

**FORM 51-102F3  
MATERIAL CHANGE REPORT**

**1. Name and Address of Company**

Med BioGene Inc. ("MBI")  
#510 – 580 Hornby Street  
Vancouver, BC V6C 3B6

**2. Date of Material Change**

October 3, 2012

**3. News Release**

A news release announcing the material change disclosed in this report and attached as Schedule A was issued by MBI on October 3, 2012. The news release was distributed by Marketwire.

**4. Summary of Material Change**

On October 3, 2012, MBI provided an update regarding the commercialization of LungExpress Dx, including an amendment to MBI's commercialization, license and research reimbursement agreement ("Commercialization Agreement") with Precision Therapeutics, Inc., and ongoing litigation with Signal Genetics LLC and Respira Health LLC.

**5. Full Description of Material Change**

MBI provided an update regarding the commercialization of LungExpress Dx, including an amendment to MBI's Commercialization Agreement with Precision Therapeutics, Inc., and ongoing litigation with Signal Genetics LLC and Respira Health LLC, as more fully set forth in the news release issued by MBI on October 3, 2012 and attached hereto as Schedule A. A redacted copy of the amendment to the Commercialization Agreement is attached hereto as Schedule B.

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

Not applicable.

**7. Omitted Information**

No significant facts otherwise required to be disclosed in this report have been omitted.

**8. Executive Officer**

The following executive officer of MBI is knowledgeable about the material change and may be contacted respecting the change:

Erinn B. Broshko, Chief Executive Officer  
Telephone: (800) 641-3593  
Facsimile: (888) 646-2531  
Email: [ebroshko@medbiogene.com](mailto:ebroshko@medbiogene.com)

**9. Date of Report**

October 3, 2012

**MED BIOGENE INC.**

Per: "Erinn Broshko"  
ERINN BROSHKO

## **SCHEDULE A**

**Press release of Med BioGene Inc. dated October 3, 2012**



## News Release

### MED BIOGENE PROVIDES UPDATE

**For Immediate Release**

**October 3, 2012**

VANCOUVER, BC —Med BioGene Inc. (TSXV: MBI) today provided an update regarding the commercialization of LungExpress Dx and ongoing litigation with Signal Genetics LLC and Respira Health LLC.

#### **Commercialization of LungExpress Dx**

LungExpress Dx is a proprietary gene expression-based test to improve upon staging for identifying those patients with early-stage non-small-cell lung cancer (NSCLC) who, following surgical removal of their tumor, are at higher and lower risks of mortality. In an initial study of patient specimens from the National Cancer Institute of Canada Clinical Trials Group JBR.10 trial, published in the *Journal of Clinical Oncology*, patients classified by LungExpress Dx as higher risk benefited from adjuvant chemotherapy, and those classified as lower risk did not benefit and may have experienced a detrimental effect from adjuvant chemotherapy. LungExpress Dx was subsequently validated in predicting patient mortality in four independent studies involving data from tumor specimens totaling 676 untreated early-stage NSCLC patients. LungExpress Dx is expected to provide better-informed and personalized treatment decisions to assist in the selection of patients for adjuvant chemotherapy.

On April 15, 2011, MBI closed its commercialization, license and research reimbursement agreement (the "Commercialization Agreement") with Precision Therapeutics, Inc. The Commercialization Agreement provides to Precision exclusive global rights to develop and commercialize LungExpress Dx.

LungExpress Dx is currently validated for use with frozen tumour tissue. Precision is responsible for all costs associated with the development and commercialization of LungExpress Dx and is commencing clinical studies to validate the use of LungExpress Dx with tissue preserved by RNARetain, a molecular fixative. RNARetain eliminates the need to flash-freeze specimens and to keep specimens frozen throughout storage and transport, a process that can be cumbersome and costly. It also eliminates the need for preserving tissue in formalin, which is known to cross-link and degrade the nucleic acids rendering them less suitable for specific downstream molecular applications.

These clinical studies are being conducted using patient specimens collected prospectively by Precision from a consortium of medical centers in the United States. This collection is complete and the final step of validation using RNARetain has begun.

Precision expects to commence commercialization of LungExpress Dx in its CLIA-certified laboratory by mid-2013. In advance of commercialization, Precision has established an advisory board comprised of world leaders in lung cancer research and treatment from the United States, Canada, France and Italy.

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Sean McDonald, Precision's President and Chief Executive Officer stated: "We are looking forward to completing our clinical validation studies and improving the utility and accessibility of LungExpress Dx. We are completely committed to making this important test available to patients and physicians and to improving the outcomes of cancer patients by providing personalized medicine solutions."

Erinn Broshko, Executive Chairman of Med BioGene, commented: "The commercial success of a molecular diagnostic test depends, in large measure, upon the extent of its integration into current pathological processes. The use of LungExpress Dx with RNARetain will allow pathologists to avoid the logistics involved with using flash-frozen tumor specimens and, instead, to handle and ship specimens at room temperature, thereby simplifying the process significantly. We believe that this will materially enhance the commercial prospects of our test and are encouraged by the progress made by Precision."

### **Amendment of Commercialization Agreement**

Under the terms of the Commercialization Agreement, Precision has paid to MBI license fees and research reimbursement of \$2.3 million, half of which is credited against future royalties that may be owed to MBI by Precision. In addition, MBI is eligible to receive up to \$1 million in payments based on the achievement of certain milestones, all of which are credited against future royalties that may be owed to MBI by Precision. MBI and Precision have amended, among other things, these milestone payments such that Precision will now pay to MBI, following the commercial launch of LungExpress Dx, amounts totaling \$500,000 and, following the achievement of \$5 million in net revenues from LungExpress Dx, amounts totaling \$500,000.

MBI will also receive royalty payments in the high single digits based on a percentage of Precision's future net revenues associated with the commercialization of LungExpress Dx.

Erinn Broshko further commented: "By restructuring the milestone payments in our commercialization agreement, we expect to extend MBI's cash runway following the commercialization of LungExpress Dx to allow us the opportunity to demonstrate increasing clinical and commercial success of our test. As a result of our focused burn rate, we believe that MBI currently has sufficient cash resources to continue with operations until approximately the first quarter of 2014. If Precision commercializes LungExpress Dx around the expected timeframe then, with receipt of the \$500,000 in milestone payments from Precision relating to commercial launch, we believe that MBI will have sufficient cash resources to fund operations until approximately the third quarter of 2015."

### **Litigation with Signal Genetics, LLC and Respira Health LLC**

In February 2011, Signal Genetics LLC ("Signal") and Respira Health LLC ("Respira") filed a lawsuit against MBI and Precision Therapeutics, Inc. in the Supreme Court of the State of New York asserting twelve causes of action against MBI. MBI continues to believe that the lawsuit is frivolous, vexatious and entirely without merit and is defending the lawsuit vigorously. MBI has received financial support from Precision to, among other things, conduct such defense (half of which is credited against future royalties that may be owed to MBI by Precision) and to cover any settlement or award of damages made against MBI, subject in all cases to certain threshold limits.

Discovery in the lawsuit has been completed and, on August 24, 2012, MBI filed a motion for partial summary judgment to dismiss the claims of Signal and Respira for lost profits, and causes of action for negligent misrepresentation, unfair competition and unjust enrichment. The hearing to rule on that motion has not yet been scheduled.

### **About Precision Therapeutics**

Precision is a leading life science company based in Pittsburgh, Pennsylvania, and is dedicated to improving the outcomes of cancer patients by providing personalized medicine solutions that aim to increase quality of life and cancer survival rates. Precision offers a portfolio of products developed to help guide physicians and patients with difficult clinical decisions throughout the cancer care continuum. For more information, please visit [www.precisiontherapeutics.com](http://www.precisiontherapeutics.com).

### **About Med BioGene**

MBI is a life science company based in Vancouver, British Columbia, that is currently focused on managing the license and rights to LungExpress Dx, a proprietary gene expression-based test for early-stage non-small-cell lung cancer. LungExpress Dx is expected to provide better-informed and personalized treatment decisions to assist in the selection of patients for adjuvant chemotherapy. MBI has partnered with Precision Therapeutics for the global commercialization of LungExpress Dx. MBI's common shares are traded on the TSX Venture Exchange. For more information, please visit [www.medbiogene.com](http://www.medbiogene.com).

### **Further Information**

For information, please contact:

Erinn B. Broshko  
Executive Chairman  
(800) 641-3593  
[ebroshko@medbiogene.com](mailto:ebroshko@medbiogene.com)

**The TSX Venture Exchange does not accept responsibility for the adequacy or accuracy of this release.**

*Certain statements in this press release contain forward-looking statements and information ("forward-looking statements") under applicable United States and Canadian securities legislation. Words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward looking statements include, but are not limited to, that with respect to the timing, completion and/or results of clinical trials or studies, the timing for commercialization of any products, future profits, future product revenues, future shareholder value, future operations and plans, the completion and use of proceeds from transactions or financings and the prospects for negotiating partnerships or collaborations and their timing. These forward-looking statements are only a prediction based upon the party's current expectations, and actual events or results may differ materially. A party may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on uncertain assumptions that could cause a party's actual results and the timing of events to differ materially from those anticipated in such forward-looking information. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. A party's forward-looking statements do not reflect the potential impact of any future partnerships, collaborations, acquisitions, mergers, dispositions, joint ventures or investments that that party may make. All forward-looking statements are qualified in their entirety by this cautionary statement and a party undertakes no obligation to revise or update any forward-looking statements as a result of new information, future events or otherwise after the date of this press release, other than as required by applicable law. Certain information included in this press release in respect of Precision and its scientific, clinical and/or commercialization efforts have been provided to MBI by Precision. MBI may not have been able to confirm the accuracy of such information and you should not place undue reliance on any such information, including any information regarding Precision that would constitute forward-looking information. A redacted copy of the amended Commercialization Agreement may be found at [www.sedar.com](http://www.sedar.com). Each trademark, trade name or service mark of any entity appearing in this news release belongs to its holder.*

## **SCHEDULE B**

**Amendment No. 2 to the Commercialization, License and Research Reimbursement Agreement between Med BioGene Inc. and Precision Therapeutics, Inc.**

**AMENDMENT NO. 2 TO  
COMMERCIALIZATION, LICENSE AND RESEARCH REIMBURSEMENT  
AGREEMENT**

This Amendment No. 2 (the “**Amendment**”) to Commercialization, License and Research Reimbursement Agreement is made and entered into as of September 24, 2012 by and between Med BioGene Inc. (“**MBI**”) and Precision Therapeutics, Inc. (“**PTI**”). MBI and PTI are referred to herein individually as a “**Party**,” or collectively as the “**Parties**.” Capitalized terms used but not defined in the Amendment shall have the meanings given to them in the Agreement (as defined below).

**BACKGROUND**

**WHEREAS**, the Parties hereto have entered into that certain Commercialization, License and Research Reimbursement Agreement dated March 1, 2011 as amended by Amendment No. 1 to Commercialization, License and Research Reimbursement Agreement dated March 24, 2011 (collectively, the “**Agreement**”). The parties hereto now deem it to be in their respective best interests to amend the Agreement as provided below.

**WHEREAS**, pursuant to Section 12.08 of the Agreement, the terms of the Agreement may be waived and amended with the written consent of the Parties.

**NOW, THEREFORE**, in consideration of the foregoing premises and for other good and valuable consideration, receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Section 3.01(2)(a) of the Agreement shall be deleted in its entirety and replaced with the following Section 3.01(2)(a):

“(2) PTI shall, at its sole cost and expense, utilize reasonable efforts to:

- (a) market, sell and otherwise commercialize by the end of Q2 2013 a Product for use with patient specimens preserved by RNARetain (or similar product) as a clinical service under CLIA. For the avoidance of doubt, PTI is conducting clinical studies to validate the use of a Product with patient specimens preserved by RNARetain (or a similar product) and will utilize reasonable efforts and sound and reasonable scientific practice and judgment to complete these clinical studies to allow it to market, sell and otherwise commercialize by the end of Q2 2013 a Product as a clinical service under CLIA. In the event that the results of these studies are such that it is not feasible for a Product to be implemented as a clinical service, then PTI's obligation under this Section 3.01(2)(a) to use reasonable efforts to market, sell, or otherwise commercialize a Product will have been fully satisfied; and”

2. Section 4.02 of the Agreement shall be deleted in its entirety and replaced with the following Section 4.02:

**“4.02 Milestone Payments to MBI.**

PTI shall pay to MBI the following non-refundable one-time milestone payments upon the achievement by PTI, its Affiliates or sublicensees of the following events. PTI shall pay to MBI each such amount within thirty (30) days after the achievement of the applicable milestone event:

- (a) \$100,000 upon the commercial launch of the Product as a clinical service under CLIA;
- (b) \$200,000 upon the later of January 1, 2014 or the commercial launch of the Product as a clinical service under CLIA;
- (c) \$200,000 upon the later of January 1, 2015 or the commercial launch of the Product as a clinical service under CLIA;
- (d) \$300,000 upon the later of October 1, 2015 or the achievement of \$5 million in Net Revenues from commercialization of Products; and
- (e) \$200,000 upon the later of March 1, 2016 or the achievement of \$5 million in Net Revenues from commercialization of Products.

These \$1,000,000 in milestone payments will be fully credited to, reduce and may be fully set-off in their entirety against, PTI's royalty payment obligations under Section 4.04.”

3. Section 4.04(1)(a) of the Agreement shall be deleted in its entirety and replaced with the following Section 4.04(1)(a):

- “(a) in each country where the Products sold (or, in such case where a service performed constitutes a Product, the location where such services are performed) are covered by one or more Valid Patent Claims within the MBI Technology and/or Improvements, a non-refundable royalty of *[percent redacted]*% of Net Revenues; provided that, upon all applicable payments by PTI to MBI under Sections 4.01, 4.02, 4.03 and 11.03, and Section 2.01 of the Support Agreement, being fully credited to, and fully set-off in their entirety against, PTI's royalty payment obligations under this Section 4.04(1)(a), then the aforementioned non-refundable royalty shall from that time going forward be reduced from *[percent redacted]*% to *[percent redacted]*% of Net Revenues; and”

4. Except as modified hereby, all of the terms and conditions of the Agreement remain in full force and effect and are hereby reaffirmed, ratified and approved. This Amendment, together with the Agreement, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Amendment shall affect, or be used to interpret, change or restrict, the

express terms and conditions of this Amendment. Hereafter references to the Agreement in any document or other agreement shall be deemed to constitute references to the Agreement as amended by this Amendment. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Execution and delivery of this Amendment may be made and evidenced by facsimile transmission or by scanned copy delivered by email. This Amendment shall be construed and enforced in accordance with and governed by the internal laws of the State of Delaware, without regard to its principles of conflicts of laws.

**[SIGNATURE PAGES FOLLOW]**

**IN WITNESS WHEREOF**, the Parties hereto have caused this Amendment to be executed by their duly authorized representatives as of the date first above written.

**MED BIOGENE INC.**

per:

*“Erinn Broshko” (signed)*

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Erinn Broshko  
Executive Chairman

**PRECISION THERAPEUTICS, INC.**

per:

*“Damian Rippole” (signed)*

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Damian Rippole  
Chief Financial Officer