withheld or delayed. Whenever in this Agreement provisions are made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised. As used in this Agreement, the words include and including, and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words without limitation.

19.13 **Rights Upon Insolvency.** All rights and licenses to Licensed Technology granted under or pursuant to this Agreement by PreMD to AstraZeneca are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ( **Title 11** ), licenses of rights to intellectual property as defined in Title 11. PreMD agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such Licensed Technology. If a case is commenced by or against PreMD under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, PreMD (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall either perform all of the obligations provided in this Agreement to be performed by PreMD or provide to AstraZeneca all such intellectual property

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(including all embodiments thereof) held by PreMD and such successors and assigns, as AstraZeneca may elect in a written request, immediately upon such request. If a Title 11 case is commenced by or against PreMD, this Agreement is rejected as provided in Title 11 and AstraZeneca elects to retain its rights hereunder as provided in Title 11, then PreMD (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall to the extent provided in this license, and to the requirements of 11 U.S.C. § 365(n) provide to AstraZeneca all such intellectual property (including all embodiments thereof) held by PreMD and such successors and assigns immediately upon AstraZeneca's written request therefor. All rights, powers and remedies of AstraZeneca, as a licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, Title 11) in the event of the commencement of a Title 11 case by or against PreMD. AstraZeneca, in addition to the rights, powers and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including Title 11) in such event.

19.14 This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission shall be as effective as an original executed signature page.

## ARTICLE XX

### TAXES

20.1 AstraZeneca will make all payments to PreMD under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

20.2 Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by AstraZeneca on behalf of PreMD to the appropriate governmental authority, and AstraZeneca will furnish PreMD with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by PreMD.

20.3 AstraZeneca and PreMD will cooperate with respect to all documentation required by any taxing authority or reasonably requested by AstraZeneca to secure a reduction in the rate of applicable withholding taxes. On the date of execution of this Agreement, PreMD will deliver to AstraZeneca an accurate and complete Internal Revenue Service Form W-8BEN certifying that PreMD, as licensor, is entitled to the applicable benefits under the Income Tax Treaty between Canada and the United States.

20.4 If AstraZeneca had a duty to withhold taxes in connection with any payment it made to PreMD under this Agreement but AstraZeneca failed to withhold, and such taxes were assessed against and paid by AstraZeneca, then PreMD will indemnify and hold harmless AstraZeneca from and against such taxes but excluding any penalties. If AstraZeneca makes a claim under this Section 20.4, AstraZeneca will comply with the obligations imposed by Section 20.2 as if AstraZeneca had withheld taxes from a payment to PreMD.

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20.5 Each Party shall be responsible for, and shall pay when due, any foreign, federal, state or local taxes and assessments (including income, Social Security, withholding and employment, franchise, property and Indirect Taxes) relating to any income or other consideration that such Party or any of its employees or agents derives, directly or indirectly, from this Agreement or for providing compensation, contributions and benefits to its employees and agents hereunder.

**[THE REMAINDER OF THIS PAGE IS INTENTIONALLY BLANK]**

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IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the day and year first written above.

**ASTRAZENECA PHARMACEUTICALS LP**

By: /s/ Tony Zook  
Name: Tony Zook  
Title: Chief Executive Officer,  
AstraZeneca North America

**PREMD INC.**

By: /s/ H.B. Brent Norton  
Name: Dr. H.B. Brent Norton  
Title: President and Chief Executive Officer

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**Appendix A**

**Licensed Know-How**

**Device Master Record (DMR):** Contains all procedures (processes and methods), formulations, diagrams, quality control tests (in process and final) required to manufacture product. PreMD has DMRs for:

PREVU\* POC Reagent Kit (manufactured by Fisher Diagnostics),

PREVU\* POC Cordless Spectrometer (manufactured by Jabil Circuit Inc.)

PREVU\* LT Detector Reagent (manufactured by Fisher Diagnostics)

PREVU\* LT Test Kit (manufactured by SouthMedic)

**Protocols:** PreMD followed IRB-approved protocols in its clinical trials. The following comprise the pivotal clinical studies that were conducted for PREVU\* products:

(I) PREVU\* POC

Angiography Studies (data used in K014018, PreMD's first 510(k) submission for PREVU\* POC)

Cleveland Clinic Foundation Angiography Study (99G1)

CHRC Angiography Study

PASA 510(k) → submitted to FDA on June 5, 2007

PASA CIMT protocol (04K1)

(II) PREVU\* LT

PREPARE 510(k), K063314

PREPARE protocol (03B1)

**Regulatory Submissions in US:** 510(k) documents submitted to FDA for PREVU\* POC and PREVU\* LT are listed below:

(I) PREVU\* POC

Edgar Filing: PreMD Inc. - Form 6-K

K011760 submitted to FDA in June 2001 FDA NSE letter received in September 2001

K014018 submitted to FDA in October 2001 FDA clearance received in June 2002

K062092 (Special 510(k) for cordless spectrophotometer) submitted to FDA in July 2006 FDA clearance received in September 2006

PASA 510(k) (K unknown) submitted to FDA in June 2007 FDA response expected in September 2007

(II) PREVU\* LT

K063314 submitted to FDA in November 2006 FDA NSE letter received in March 2007→ PreMD is discussing re-submission of a 510(k) with new data and IFU with FDA.

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**Toxicology / Safety Reports:** A toxicology study was carried out by a third party, Cantox Health Sciences International on the PREVU\* POC reagents. They were all found to be safe for use on the skin. Report is available at PreMD.

PREVU\* LT Tape is a hypoallergenic tape. MSDS for tape, provided by 3M (manufacturer of tape), is available at PreMD.

**PreMD Trade Marks**

Mark	Jurisdiction	Date Filed	Application Number	Status	Registration Number
Cholesterol 1,2,3	United States	21-March-00	76/006,213	Registered	2705836
PREVU*	United States	18-May-07	77/184341	In Progress	

**Marks under common law**

1. PREVU\* POC
2. PREVU\* LT
3. PREVU\* PT

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## Appendix B

## PreMD Patents and Patent Applications

## PATENT TITLE: MULTILAYER ANALYTICAL ELEMENT

INVENTOR(S): Alexander M. MALEEV, Yevgeney B. BABLYUK, Ivan A. KOCHETOV, Alexandr S. PARFENOV, Yury M. LOPUKHIN, Alexandr B. RABOVSKI

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
Australia	41694/96	Dec. 14, 1995	0702663	June 3, 1999	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Belgium	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Brazil	PI9510038-5	Dec. 14, 1995	N/A	N/A	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Canada	2,207,555	Dec. 14, 1995	2,207,555	Feb. 24, 2004	Maintenance fee due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
China	95197367.3	Dec. 14, 1995	ZL95197367.3	June 23, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Europe	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Expires <b>Dec. 14, 2015.</b>	Dec. 14, 2015
France	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Germany	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Greece	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Ireland	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Italy	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Japan	8517984	Dec. 14, 1995	3755007	Jan. 6, 2006	Renewal due <b>Jan. 6, 2009.</b>	Jan. 6, 2015
Korea	97-704028	Dec. 14, 1995	235211	Sept. 21, 1999	Renewal due <b>Sept. 30, 2007.</b>	Sept. 30, 2015
Mexico	974469	Dec. 14, 1995	227267	April 15, 2005	Renewal due <b>Dec. 1, 2010.</b>	Dec. 1, 2015
Netherlands	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
PCT	PCT/CA95/00698	Dec. 14, 1995	N/A	N/A	Entered national phase.	
Portugal	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Spain	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
Sweden	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
United Kingdom	95940097.9	Dec. 14, 1995	0797774	Nov. 10, 2004	Renewal due <b>Dec. 14, 2007.</b>	Dec. 14, 2015
United States	08/849,252	Dec. 14, 1995	6,605,440	Aug. 12, 2003	Renewal due <b>Feb. 12, 2011.</b>	Feb. 12, 2015

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**PATENT TITLE: METHOD FOR IDENTIFYING CHOLESTEROL IN THE SKIN TISSUE****INVENTOR(S): Alexandr S. PARFENOV and Yuri M. LOPUKHIN**

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
Brazil	PI9807594-2	Jan. 26, 1998	N/A	N/A	Renewal due <b>Jan. 26, 2008.</b>	Jan. 26, 2018
Canada	2,281,769	Jan. 26, 1998	2281769	March 21, 2006	Maintenance fee due <b>Jan. 26, 2008.</b>	Jan. 26, 2018
Europe	98901608.4	Jan. 26, 1998	N/A	N/A	Renewal due <b>Jan. 26, 2008.</b>	Jan. 26, 2018
Hong Kong	105898.2	Sept. 19, 2000	N/A	N/A	Renewal due <b>Jan. 26, 2008.</b>	Jan. 26, 2018
Japan	10-536529	Jan. 26, 1998	3694324	July 1, 2005	Renewal due <b>July 1, 2008.</b>	Jan. 26, 2018
PCT	PCT/RU98/00010	Jan. 26, 1998	N/A	N/A	Entered national phase.	
United States	09/367,724	Jan. 26, 1998	6,365,363	April 2, 2002	Renewal due <b>Oct. 2, 2009.</b>	Jan. 26, 2018

**PATENT TITLE: CHOLESTEROL TEST****INVENTOR(S): Jury M. LOPUKHIN, Viktor V. ZUEVSKY, Alexandr B. RABOVSKY, Irina P. ANDRIANOVA**

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
Austria	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 26, 2009
Canada	588,652	Jan. 19, 1989	1,335,968	June 20, 1995	Maintenance fee due <b>June 20, 2008.</b>	June 20, 2012
Europe	89100828.6	Jan. 18, 1989	0338189	April 24, 1996		Jan. 18, 2009
France	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009
Germany	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009
Italy	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009
Sweden	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009
Switzerland	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009
United Kingdom	89100828.6	Jan. 18, 1989	0338189	April 24, 1996	Renewal due <b>Jan. 18, 2008.</b>	Jan. 18, 2009

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**PATENT TITLE: SPECTROPHOTOMETRIC MEASUREMENT IN COLOR-BASED BIOCHEMICAL AND IMMUNOLOGICAL ASSAYS****INVENTOR(S): Michael J. EVELEGH****ARTICLE XXXI**

<b>Country</b>	<b>Application No.</b>	<b>Filing Date</b>	<b>Patent No.</b>	<b>Issue Date</b>	<b>Due Date</b>	<b>Expiration Date</b>
Australia	66734/00	August 4, 2000	781034	Aug. 18, 2005	Renewal due <b>Aug. 4, 2007.</b>	Aug. 4, 2020
Brazil	PI0013096-6	August 4, 2000	N/A	N/A	Renewal due <b>Aug. 4, 2008.</b>	Aug. 4, 2020
China	813497.9	August 4, 2000	N/A	N/A	Application Pending.	
China (Divisional)	200710096878.X	August 4, 2000	N/A	N/A	Application Pending.	
Europe	00954181.4	August 4, 2000	N/A	N/A	Renewal due <b>Aug. 4, 2008.</b>	
Hong Kong	3106071.6	August 25, 2003	N/A	N/A	Renewal due <b>Aug. 4, 2009.</b>	
India	IN/PCT/2002/00307	March 4, 2002	N/A	N/A	Pending.	
Japan	2001-515964	August 4, 2000	N/A	N/A	Examination due <b>Aug. 4, 2007.</b>	
PCT	PCT/CA00/00918	August 4, 2000	N/A	N/A	Closed. Provisional US Application replaced with PCT Application.	
Russia	2002103517	August 4, 2000	2271539	March 10, 2006	Renewal due <b>Aug. 4, 2007.</b>	Aug. 4, 2020
United States	09/830,708	April 30, 2001	N/A	N/A	Abandoned in favor of the continuation.	
United States (Continuation)	10/887,737	July 9, 2004	N/A	N/A	Application Pending.	

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



**PATENT TITLE: DIRECT ASSAY OF CHOLESTEROL ON SKIN SAMPLES REMOVED BY TAPE STRIPPING****INVENTOR(S): Peter HORSEWOOD and Robert ZAWYDIWSKI**

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
Australia	2005238099	April 28, 2005	N/A	N/A	Exam due <b>Sept. 27, 2007.</b>	
Brazil	PI0510352-5	April 28, 2005	N/A	N/A	Renewal due <b>April 28, 2010.</b> Renewal due <b>April 28, 2008.</b>	
Canada	2,465,427	April 28, 2004	N/A	N/A	Exam due <b>April 28, 2008.</b> Maintenance fee due <b>April 28, 2008.</b>	April 28, 2024
Canada	2,563,973	April 28, 2005	N/A	N/A	Exam due <b>April 28, 2009.</b> Maintenance fee due <b>April 28, 2008.</b>	
China	200580013893.2	April 28, 2005	N/A	N/A	Exam due <b>April 28, 2010.</b> Application Pending.	
Europe	05738502.3	April 28, 2005	N/A	N/A	Renewal Due <b>April 28, 2008.</b>	
Hong Kong	07101674.4	February 12, 2007	N/A	N/A	Renewal due <b>April 28, 2012.</b>	
India	3171/KOLNP/2006	April 28, 2005	N/A	N/A	Exam due <b>April 28, 2008.</b>	
Japan	2007-509839	April 28, 2005	N/A	N/A	Exam due <b>April 28, 2008.</b>	
Mexico	PA/A/2006/012326	April 28, 2005	N/A	N/A	Application Pending.	
PCT	PCT/CA2005/000642	April 28, 2005	N/A	N/A	To be closed.	
Russia	2006137332	April 28, 2005	N/A	N/A	Reply due <b>June 23, 2007.</b>	
United States	10/835,397	April 30, 2004	N/A	N/A	Application Pending Allowed	
United States	11/116,412	April 28, 2005	N/A	N/A	Issue fee due <b>Aug. 10, 2007.</b> Application Pending.	

(Continuation)

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**PATENT TITLE: METHOD AND APPARATUS FOR NON-INVASIVE MEASUREMENT OF SKIN-TISSUE CHOLESTEROL**

**INVENTOR(S): Peter HORSEWOOD**

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
PCT	PCT/CA2006/000293	Feb. 28, 2006	N/A	N/A	File Applications in other countries by <b>August 28, 2007.</b>	
United States	60/656381	Feb. 28, 2005	N/A	N/A	Closed. Provisional US Application replaced with PCT Application.	Feb. 28, 2006

**PATENT TITLE: DIRECT ASSAY OF PROTEIN IN SKIN SAMPLES REMOVED BY TAPE STRIPPING**

**INVENTOR(S): Peter HORSEWOOD and Robert ZAWYDIWSKI**

Country	Application No.	Filing Date	Patent No.	Issue Date	Due Date	Expiration Date
PCT	PCT/CA2006/000831	May 19, 2006	N/A	N/A	File Applications in other Countries by <b>Nov. 20, 2007.</b>	
United States	60/682,837	May 20, 2005	N/A	N/A	Closed. Provisional US Application replaced with PCT Application.	May 20, 2006

**PATENT TITLE: SKIN SAMPLING AND TESTING DEVICE**

United States [\*\*\*] Jan. 16, 2007 N/A N/A [\*\*\*]

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Appendix C**

**PreMD Improvement Intellectual Property**

{The remainder of this page is intentionally blank. The schedule will be created and updated according to the Agreement}

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix D**

**PreMD Trademarks**

**PreMD Trade Marks**

Mark	Jurisdiction	Date Filed	Application	Status	Registration
			Number		Number
Cholesterol 1,2,3	United States	21-March-00	76/006,213	Registered	2705836
PREVU*	United States	18-May-07	77/184341	In Progress	

**Marks under common law**

4. PREVU\* POC

5. PREVU\* LT

6. PREVU\* PT

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Appendix E**

**PREVU\* LT Product Description And Drawing**

**PREVU\* LT Product Description:**

Patients will be asked to wash their hands and the palm area will then be cleansed with an alcohol swab.

Pressure will be applied to the protective cover on the sample collection device by rubbing a thumb across the covered tape. This ensures that the tape on the device will stick to the device.

The protective cover will be removed from the tape on the sample collection device and the tape applied to the cleaned and dried palmar (hand) surface. Pressure will be applied to the tape by rubbing a thumb across the back of the sample collection device such that the tape will stick to the palm.

The sample collection device will then be removed and reapplied to a different area of the palm and pressure again applied. Application and removal of the sample collection device will be done for a total of 10 times.

After the final application, the sample collection device will be closed, donor information completed on the label and the sample collection device sent to the lab for processing.

At the lab:

The PREVU\* LT sample collection device will be cut into predetermined sticks for testing using the laser cutter.

The sticks will be placed into designated wells of a 96 well microtiter plate and the position recorded such that all samples can be identified with the donor. Blank sticks will be included in the wells as negative controls and the plate loaded onto an automated microwell plate washer/reader for testing.

Detector reagent will be added to all wells and the plate incubated at ambient room temperature (20-24°C).

The detector reagent will be aspirated after 15 minutes and the wells/sticks washed 4 times with a buffer solution containing detergent.

After the last wash the sticks will be added to the substrate solution specific for the detector enzyme and the plates incubated at ambient room temperature (20-24°C).

The reaction will be stopped after 15 minutes by the removal of the sticks and addition of dilute acid to all wells.

The OD at 450 nm will be read for all wells.

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**PREVU\* LT Product Drawing:**

[GRAPHIC]

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix F**

**Summary of PREVU\* POC Product**

**Summary and Explanation of the Test**

Elevated serum cholesterol is a recognized risk factor for coronary artery disease (CAD) and there is strong evidence for a reduction of CAD after lowering of high cholesterol levels. In addition, serum cholesterol can be separated into low-density lipoprotein (LDL) and high-density lipoprotein (HDL) components. CAD risk is increased when LDL is elevated and when HDL is reduced.

Besides its quantification in the blood, cholesterol can also be measured in the skin. Skin contains approximately 11%, by weight, of all body cholesterol and has been cited as mirroring vascular changes associated with age and atherosclerosis. A number of studies have demonstrated a relationship between skin cholesterol levels and CAD and more recently studies showing a relationship between skin cholesterol levels and treadmill stress test outcome. Skin cholesterol correlated with angiographically and coronary calcium proven CAD has been reported.

PREVU\* POC employs a synthetic copolymer conjugated with digitonin and horseradish peroxidase to detect and quantify the amount of cholesterol in the patient's epidermis.

PREVU\* POC is an *in vitro* diagnostic test, which can be used in conjunction with clinical evaluation and other lipoprotein tests as part of risk assessment for coronary artery disease.

**Principle of the Procedure**

PREVU\* POC is a rapid two-step test for the detection of skin cholesterol. The test is performed on the palmar surface of the hand and requires no prior fasting. A solution containing digitonin-labelled copolymer (detector) is first placed on the palm of the hand for one minute. The digitonin complexes with cholesterol in the skin. After one minute, the palm is blotted dry with a blotting stick. A second indicator reagent is then added to the test sites and incubates for two minutes. The substrate in the colorless indicator reacts with the horseradish peroxidase conjugated to the copolymer to produce a blue colour, the intensity of which is proportional to the amount of cholesterol detected.

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**



**PREVU\* POC Test Kit**

[GRAPHIC]

A hand-held reader is used to generate a numeric value for skin cholesterol. Negative and positive controls applied to the palm in parallel with the detector reagent serve to monitor test performance.

[GRAPHIC]

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix G**

**PREVU\* PT Product Prototype Drawing and Summary**

**PREVU\* PT Prototype Summary:**

PREVU\* PT is a single-use home *in vitro* test for the detection of skin cholesterol. Its simple use allows completing the test in minutes. The test is performed on the palmer surface of the hand and requires no prior fasting. The color comparator strip allows a simple, visually-interpretive scoring of the assay results.

**Principle of the Prototype Procedure:**

The consumer washes his/her hands with soap and water, and dries them thoroughly.

The consumer takes the Indicator Bottle and soaks the Indicator Pad.

The consumer takes the Alcohol Wipe and thoroughly cleans the entire palm of the right hand.

The consumer opens the Detector Cartridge. The hand is placed on the Detector Cartridge for 1 minute.

After 1 minute the consumer removes the hand and blots in three different areas of the Blotting Pad (Section 2).

The hand is placed on the Indicator Pad (Section 3) for 1 minute.

After 1 minute, the hand is removed from the Indicator Pad and the test result is measured. For a valid test, the Positive Control must be a blue colour. The colour card is used to measure the Test Spot. The colour from the card that is closest to the test spot indicates the test result.

**PREVU\* PT Prototype Materials:**

1. [\*\*\*]:
  - a. [\*\*\*]
  - b. [\*\*\*]
  - c. [\*\*\*].
  - d. [\*\*\*] [\*\*\*] [\*\*\*].

e. [\*\*\*].

2. [\*\*\*].

3. [\*\*\*]

4. [\*\*\*]

5. [\*\*\*]

6. [\*\*\*]

**PREVU PT Product Prototype Drawing:**

[GRAPHIC]

As of November 3, 2004

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix H**

**PREVU\* POC Product Specifications**

**Test Kit**

Each PREVU\* POC Test Kit contains 40 individual tests. Each kit contains the following components:

1. Detector Reagent

[\*\*\*]

2. Positive Control

[\*\*\*]

3. Indicator Reagent

[\*\*\*]

4. 5 Anti-static Bags for Foam Pads

5. 1 Labeled Outer Box

6. 44 Foam Pads

7. 40 Alcohol Swabs

8. 40 Double-ended Blotting Sticks

9. 40 Wet-Nap®

10. 1 Product Insert

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Spectrometer Specifications**

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Trademarks of Seiko Instruments USA Inc.

Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Labeling**

**Test Kit Labeling**

[GRAPHIC]

**Cordless Reader Labeling**

[GRAPHIC]

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix I**

**Marketing Plan**

**Industry:**

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Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



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**Appendix J**

**Specified Assets**

PREVU\* Website files and PreMD's copyright interest thereto

prevu.com domain name and PreMD's copyright interest thereto

PREVU\* toll free number 1-866-283-8328

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

## Appendix K

## Royalty Report

## ROYALTY REPORT FOR SALES OF PRODUCT

(INCLUDING PREVU\* PT PRODUCT, PREVU\* POC PRODUCT AND PREVU\* LT PRODUCT)

Calendar Year: \_\_\_\_\_

Quarter Ending: \_\_\_\_\_

All amounts in U.S. Dollars.

This report is subject to terms of the AstraZeneca-PreMD License, Development and Supply Agreement (the Agreement).

## 1. ROYALTY REPORT FOR SALES OF PRODUCT (EXCLUDING READER)

Table 1: Royalty for Sales of Product (excluding Reader)

Item	Description	Amount
<b>INFORMATION FOR CURRENT QUARTER AND CALENDAR YEAR</b>		
	<b>Gross Invoiced Amount on Sales of Product (excluding Reader) in Current Quarter</b>	\$
	<i>Less:</i>	
	Trade, Quantity or Prompt Settlement Discounts (including Chargebacks and Allowances)	\$
	Amounts Repaid or Credited for Rejection, Returned Goods, Recalled Goods, or Price Reductions	\$
	Rebates Paid by Governmental or Regulatory Authority	\$
	Uncollected Invoiced Amounts, including Bad Debts	\$
	Taxes	\$
	Custom Duties, Custom Levies, and Import Fees	\$
	Any other Similar and Customary Deductions Consistent with GAAP	\$
<b>A</b>	<b>Total Net Sales (excluding Reader) for Current Quarter</b>	\$
<b>B</b>	<b>Total Net Sales (excluding Reader) for Previous Quarters in Same Calendar Year</b>	\$
<b>C</b>	<b>Total Net Sales (excluding Reader) in Calendar Year</b>	\$
<b>D</b>	<b>Royalty Threshold</b>	\$ [***]
<b>E</b>	<b>Number of Units of Product (excluding Reader) Sold in Current Quarter</b>	
<b>F</b>	<b>Number of Units of Product (excluding Reader) Sold in Previous Quarters in Same Calendar Year</b>	

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Table 1: Royalty for Sales of Product (excluding Reader)

Item	Description	Amount
	<b>Price Per Unit</b>	<b>\$</b>
<b>ROYALTY CALCULATION</b>		
<i>Instructions:</i>		
<i>If Item C is equal to or less than Item D, go to Item G to calculate royalty for current quarter.</i>		
<i>If Item C is greater than Item D, go to Item J to calculate royalty for current quarter.</i>		
[***]	[***]	
[***]	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
[***]	[***]	
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
<b>TOTAL ROYALTY IN CURRENT QUARTER: GREATER AMOUNT BETWEEN ITEM K AND ITEM L (IF APPLICABLE) PLUS ITEM M</b>		<b>\$</b>
<b>N</b>	<b>Total Royalty in Calendar Year</b>	<b>\$</b>

Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.





Appendix L

Rolling Demand Forecast

Year 1

United States

PRODUCT	Month												Total	
	x	x+1	x+2	x+3	x+4	x+5	x+6	x+7	x+8	x+9	x+10	x+11		x+12
PREVU* POC														0
Reader														0
<b>Total Forecast</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

BINDING

NON-BINDING

RDF due to PreMD the 10th day of each month.

Binding period is the next 3 month period.

Non-binding period is the last 9 month period.

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**Appendix M**

**Quality Control**

Quality Control tests and assays attached include the different suppliers Quality Control Procedures:

1. Reader:

a. Inspection and Packout Appendix M1

b. PCB Inspection Visual Appendix M2

c. Final Inspection Appendix M3

2. Reagents:

a. PREVU Reagents Quality Control Appendix M4

3. Tape Test Device Production and Inspection Appendix M5

[GRAPHIC]

[GRAPHIC]

[GRAPHIC]

**Appendix M4**

**PREVU \* Reagents Quality Control**

**PREVU\* Reagents Quality Control**

Revision History:

<b>Rev #</b>	<b>Date</b>	<b>By</b>	<b>Description of Revision</b>
Trial 3515A	06/16/06	B. Saunders	New trial issue. Updated customer document into Fisher Middletown format.
	7/17/06	B. Saunders	Updated to remove calculations moved to PMR and for Lab comments
	9/18/06	B. Saunders	Clarified use of positive displacement pipettes

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Purpose

To describe the quality control procedure testing of bulk prepared detector (digitonin-HRP-polymer conjugate) and release of the POC kit.

Responsibility

Manager is responsible for reviewing the completed results to ensure that the information entered by the operator is complete and accurate and that all calculations are correct.

**Part A. HRP Assay**

I. Equipment and Materials

- A. Positive displacement Pipetters of appropriate size
- B. Multi-channel pipettor
- C. Positive displacement Pipette tips of appropriate size
- D. Microplate ELISA reader equipped with 450nm filter
- E. Tubes of appropriate size
- F. NUNC-Immuno Module U8 Polysorp Stripwell (Fisher PN# 12-565-118)

Component	Supplier	Product Number	Lot Number
HRP Enzyme Standard	PreMD	Contact PreMD	
Reference Detector (PRL)	In-House	360097PR	
Bulk Test Detector	In-House	360097PR	
StabilZyme Select	Surmodics	SZ03	
Enhanced K-Blue Substrate	Neogen	RM1021	
1N Sulphuric Acid	N/A	N/A	

Checked By:

Date:

II. HRP Activity Assay:

Check of POC detector conjugate equivalent to HRP reference.

- A. Bring all reagents to room temperature (18-25°C).

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- B. Prepare 0.1 mL of a  $1/2$  dilution test detector conjugate in StabilZyme diluent [one part Stabilzyme Select plus one part water] using the following volumes of bulk detector and diluent. Use positive displacement pipettes:

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Volumes required:

<b>Material</b>	<b>Volume</b>
Bulk Test Detector	0.050 mL
StabilZyme Diluent	0.050 mL

- C. Prepare 0.1 mL of a 1:2 dilution reference detector conjugate in StabilZyme diluent [one part Stabilzyme Select plus one part water] using the following volumes of bulk detector and diluent. Use positive displacement pipettes:

Volumes required:

<b>Material</b>	<b>Volume</b>
Reference Test Detector	0.050 mL
StabilZyme Diluent	0.050 mL

- D. To triplicate wells of uncoated round-bottom stripwells, add 5 uL aliquots of diluent (wells B1-B3), horseradish peroxidase enzyme standard (wells C1-C3), diluted reference detector (wells D1-D3) and diluted test detector (wells E1-E3).
- E. Use a multichannel pipettor to add 100 uL of Enhanced K-Blue substrate to all wells including a well containing no reagents (well A1, machine blank). Start timer immediately after addition to first strip of wells. After adding substrate to last wells gently tap plate to mix.
- F. Cover stripwells using an opaque cover and incubate for 5 minutes at room temperature in the dark.
- G. Just before the end of the incubation (at about 4 min. 45 sec.) remove the cover from the plate. Use a multichannel pipettor to add 50 uL of 1N sulphuric acid to each well to stop the reaction after 5 min. Add the acid to the wells in the same order as the substrate was added to ensure equal time for substrate incubations. Tap the plate to gently mix.
- H. Read optical density (OD) at 450 nm blanked against well containing substrate/acid only. Read plate within 10 min. of adding acid.
- I. Record results on test sheet. Calculate the ratio of reference detector to HRP standard and test detector to HRP standard.

### III. Validity Criteria:

#### A. General:

- Machine Blank, Diluent Blank, and HRP Enzyme Standard must satisfy their expected ranges for valid assay (Blank  $\leq$  0.100; Diluent  $\leq$  0.050; Free HRP Enzyme Std. = 0.92-1.24)
- Repeat assay if validity criteria are not satisfied.

## Edgar Filing: PreMD Inc. - Form 6-K

Note: Thermo-Fisher form IT 123-20-DET is a document for PREMD Bulk Detector and records Bill of Materials, all volumes of reagents used in the manufacture and any calculations done, the Lots # of all reagents used, the person who performed each step, the person who verified each step and the date for each step. This is also the document on which the actual test values are recorded. The guidelines state that if the testing fails, a statement of non-compliance has to be issued and discussion for follow up action has to be convened.

All results are documented on this form and raw data attached.

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B. Diluted test detector:

Test detector must exhibit a ratio to HRP standard between 0.83 and 0.93.

Repeat assay if validity criteria is not satisfied.

IV. Documentation

Attach raw data to document

**Part B. Skin Cholesterol Assay**

I. Compare reference and test detectors on seven (7) individuals. Test the reference detector on the left hand and the test detector on the right hand.

II. Equipment needed:

a. Test reader and computer (PreMD supplied)

b. Test detector Lot # \_\_\_\_\_

c. Reference Detector Lot # \_\_\_\_\_

d. Indicator Lot# \_\_\_\_\_

III. Setup the reader system per manufacturers instructions.

IV. Bring all reagents to room temperature.

V. Record results on test sheet

VI. Validity Criteria:

Test detector must be +/- 10 % of reference detector.

VII. Documentation

Attach raw data to document

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as**

**amended.**



[GRAPHIC]

[GRAPHIC]

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**Appendix N**

**Quality Agreement**

**QUALITY AGREEMENT**

**BETWEEN**

**PreMD Inc.**

**(Toronto, Canada)**

**And**

**AstraZeneca Pharmaceuticals LP**

**(Wilmington, Delaware, U.S.A.)**

**For the Coordination of PREVU\* Products for Professional Use**

**Quality Agreement PMD:AZ-070516-2**

**AZ QAA Reference Number: VZ18.0**

**Effective Date:**

**Distribution List:**

PreMD Inc.  
AstraZeneca

Regulatory and Quality Department  
*Operations Quality and Compliance Department*

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**The undersigned hereby confirm that attached hereto is the Quality Agreement referenced in Section 7.1 of the License, Development and Supply Agreement.**

/s/ Laila A. Gurney

Laila A. Gurney, M.Sc., RAC

Date

Director, Clinical, Quality and Regulatory Affairs

PreMD Inc.

/s/ Michael J. Evelegh

Michael J. Evelegh, PhD.

Date

Executive Vice-President, Clinical and Regulatory Affairs

PreMD Inc.

/s/ Jose Cruz

Jose Cruz, M.Sc.

Date

Director, QA GMP Systems & Compliance

AstraZeneca Pharmaceuticals LP

/s/ Christina Vietri

Christina Vietri, M.Sc.

Date

Senior Manager, GMP Systems & Compliance

AstraZeneca Pharmaceuticals LP

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**GLOSSARY**

Any terms not otherwise defined in this Agreement shall have the meaning set forth in the License, Development and Supply Agreement.

**AstraZeneca:** AstraZeneca Pharmaceuticals LP

**Bill of Lading (BOL):** a contract for the carriage of goods. It provides:

- A receipt to the shipper that the goods have been accepted for transport;
- indicates the Shipping and Delivery addresses;
- number of pallets, weight, # of containers;
- Product description;
- finished good part number;
- purchase order number;
- quantity of Product; and
- lot / serial number.

**CAPA:** Corrective and preventative actions.

**Device History Record (DHR):** a compilation of records containing the Production history of a finished device, as per the Device Master Record.

**Device Master Record (DMR):** a master compilation of documents containing the procedures and specifications for a finished device.

**FDA:** Food and Drug Administration of The United States of America.

**FDA Quality Systems Regulations: U.S. 21 CFR parts 803, 812 and 820.**

**Identifier:** a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.

**License, Development and Supply Agreement:** the License, Development and Supply Agreement between the parties hereto dated as of the date hereof, as the same may be amended from time to time.

**Non-Conformance Report:** means a documented evaluation and investigation of product that does not conform to specified requirements as provided in the Device Master Record.

**Observation:** Inspection Observations issued by FDA on Form 483 pursuant to section 704(b) of the FDCA.

**PreMD:** PreMD Inc.

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



**Product:** Finished medical devices (listed in Appendix I).

**Significant Change:** a change that could reasonably be expected to affect the identity, safety or effectiveness of a medical device. It includes a change to any of the following:

(a) the manufacturing process facility or equipment;

(b) the manufacturing quality control procedures, including the methods, equipment, tests or procedures used to control and/or monitor the quality of the device or of the materials used in its manufacture;

(c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories;

(d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.

(e) supplier or material supplied for the manufacture, packaging, labeling, testing, storage, or transport of the materials or product.

**System:** a medical device comprising a number of components or parts intended to be used together to fulfill some or all of the device's intended functions, and that is sold under a single name.

**Test kit:** an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.

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**1. PURPOSE**

- 1.1 This Agreement covers responsibilities of PreMD and AstraZeneca, for the manufacturing, packaging, safety, effectiveness, labelling, testing, storage and release for each Product listed in Appendix I.
- 1.2 This Agreement is entered into pursuant to and is subject to the License, Development and Supply Agreement. In the event of any conflict between the provisions of this Agreement and the provisions of the License, Development and Supply Agreement, the provisions of the License, Development and Supply Agreement shall govern.  
This Agreement shall come into effect on the Effective Date and shall terminate when the License, Development and Supply Agreement terminates with the exception of necessary activities associated with the Product distributed by AstraZeneca remaining in the field with an expiration date for which records would need to be maintained, complaints handled and Medical Device Reportable Events under 21 C.F.R. Part 803 reported.
- 1.3 To indicate those areas of responsibility for Quality issues of PreMD for control of its operating affiliates or contractors.
- 1.4 To provide guidelines that will ensure compliance with Good Manufacturing Practices, as defined by ISO 13485, and FDA Quality Systems Regulations, each as amended from time to time. To the extent that the terms and conditions of this Agreement or the License, Development and Supply Agreement are inconsistent with the requirements of Good Manufacturing Practices, as defined by ISO 13485, and FDA Quality Systems Regulations, each as amended from time to time, compliance with such requirements shall be deemed compliance with the terms of this Agreement and the License, Development and Supply Agreement.
- 1.5 PreMD is responsible to ensure that the Product satisfies ISO 13485, and FDA Quality Systems Regulations, as amended from time to time.
- 1.6 At a minimum, all parties shall review this Agreement within four years from the current revision's effective date. As necessary, the document should be revised to capture this review and/or any changes in requirements, operations and/or Products. The parties must approve any revisions to this Agreement.
- NOTE: PreMD is responsible for the coordination of Quality related activities with its contract manufacturers, suppliers and laboratories.

**2. CHANGES AND NON-CONFORMANCE REPORTING**

- 2.1 PreMD shall review with AstraZeneca all planned and unplanned Significant Changes having a potential impact to Product Quality sufficiently in advance of the anticipated date of implementation to permit adequate discussion. AstraZeneca shall review and approve Significant Changes affecting Products manufactured for AstraZeneca by PreMD or PreMD's contractors and shall provide PreMD with feedback within a reasonable timeframe.

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- 2.2 PreMD shall provide all planned and unplanned change control documents, Non-Conformance Reports, including risk assessments and CAPA, and laboratory investigation reports to AstraZeneca. PreMD shall provide the foregoing to AstraZeneca at least annually and otherwise on a more frequent basis that is mutually agreed to by the parties.
- 2.3 A Non-Conformance Report is required in a situation wherein there has been a failure to comply with a requirement of an approved specification. This is a departure that was not anticipated. For non-conformances due to manufacturing or packaging of Product for AstraZeneca, which affect or could affect the currently marketed Product or the ability to market the Product, PreMD will contact AstraZeneca (contacts are indicated in Appendix II) within 2 days of learning about the non-conformance (provided that if at the time of receipt of such report the office of PreMD is closed, then the same shall be provided within 1 day after the next day on which the office of PreMD is open for business). Copies of all applicable Non-Conformance Reports must be included in the Device History Record. PreMD shall provide AstraZeneca with a copy of Non-Conformance Reports, including risk assessments and CAPA, and laboratory investigation reports. PreMD shall provide the foregoing to AstraZeneca at least annually and otherwise on a more frequent basis that is mutually agreed to by the parties.
- 2.4 Materials that fail for identification or efficacy, render the Product unsafe, or violate label claims, must be investigated and documented in a Non-Conformance Report along with the appropriate disposition (including, for example, rework to make any such Product conforming). Documentation shall include the justification for use of nonconforming product and the appropriate signatures of the individual(s) authorizing the use. Notwithstanding the foregoing, any such non-conforming Product shall never be used until such time as the Product shall otherwise conform.
- 2.5 Changes to any manufacturing, packaging, cleaning, or analytical test procedures must be evaluated by PreMD prior to the change being made to assess any potential impact on validation.
- 2.6 AstraZeneca must be notified of and approve changes in accordance with the License, Development, and Supply Agreement, prior to any change in contract manufacturers, packaging, labeling, and/or Product testing locations.

### **3. FACILITY**

- 3.1 PreMD shall ensure that its contract manufacturing facilities meet all applicable current Good Manufacturing Practice (cGMP) requirements as defined in ISO 13485, and FDA Quality Systems Regulations as well as requirements established by applicable federal,

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state / provincial, and local laws. Any changes to contract manufacturing facilities and/or manufacturing processes that affect the Products listed in Appendix I require AstraZeneca approval (refer to Appendix II for contacts).

- 3.2 Any governmental and/or regulatory visits to the facility (both PreMD and contract manufacturing facilities, listed in Appendix IV) related to AstraZeneca Products require immediate AstraZeneca notification (refer to Appendix II for contacts). If any samples are taken, PreMD shall collect duplicate samples from the same lot and location.
- 3.3 PreMD shall ensure that all components, materials, and finished Products are stored in accordance with the Product specifications in areas that are in compliance with federal and provincial / state regulations. Areas shall be clean and controlled to prevent contamination and/or deterioration in storage and in use. Appropriate pest control programs shall be in place to prevent contamination. Areas shall be controlled and monitored for temperature, humidity, and security to ensure Product quality is not compromised.
- 3.4 PreMD shall conduct periodic audits of its suppliers and contract manufacturers and testing facilities to assess compliance to all applicable requirements such as ISO 13485 and FDA QSR regulations. PreMD shall have a system in place to identify and communicate observed deficiencies to these suppliers and contractors, as well as a system to ensure tracking and completion of associated CAPA.

#### **4. DOCUMENTATION REQUIREMENTS**

Documents must be provided in English.

#### **DISTRIBUTION:**

- 4.1 AstraZeneca may request to review applicable facilities and documentation relating to the manufacture, testing, labelling, and storage of the Product from PreMD annually or more frequently, if there are quality or regulatory concerns. PreMD shall allow AstraZeneca to review such facilities and documentation, by either providing copies of these documents to AstraZeneca or arranging for AstraZeneca to visit its contract manufacturing facilities to review the facilities and documents on site (see section 9.4).
- 4.2 The following documentation comprises the **PRODUCT DOCUMENT FILE**.

#### **Certificate of Conformance**

#### **Confirmation of quantity shipped (i.e. Bill of Lading)**

The Certificate of Conformance shall include the following:

Supplier Name,

Date of final quality control release,

Purchase Order Number,

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Catalogue/Part Number and Revision,

Quantity/Count,

Lot / Serial number,

Expiration date,

A statement certifying that the shipment was manufactured and tested in accordance with the applicable Device Master Records and signed by PreMD Quality Management (as set out below).

A copy of the complete Product Document File that is approved by PreMD shall be provided to AstraZeneca Quality Assurance (Appendix II) for the PREVU\* POC Spectrometer, and copy of the Certificate of Conformance that is approved by PreMD shall be provided to AstraZeneca by PreMD's contract manufacturer for the PREVU\* POC reagent kits no less than 5 days prior to each batch or lot of Product being scheduled for pick up by or on behalf of AstraZeneca.

PreMD shall provide AstraZeneca with Non-Conformance Reports, including risk assessments and CAPA and laboratory investigation reports for the reagents, if applicable, no less than annually.

4.3 The Product Document File (other than the Bill of Lading) shall be submitted to AstraZeneca Quality Assurance prior to shipment of each Product listed in Appendix I.

## **5. MATERIALS - SPECIFICATIONS AND QUALITY**

5.1 PreMD shall ensure that its contract manufacturers order and receive raw materials from PreMD approved suppliers for manufacture of the Products listed in Appendix I. A list of approved raw material suppliers shall be made available to AstraZeneca upon request and automatically after changes to Suppliers (List of Suppliers, identifying Critical ones, shall be included as an attachment to this Agreement as Appendix V).

5.2 All raw materials shall be received and tested (if applicable) by PreMD's contract manufacturers according to the receiving criteria outlined in the Products' Device Master Records.

5.3 Raw materials that do not meet specification, as defined in the Device Master Record, must be quarantined until material disposition has been determined. Refer to section 2 for Non-Conformance reporting requirements.

5.4 Material lots must be traceable to specific batches of bulk Product. Material traceability is achieved most effectively through the use of control numbers (or batch numbers) that are issued for each batch of incoming material. Control numbers are included in the Device History Record. PreMD is responsible for ensuring traceability of all Product lots.

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5.5 For reagent kits, a retained sample, of at least twice the quantity required for full testing, of each lot of raw material used shall be kept in a suitable container for two (2) years after the date of expiration; for greater certainty, a container in which the raw materials were originally delivered shall be considered to be a suitable container for the purposes hereof. If the material has been retested and granted an extension, the original sample will be retained based on the new date of expiration. PreMD is responsible for retention sample program execution and management.

5.6 Components will be given expiry dates based on supporting stability data and approval by PreMD. On expiry, the components must be quarantined and fully retested if an extension is to be granted. If the components still meet all the requirements of the specification, an extension may be granted.

**Note: The extended expiry periods for all components must have supporting stability data and meet requirements noted in section 2 of this Agreement.**

5.7 All chemical raw and packaging materials must be stored under normal warehousing conditions in their original containers unless special storage conditions are required by the Product Specifications to support the expiration period assigned. PreMD and PreMD's contractors shall prevent the contamination and/or deterioration of these materials in storage and in use. Proper stock rotation shall be practiced to assure a First In First Out or First Expiry First Out (FIFO or FEFO) system of materials handling.

## **6. MANUFACTURING INSTRUCTIONS**

6.1 PreMD shall ensure that its contract manufacturers manufacture, package, test, and store AstraZeneca Products listed in Appendix I, as outlined in the applicable approved Device Master Records.

6.2 Device History Records must be maintained for the life of the Product plus two (2) years.

6.3 PreMD shall maintain Device Master Records (including validation protocols and reports) and complaint files, including Medical Device Reports (MDR) for AstraZeneca Products for the expected lifetime of the device, but no less than two years from the date of release of the last batch for commercial distribution.

## **7. LABELLING REQUIREMENTS**

7.1 PreMD shall ensure that Products are labelled according to regulatory requirements in the jurisdiction in which they will be sold by AstraZeneca. In cases where labelling undergoes review and approval by regulatory authorities (such as the US FDA), the approved labelling shall be used. Regulatory Label submission and approval shall be the responsibility of PreMD or AstraZeneca as defined in the License, Development and Supply Agreement.

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**8. VALIDATION**

- 8.1 Validation of manufacturing processes, packaging processes, cleaning activities and analytical methods related to the Products listed in Appendix I is the responsibility of PreMD. All validations must be completed prior to the release of commercial Product.
- 8.2 Any revalidation required as the result of changes must be completed prior to implementation of the change.
- 8.3 PreMD shall notify AstraZeneca of all Significant Changes that require revalidation in advance of revalidation activities. PreMD shall provide AstraZeneca with change control documentation for these activities. Change Control and Validation reports must be reviewed by PreMD and AstraZeneca prior to implementation.

**9. PRODUCT QUALITY**

- 9.1 Product shall be tested by PreMD's contract manufacturers in accordance with approved specifications and procedures, as outlined in the Device Master Record. PreMD shall ensure that any testing functions contracted out will be compliant to cGMP requirements as defined in ISO 13485, and FDA Quality Systems Regulations and applicable government regulations. PreMD shall ensure that no Significant Changes are made at contract manufacture or testing sites without prior written approval as defined in sections 2 and 8 of this Agreement.
- 9.2 PreMD shall ensure that measuring and testing equipment used by PreMD's contract manufacturers for manufacturing and testing of AstraZeneca's Products are capable, reliable and periodically serviced and/or calibrated according to written procedures.
- 9.3 At a reasonable frequency as determined by PreMD and AstraZeneca, AstraZeneca may, at its discretion, require submission of samples and test results.
- 9.4 AstraZeneca assumes the right to be represented in the audit of PreMD or its contract manufacturing facilities, given reasonable notice in consultation with PreMD, by one or more designated individuals once per calendar year or more frequently if AstraZeneca suspects that Product quality is jeopardized during manufacturing runs of Product for AstraZeneca. PreMD shall contact AstraZeneca to provide reasonable notice of intended dates of audits.
- 9.5 PreMD is responsible to inform AstraZeneca in advance (or immediately upon initiation of inspection) of any visit to PreMD or its contract manufacturing facilities by any health authority/regulator (Canada's Therapeutic Products Directorate, FDA, etc.). PreMD must provide AstraZeneca with a written report and corrective action plan, if any Observations are cited relating to AstraZeneca's Products within 10 days of receipt of observation report from Regulatory Authority.

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- 9.6 PreMD shall notify AstraZeneca in the event any batch or portion of a batch of Product or bulk Product does not meet all the requirements of the respective specification. At PreMD's option, such batches or bulk Product shall be destroyed or shall be quarantined at the place of manufacture. AstraZeneca will be advised by PreMD if the nature of the defect affects or could affect the currently marketed Product or the ability to market the Product. The defective Product or bulk Product must remain in quarantine until a disposition is made by PreMD or until the same is destroyed. In the event of destruction, PreMD shall provide the certifications required under Section 10.4 of the License, Development and Supply Agreement. PreMD or PreMD's contractors shall maintain or make readily available upon inspection Certificates of Destruction documents.
- 9.7 Reasonable measures shall be taken to ensure that every material used in the manufacture of AstraZeneca's Products shall be compatible with other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.
- 9.8 PreMD shall ensure that sufficient quantity of finished Product is retained for each batch produced. The quantity retained should be a sufficient amount to allow for two times the testing quantity.
- 9.9 PreMD shall ensure that all Product licenses and registrations are up to date and renewed, as required by regulation.

**10. ANNUAL BATCH RECORD REVIEW**

- 10.1 PreMD shall perform the Annual Batch Record Review and shall submit a report to AstraZeneca annually within 2 months of the conclusion of each Calendar Year. Annual Batch Record Review requirements are as outlined in Appendix III.

**11. STABILITY TESTING**

- 11.1 PreMD shall ensure that all regulatory requirements for regular stability testing of chemical components and finished Product is completed according to the Stability Test Program set out on Appendix O to the License, Development and Supply Agreement. PreMD will provide written annual stability reports to AstraZeneca (as part of the Annual Batch Record Review) demonstrating compliance with approved protocols. PreMD shall ensure that such Stability Test Program is in compliance with the applicable regulatory filings.
- 11.2 PreMD shall notify AstraZeneca, within one day of PreMD being advised thereof, of any Finished Good or reagent failing to meet minimum acceptable standards as defined in specifications in the Device Master Record and the approved stability protocol (provided that if at the time of receipt of such advice the office of PreMD is closed, then the same shall be provided within 1 day after the next day on which the office of PreMD is open for business).

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**12. COMPLAINT PROCESSING**

- 12.1 All consumer complaints are to be received by the Information Center (IC) at AstraZeneca. Refer to the applicable sections of the License, Development and Supply Agreement, including Section 5.6 for timelines required for each party to report complaints to the other.
- 12.2 Refer to Appendix II for the appropriate contact information.
- 12.3 AstraZeneca is responsible for maintaining and retaining copies of distribution records for Products for the longer of (a) the projected useful life of the device, (b) three years after the device is shipped.

**13. PRODUCT RECALL**

- 13.1 Product recall means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device:
- may be hazardous to health;
  - may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
  - may not meet the requirements of the FDA Quality Systems Regulations.

- 13.2 In the event of a situation requiring Product recall evaluation as deemed necessary by the parties outlined in this Agreement the party identifying the issue will immediately contact the other party to review available information and the parties shall otherwise comply with the provisions of Article 13 of the License, Development and Supply Agreement.

**Refer to Appendix II for the individuals required to be contacted in the event of a Product recall situation.**

- 13.3 All affected Product shipments will be halted and procedures to prohibit further release of Products (by PreMD and AstraZeneca) will be implemented until a decision has been determined regarding recall of impacted Products.

AstraZeneca and PreMD will mutually determine the appropriate course of action according to applicable federal, provincial / state and local regulations.

- 13.4 AstraZeneca will conduct the Product recall according to AstraZeneca procedures and applicable federal, provincial/state, and local regulations. PreMD will take appropriate action to assist AstraZeneca, according to PreMD procedures and applicable regulations.

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**14. TRANSPORTATION AND STORAGE**

14.1 PreMD is responsible to ensure its contractors do not store the Product under conditions outside of label claim or defined storage conditions that may affect its compliance with specifications for that Product.

Note: PREVU\* POC reagents are to be stored between 2°C – 8°C.

14.2 AstraZeneca is responsible to ensure that neither it nor its agents or representatives: (a) ship Product under conditions outside of allowable storage conditions that may affect its compliance with specifications for that Product; or (b) store Product under conditions outside of label claim or defined storage conditions that may affect its compliance with specifications for that Product. AstraZeneca is responsible for controlling shipping and storage temperatures after Product has been picked up from PreMD's contract manufacturers.

**15. PERFORMANCE MEASUREMENT AND FEEDBACK**

15.1 Cross-functional feedback sessions may be held to address quality issues as per performance measurements and other issues relating to PreMD processing, contract manufacturers, components etc.

**16. CONTACT INFORMATION**

16.1 Pursuant to Section 19.3 of the License, Development and Supply Agreement, either party may from time to time change the contact information set forth in Appendix II by giving the other party prior written notice of the new contact information and the date upon which such new contact information will become effective.

**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Appendix O**

**Stability Test Program**

Reagents Stability Test Program

**Work Instructions:**

WI7511 LT Detector Stability Protocol

WI7503 PREVU\* LT Sample Acquisition

WI7505 Ponceau Protein Assay for Skin Samples Taken with PREVU\* LT

WI7525 Protocol for Stability Testing of LT Sampling Devices

WI7524 Protocol for Stability Testing of PREVU POC Detector

WI7523 Protocol for Stability Testing of PREVU\* POC Kit Detector

**Forms:**

F7550 Stability Testing of PREVU\* LT Devices

F7548 Stability Testing of PREVU\* POC Detector

F7549 Stability Testing of PREVU\* LT Detector Form  
[GRAPHIC]  
[GRAPHIC]  
[GRAPHIC]

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**FORM 51-102F3**

**MATERIAL CHANGE REPORT**

**ITEM 1 Name and Address of Company**

PreMD Inc. (the **Company** )

4211 Yonge Street

Suite 615

Toronto, ON

M2P 2A9

**ITEM 2 Date of Material Change**

July 16, 2007

**ITEM 3 News Release**

A press release was disseminated on July 16, 2007 through Canada NewsWire.

**ITEM 4 Summary of Material Change**

The Company announced that it entered into an exclusive licensing agreement with AstraZeneca Pharmaceuticals LP ( **AstraZeneca** ) for the U.S. marketing and distribution of a novel non-invasive skin cholesterol test, currently marketed as PREVU\*. Under the terms of the agreement, AstraZeneca will have the exclusive right to market and distribute the skin test in the U.S. healthcare community and a three month exclusive right to negotiate a global contract with the Company. In addition, pursuant to the terms of the agreement, the Company will receive an upfront payment of US\$500,000 and will be eligible for additional milestone payments of up to US\$6 million upon attainment of various development and revenue targets. The Company will also receive a 20% royalty rate on net sales on product sold by AstraZeneca for the first US\$30 million in annual sales, after which the rate will increase to 25%.

**ITEM 5 Full Description of Material Change**

See press release dated July 16, 2007, attached hereto as Schedule A .

**ITEM 6 Reliance on Section 7.1(2) or (3) of National Instrument 51-102**

N/A

**ITEM 7 Omitted Information**

N/A

**ITEM 8**    **Executive Officer**

Ron Hosking

Vice President, Finance and Chief Financial Officer

Telephone: 416.222.3449

Fax: 416.222.4533

**ITEM 9**    **Date of Report**

July 26, 2007

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**SCHEDULE A**

**News release via Canada NewsWire, Toronto 416-863-9350**

**Attention Business Editors:**

**PreMD Signs Marketing and Distribution Agreement with AstraZeneca**

**PreMD and AstraZeneca Team to Promote Novel Non-Invasive Skin Cholesterol Test in the United States**

TORONTO, July 16 /CNW/ - Predictive medicine company PreMD Inc. (TSX: PMD; Amex: PME) announced today that it has entered into an exclusive licensing agreement with AstraZeneca Pharmaceuticals LP for the U.S. marketing and distribution of a novel non-invasive skin cholesterol test, currently marketed as PREVU(x), that helps assess an individual's risk of coronary heart disease. This is the first test in the world to use skin cholesterol to evaluate risk of advanced atherosclerosis. Under the terms of the agreement, AstraZeneca will have the exclusive right to market and distribute the skin test into the healthcare community, including physician offices, hospitals, retail chains and other institutions in the U.S., and a three month exclusive right to negotiate a global contract with PreMD. AstraZeneca and PreMD will explore a range of options for bringing this product to healthcare professionals and patients while awaiting the U.S. Food and Drug Administration (FDA) response to PreMD's recent application for an expanded regulatory label.

In the agreement, PreMD will receive an upfront payment of U.S. \$500,000 and will be eligible for additional milestone payments of up to U.S. \$6 million on attainment of various development and revenue targets. PreMD will also receive a 20 percent royalty rate on net sales on product sold by AstraZeneca for the first U.S. \$30 million in annual sales, after which the rate will increase to 25 percent. In addition, AstraZeneca will fund any additional clinical trials that may be desired, which PreMD would help to execute.

PreMD retains exclusive rights to promote PREVU(x) products to the life-insurance industry and other future applications of the technology under the PREVU(x) brand. PreMD will retain responsibility for regulatory filings in the U.S. Both companies will contribute scientific and commercial expertise to the product as well as future product development.

I am pleased to announce this significant step in the strategic plan that we revealed to shareholders earlier this year," said Brent Norton, president and chief executive officer of PreMD Inc. "As AstraZeneca is one of the world's foremost leaders in cardiovascular medicine, we are delighted to partner with them on the entire line of our skin cholesterol tests. This includes a Point of Care test, which has been cleared for sale by the FDA; a lab-processed format of that technology; as well as other clinically directed formats of the technology that may be developed during the term of the agreement. We are confident that AstraZeneca will successfully position our products in the marketplace to medical and clinical professionals so that patients can benefit from this technology. In the U.S., the company is a \$12.44 billion healthcare business with more than 12,000 employees.

This collaboration will support the use of innovative, cost-effective technology to improve cardiovascular health by helping to identify patients at increased risk of having cardiovascular diseases such as heart attack or stroke," said Adele Gulfo, Vice President, Healthcare Innovation and Corporate Strategy at AstraZeneca. "Identifying patients before they have an event is one of the most important challenges in American healthcare today. Gulfo leads the AstraZeneca Healthcare Innovation Center, which developed this collaboration with PreMD. The Healthcare Innovation Center is a dedicated U.S. operation designed to drive business growth and improve patient health by working with external partners to incubate ways of improving the delivery and management of healthcare and enhancing the value of AstraZeneca's medicines for the patients who need them.

AstraZeneca and PreMD will explore multiple options for bringing this product to healthcare professionals, seeking to ensure that patients benefit from the test. AstraZeneca hopes to begin marketing and distributing the product line to healthcare professionals in the U.S. in 2008.

### Conference Call and Webcast

PreMD will hold a conference call and webcast today, July 16, 2007 at 11:00 a.m. ET. To access the conference call, please dial 416-644-3418 or 1-800-732-9303. A live audio webcast will be available at [www.premdinc.com](http://www.premdinc.com), and will be subsequently archived for three months. To access the replay via telephone, which will be available until July 24, please dial 416-640-1917 or 1-877-289-8525 and enter the passcode 21240666 followed by the number sign.

### About PreMD's skin cholesterol-testing products

Skin cholesterol testing products, currently marketed as PREVU(x), the company's lead product line, was designed to address the enormous problem of cholesterol level detection in relation to cardiovascular disease and the limitations of current cholesterol testing options. Through a non-invasive and cost-effective procedure, the skin cholesterol test platform provides highly sensitive and reliable skin cholesterol level results by measuring the amount of cholesterol that has accumulated in the skin tissues, as opposed to blood. There is no fasting or other patient preparation required for the test. Clinical studies have shown that as cholesterol accumulates on artery walls it also accumulates in other tissues, including the skin. High levels of skin cholesterol are correlated with higher incidence of coronary artery disease (CAD).

### About PreMD

PreMD Inc. is a world leader in predictive medicine, dedicated to developing rapid, non-invasive tests for the early detection of life-threatening diseases. PreMD's cardiovascular products are currently branded as PREVU(x) Skin Sterol Test. The company's cancer tests include ColorectAlert(TM), LungAlert(TM) and a breast cancer test. PreMD's head office is located in Toronto, and its research and product development facility is at McMaster University in Hamilton, Ontario. For further information, please visit [www.premdinc.com](http://www.premdinc.com).

This press release contains forward-looking statements. These statements involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the successful development or marketing of the Company's products, the competitiveness of the Company's products if successfully commercialized, the lack of operating profit and availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, product liability, reliance on third-party manufacturers, the ability of the Company to take advantage of business opportunities, uncertainties related to the regulatory process, and general changes in economic conditions.

In addition, while the Company routinely obtains patents for its products and technology, the protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates.

Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned not to rely on these forward-looking statements. PreMD is providing this information as of the date of this press release and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

(x) Trademark

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/For further information: Brent Norton, President and CEO, Tel: (416) 222-3449 ext. 22, Email: [bnorton\(at\)premdinc.com](mailto:bnorton(at)premdinc.com); Ron Hosking, Vice President Finance and CFO, Tel: (416) 222-3449 ext. 24, Email: [rhosking\(at\)premdinc.com](mailto:rhosking(at)premdinc.com); Michelle Rabba, Manager, Corporate Communications, Tel: (416) 222-3449 ext. 25, Email: [mrabba\(at\)premdinc.com/](mailto:mrabba(at)premdinc.com/)

(PMD, PME)

CO: PreMD Inc.

CNW 09:00e 16-JUL-07