Preferinary Matters
Preferinary Matters
License to CHBO
Accessory Rights and Obligations
Accessory Rights and Obligations
Representations and Warranties
Industriation
Matters Relating to the Proceeding
Matters Relating to the Proceeding
Schedule A: Health Audustrias
Schedule A: Health Audustrias

# PUBLIC HEALTH ACCESS AGREEMENT

# IN RESPECT OF LONG QT GENE PATENTS

- BY AND BETWEEN -

# CHILDREN'S HOSPITAL OF EASTERN ONTARIO

- And –

TRANSGENOMIC, INC.

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1	Purpose	3	
2.	Preliminary Matters		
3.	License to CHEO	5	
4.	Accessory Rights and Obligations	9	
5.	Representations and Warranties	9	
6.	Indemnification	10	
7.	Matters Relating to the Proceeding	11	
8.	General Provisions	11	
Schedule A: Health Authorities 1		16	
Sc	Schedule B: Standard License Agreement 1		

## THIS AGREEMENT is made between:

Children's Hospital of Eastern Ontario, a pediatric health and research centre located at 401 Smyth Rd, Ottawa, Ontario, K1H 8L1 (hereinafter "CHEO")

and

Transgenomic, Inc., a Delaware corporation providing laboratory services, genetic assays and platforms, with corporate headquarters at 12325 Emmet Street, Omaha, Nebraska, USA 68164 (hereinafter "Transgenomic")

CHEO and Transgenomic agree as follows:

## 1. Purpose

1.1.1 CHEO and Transgenomic enter into this Agreement in the spirit of removing barriers that the Long QT Patents might form against not-for-profit Long QT Testing in Canada. It is agreed that, subject to the terms and conditions of this Agreement, the Long QT Patents will not stand in the way of Canadians having access to their own genetic information and the benefits of such access for the detection, diagnosis and treatment of disease when such genetic information is procured on a not-for-profit basis from CHEO or a third party that has been licensed by Transgenomic in furtherance of this Agreement.

## 2. Preliminary Matters

#### 2.1 Background

- 2.1.1 CHEO has commenced litigation under section 60 of the Patent Act, RSC 1985, c P-4 (the "Patent Act") against University of Utah Research Foundation ("UURF"), Genzyme Genetics ("Genzyme"), and Yale University ("Yale") seeking declarations by the Federal Court that certain claims of the patents defined below as "Long QT Patents" are invalid, void or not infringed by tests that CHEO proposes to conduct. In the course of the Proceeding, Transgenomic was assigned the interests of UURF, Yale, and Esoterix Genetic Laboratories, LLC (the successor in title to Genzyme) to the Long QT Patents and became the sole defendant in the Proceeding. Now, CHEO and Transgenomic desire to resolve the Proceeding amicably.
- 2.1.2 CHEO and Transgenomic intend that, through this Agreement, CHEO and any other Canadian not-for-profit entity which chooses to participate will be permitted to provide Long QT Testing under the Long QT Patents on a not-for-profit basis to persons entitled to healthcare under the Canadian healthcare system and to carry out not-for-profit patient care and research. At the same time, CHEO and Transgenomic do not intend to create an avenue allowing for-profit entities to have the freedom to profit from Transgenomic's intellectual property.

#### 2.2 Definitions

2.2.1 When used in this Agreement:

- 2.2.2 "at a profit" means any performance for which funding or reimbursement, as the case may be, is not at or below cost;
- 2.2.3 "at or below cost" has the meaning set out in Section 3.2 of this Agreement;
- 2.2.4 "Effective Date" means March 8, 2016;

c.

- 2.2.5 "Health Authority" means, in singular or plural usage as required by the context, an agent of the Canadian government or of a Canadian provincial or territorial government that regulates, oversees, funds or reimburses the performance of gene testing or any other medical services, directly or indirectly, by authority of statute, including but not limited to:
  - a. any body administering a "health care insurance plan" within the meaning of the *Canada Health Act*, RSC 1985, c C-6, including but not limited to entities listed in Schedule A;
  - b. any governmental entity that replaces the function of the aforementioned bodies; and
    - any entity of the Canadian government or of a Canadian provincial or territorial government under the control of any of the aforementioned bodies.
- 2.2.6 "Long QT Patent", in singular or plural usage as required by the context, means:
  - a. Canadian Patent No. 2 240 737, titled "A LONG QT SYNDROME GENE WHICH ENCODES KVLQT1 AND ITS ASSOCIATION WITH MINK";
  - b. Canadian Patent No. 2 336 236, titled "MUTATIONS IN AND GENOMIC STRUCTURE OF HERG- A LONG QT SYNDROME GENE";
  - c. Canadian Patent No. 2 337 491, titled "HUMAN MINK GENE MUTATIONS ASSOCIATED WITH ARRHYTHMIA";
  - d. Canadian Patent No. 2 369 812, titled "MINK-RELATED GENES, FORMATION OF POTASSIUM CHANNELS AND ASSOCIATION WITH CARDIAC ARRHYTHMIA"; and/or
  - e. Canadian Patent No. 2 416 545, titled "COMMON POLYMORPHISM IN SCN5A IMPLICATED IN DRUG-INDUCED CARDIAC ARRHYTHMIA".
- 2.2.7 "Long QT Genes" means the following genes as embodied in nucleic acids, in a mutated or unmutated state:
  - a. KCNQ1, also called KVLQT1, KCNA9 or KCNA8;

- KCNH2, also called HERG, ERG1 or KV11.1;
- KCNE1, also called MINK or ISK;
- d. KCNE2, also called MIRP1; and
- e. SCN5A, also called NAV1.5;
- 2.2.8 "Long QT Test", in singular or plural usage as required by the context, means any process, machine, manufacture or composition of matter used for:
  - a. research concerning the Long QT Genes or their associated RNAs or polypeptides,
  - b. screening for any mutations within one or more of the Long QT Genes or their functional products (*e.g.*, RNAs or proteins), and/or
  - c. diagnosis relating to the screening set forth,

whether or not the research, screening or diagnosis also involves genes other than the Long QT Genes;

2.2.9 "Party" and "Parties" mean:

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- a. CHEO, and/or
- b. Transgenomic.
- 2.2.10 "Proceeding" means Children's Hospital of Eastern Ontario v. Transgenomic, Inc., having Federal Court of Canada File Number T-2249-14;
- 2.2.11 "Territory" means the whole of Canada; and
- 2.2.12 "Unexpired Claim", in singular or plural usage as required by the context, means any claim in an unexpired Long QT Patent, which has not been held void or invalid by a decision of a Canadian court or other governmental agency that is unappealable or unappealed within the time allowed for appeal.

# 2.3 Consideration and Disposition of Litigation

2.3.1 As good and sufficient consideration for the rights granted and obligations undertaken in this Agreement, CHEO shall discontinue the Proceeding with prejudice on a without-costs basis within seven days of the Effective Date.

## 3. License to CHEO

#### 3.1 Grant of License

3.1.1 Subject to the terms and conditions of this Agreement, Transgenomic hereby grants to CHEO, effective solely upon dismissal of the Proceeding with prejudice, and solely to the extent of Transgenomic's legal right to do so, a

LEGAL\_US\_W # 82943584.15 LEGAL\_1:38652656.1 personal, non-exclusive, non-transferable, non-sublicensable license solely under the Long QT Patents to: (i) undertake or make (but not to have undertaken or made) Long QT Tests in the Territory; (ii) use the Long QT Tests undertaken or manufactured pursuant to Section 3.1.1(i) to (a) conduct internal, not-for-profit research concerning the Long QT Genes or their associated RNAs or polypeptides (provided that, for clarity, such research may not be carried out for any commercial purposes or carried out on behalf of or for the benefit of any third party other than a patient as provided below), (b) screen for any mutations within one or more of the Long QT Genes or their functional products (e.g. RNAs or proteins), and (c) carry out diagnoses based on the screening set forth in Section 3.1.1(ii)(b) hereof; (iii) advertise the screening and diagnosis services set forth in Sections 3.1.1(ii)(b) and 3.1.1(ii)(c) hereof solely in the Territory; and/or (iv) sell the screening and diagnosis services set forth in Sections 3.1.1(ii)(b) and 3.1.1(ii)(c) solely in the Territory, in all cases only where all of the following conditions are met:

- a. the Long QT Tests are performed by CHEO and otherwise sold by CHEO at or below cost;
- b. the screening and diagnosis services set forth in Sections 3.1.1(ii)(b) and 3.1.1(ii)(c) are performed on research subjects or patients who are citizens or residents of Canada, who are refugees in Canada, or who are present in Canada for reasons other than receiving medical services, purchasing medical or pharmaceutical products or services, or otherwise receiving the benefit of the Canadian healthcare system; and
- c. the Long QT Tests are performed pursuant to a healthcare professional's recommendation or direction.
- 3.1.2 **No Exclusivity**. The licenses granted herein are non-exclusive, and subject to the terms of this Agreement, Transgenomic reserves all rights to use, commercialize, license, and otherwise exploit all aspects of the Long QT Patents for any use or purpose.
- 3.1.3 CHEO will not be obliged to pay any fee or royalty to Transgenomic under the license set forth in Section 3.1.1.
- 3.1.4 CHEO shall not commence a legal proceeding challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patents, nor will CHEO assist any other entity in challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patent. In the event CHEO commences a legal proceeding challenging or assists any third party in challenging the validity, enforceability or exclusive ownership by Transgenomic of any Long QT Patent, Transgenomic may terminate this Agreement (including the license granted to CHEO hereunder and all licenses granted under Section 3.3.2) effective immediately upon notice to CHEO.
- 3.1.5 There are no implied rights or licenses granted under this Agreement, whether by implication, estoppel or otherwise. All rights not expressly granted herein by

Transgenomic are reserved by Transgenomic. For emphasis, there are no have made, have used, or similar rights granted hereunder, and, as a part of the foregoing, CHEO shall have no right to have any of its rights exercised by or on its behalf by any third party. Without limiting the foregoing, CHEO acknowledges and agrees that it may not (and that no right or license is granted under this Agreement to) (i) use any third party to undertake or manufacture the Long QT Tests, (ii) perform the Long QT Tests for or on behalf of a third-party testing provider that is not a not-for-profit entity in the Territory, and/or (iii) use or perform the Long QT Tests for any commercial purpose.

- 3.1.6 Transgenomic covenants not to bring a claim of infringement of the Long QT Patents against CHEO alleging infringement of the Long QT Patents based solely on activities coming within the scope of the license granted under Section 3.1.1. If Transgenomic commences a legal proceeding to enforce the Long QT Patents against CHEO in respect of activities not coming within the scope of the license granted under Section 3.1.1, CHEO reserves the right to challenge the validity, enforceability or ownership of the Long QT Patents in such proceeding.
- 3.1.7 The license granted to CHEO hereunder does not diminish or otherwise affect the rights of CHEO to conduct activities exempt from patent infringement in accordance with section 55.2 of the *Patent Act* and/or the common law exemption from patent infringement for non-commercial use of patented inventions.

# 3.2 Determining Use At or Below Cost

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- 3.2.1 For the purposes of this subsection only, "Fee" means a payment that reimburses or funds CHEO's performance of a Long QT Test.
- 3.2.2 A Long QT Test is performed at or below cost if the Fee charged by CHEO for the Long QT Test is less than or equal to the sum of all costs it incurs in association with the Long QT Test. Such costs may include one or more of but are not limited to the following:
  - a. payment, direct and indirect, for the labour required to administer and perform the Long QT Test and analyze test results;
    - the cost of acquiring, storing, and disposing of necessary disposable materials;
  - c. the allocable cost of validating the Long QT Test;
    - the allocable cost of equipment used, directly or indirectly, in the Long QT Test;
    - the allocable cost of any infrastructure necessary to conduct and validate the Long QT Test; and

- f. reasonably allocable overhead, whether calculated directly or based on a reasonable estimate when assessed in accordance with Generally Accepted Accounting Principles (GAAP).
- 3.2.3 If a Health Authority pays CHEO a Fee for performance of a Long QT Test that is intended to cover only some or all of the costs laid out in the previous paragraph, then the Fee paid is deemed to be less than or equal to the costs incurred, and the Long QT Test is deemed to be at or below cost.
- 3.2.4 Where CHEO has been deemed to provide a Long QT Test at or below cost in accordance with the prior paragraph, subsequent provision of a substantially similar Long QT Test by CHEO for the same or lower Fee shall be deemed to be at or below cost, whether the Fee is paid by a Health Authority or some other person.
- 3.2.5 A Long QT Test is also deemed to be "at or below cost" if CHEO is paid no Fee for that Long QT Test, including but not limited to:
  - a. if CHEO pays for costs out of a publicly-funded operating budget rather than accepting reimbursement at a rate per test, or
  - b. if CHEO or its associated researchers receive grant or other funding to conduct research.
  - 3.2.6 If CHEO intends to perform a Long QT Test at a profit, the Parties may negotiate reasonable terms before the Long QT test is undertaken.

# 3.3 No Sublicensing; Benefit to Other Not-for-profit Entities

- 3.3.1 CHEO will have no right to sublicense any of the rights granted under this Agreement to any third party.
- 3.3.2 Subject to Section 3.3.3, Transgenomic agrees, at any time following dismissal of the Proceeding with prejudice, to grant any not-for-profit entity in the Territory, promptly upon the request of the not-for-profit entity, a royalty-free, non-exclusive license to the Long QT Patents under the terms and conditions set forth in Schedule B.
- 3.3.3 Transgenomic shall not be obligated to grant a license to the Long QT Patents to any not-for-profit entity which at any time has challenged or challenges the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of and right to license the Long QT Patents.
- 3.3.4 Any not-for-profit entity in the Territory desiring to enter into a license pursuant to Section 3.3.2 is intended to be a third party beneficiary to this Agreement solely with respect to Section 3.3.2. For clarity, CHEO will have the right to enforce Section 3.3.2 against Transgenomic.

## 4. Accessory Rights and Obligations

#### 4.1 Assignment

- 4.1.1 CHEO may not assign, transfer, or otherwise delegate any of its rights or obligations under this Agreement, in part or in whole, whether directly or indirectly, and whether by operation of law, change of control, acquisition, sale, or any other similar process, to any third party without Transgenomic's prior written consent, which may not be unreasonably withheld.
- 4.1.2 If Transgenomic assigns any of the Long QT Patents, it shall require that the assignee agree to abide by all terms of this Agreement as a condition of the assignment.

## 4.2 Publicity and Disclosure

- 4.2.1 The Parties are entitled to disclose this Agreement in any forum and by any method, including by way of individual or mutual press release, promptly following discontinuance of the Proceeding and thereafter.
- 4.2.2 CHEO and Transgenomic will publish this Agreement in its entirety within a searchable and navigable location on their respective websites.

## 5. Representations and Warranties

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## 5.1 Representations and Warranties

- 5.1.1 Transgenomic and CHEO each represent and warrant to the other that:
  - a. each is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized;
  - b. each has the legal power and authority to execute, deliver and perform this Agreement;
    - the execution, delivery and performance by each of this Agreement has been duly authorized by all necessary corporate action;
      - this Agreement constitutes the legal, valid and binding obligation of each, enforceable against each other in accordance with its terms; and
  - e. the execution, delivery and performance of this Agreement will not cause or result in a violation of any law, or of any contract by which each is bound.

# 5.1.2 Transgenomic further represents and warrants to CHEO that, to the best of its knowledge, Transgenomic is the valid assignee of the Long QT Patents, and that it has the authority to grant the rights and license granted herein.

#### 5.2 Warranty Disclaimers

- 5.2.1 Nothing in this Agreement is or shall be construed as:
  - a. A warranty or representation by Transgenomic as to the validity or scope of any claim or patent within the Long QT Patents;
  - b. A warranty or representation by Transgenomic that the performance of the Long QT Tests or the exercise of any of the license rights under this Agreement is or will be free from infringement of any patent rights or other intellectual property right of any third party;
  - c. A grant by Transgenomic, whether by implication, estoppel, or otherwise, of any licenses or rights under any patents other than the Long QT Patents;
  - d. An obligation on Transgenomic to bring or prosecute any suit or action against a third party for infringement of any of the Long QT Patents; or
  - e. Subject to Section 5.1.2 of this Agreement, a representation or warranty of the ownership of the Long QT Patents.
- 5.2.2 TRANSGENOMIC MAKES NO, AND HEREBY DISCLAIMS ANY, WARRANTIES, EXPRESS OR IMPLIED, IN CONNECTION WITH THE LONG QT PATENTS, WHICH ARE LICENSED "AS IS" AND "WITH ALL FAULTS." AND, EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, TRANSGENOMIC, ON BEHALF OF ITSELF AND ITS AFFILIATES, AND THEIR LICENSORS, OFFICERS, DIRECTORS, EMPLOYEES, AND AGENTS, SPECIFICALLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WARRANTIES AS TO VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE.

#### 6. Indemnification

- 6.1 CHEO shall defend, indemnify and hold harmless Transgenomic and its affiliates, and their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys' fees arising out of or relating to: (i) the exercise of the license rights granted to CHEO hereunder, including, without limitation, any claims based on CHEO's manufacture, use, or performance of the Long QT Tests or any diagnoses made using the Long QT Tests, or (ii) the negligence, misconduct, or violation of law by CHEO or any of its officers, directors, employees, or agents with respect to this Agreement or the Long QT Tests.
- 6.2 Transgenomic shall defend, indemnify and hold harmless CHEO and its affiliates, and, their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys' fees arising out of or relating to: (i) the assignment of one or more of the Long

QT Patents by Transgenomic in breach of this Agreement, including, without limitation, a failure by Transgenomic to require that the assignee of the Long QT Patents agree to abide by all terms of this Agreement as a condition of the assignment; or (ii) the negligence, misconduct, or violation of law by Transgenomic or any of its officers, directors, employees, or agents with respect to this Agreement.

## 7. Matters Relating to the Proceeding

## 7.1 No Admissions; Costs

- 7.1.1 Nothing in this Agreement shall be construed, nor shall performance under this Agreement be construed, as acknowledgment by CHEO that the Long QT Patents or other patents claiming naturally-occurring human nucleic acids (even if isolated), or genetic testing methods, are or should be valid, or that Long QT Tests proposed to be conducted by CHEO would infringe any claim within the Long QT Patents or any other patent.
- 7.1.2 The dismissal of the Proceeding referenced in Section 2.3.1 shall be without costs. Neither party shall seek costs against the other in connection with the Proceeding, and Transgenomic shall consent to the return of all money posted as security for costs of the Proceeding.

## 7.2 Governing Law

7.2.1 This Agreement shall be governed in all respects by and construed in accordance with the laws of the Province of Ontario and federal laws of Canada. Transgenomic and CHEO hereby expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods.

## 7.3 Jurisdiction and Forum

7.3.1 CHEO and Transgenomic submit to the non-exclusive jurisdiction of the courts of Ontario for all disputes under this Agreement. CHEO and Transgenomic exclude the jurisdiction of all courts outside Canada for any court action relating to this Agreement or the Long QT Patents. In particular, CHEO and Transgenomic exclude the jurisdiction of the state and federal courts of the United States for any court action relating to this Agreement or the Long QT Patents.

## 8. General Provisions

#### 8.1 Effective Date

8.1.1 This Agreement is effective on the Effective Date and will, subject to Section 3.1.4 and 8.2, remain in effect until and terminate upon the expiry of the last-to-expire of the Long QT Patents.

#### 8.2 Termination

8.2.1 If either Party violates any condition of this Agreement (including exceeding the scope of the license granted in Section 3.1.1) and fails to remedy any such violation within forty-five (45) days after written notice thereof by the other Party specifying such violation, then the non-violating Party may, at its option, terminate this Agreement by notice in writing to such effect. Subject to Section 3.1.4, neither Transgenomic nor CHEO may terminate this Agreement for any other reason.

#### 8.3 Survival

8.3.1 Any provision of this Agreement that imposes an obligation after termination of this Agreement shall survive the termination of this Agreement.

#### 8.4 Notices

8.4.1 Any notice, request, report, payment or other communication required or permitted to be given or made under this Agreement to Transgenomic or CHEO shall be given by sending such notice by certified or registered mail, return receipt requested, by email, or by facsimile transmission confirmed by mail, to the address set forth below or to such other address as the recipient Party has specified by written notice given in conformity with this section. Any notice given in accordance with the provisions of this Paragraph shall be effective when mailed, and any notice not so given shall not be valid unless and until actually received.

To CHEO: Children's Hospital of Eastern Ontario

401 Smyth Rd

Ottawa, Ontario, Canada K1H 8L1

Attn: Gabrielle Mettler

Tel: 001 613 737 7600 x3284

Fax: 001 613 738 4822

Email: mettler@cheo.on.ca

To Transgenomic:

Transgenomic, Inc. 12325 Emmet Street

Omaha, Nebraska, USA 68164

Attn: Kristina Garman

Tel: 001 402 452 5416

Fax: 001 402 452 5461

Email: kgarman@transgenomic.com

## 8.5 Further Assurances

8.5.1 CHEO and Transgenomic shall do all things and sign all documents necessary to give effect to this Agreement.

## 8.6 Severability

8.6.1 In the event that any term, provision or covenant of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove such invalidity, illegality or unenforceability, and the remaining terms, provisions and covenants shall not in any way be affected or impaired thereby.

## 8.7 Entire Agreement and Amendment

- 8.7.1 This Agreement contains the entire understanding of CHEO and Transgenomic with respect to the matter contained herein and replaces any prior oral or written communications between CHEO and Transgenomic.
- 8.7.2 This Agreement may not be amended, modified, released, discharged or otherwise terminated, in whole or in part, except by an instrument in writing, signed by authorized representatives of the Parties hereto.

## 8.8 Successors

8.8.1 This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors.

## 8.9 Construction

8.9.1 This Agreement shall not be construed more strictly against either Party merely by virtue of the fact that the Agreement may have been drafted or prepared by one Party or its counsel, it being recognized that CHEO and Transgenomic have contributed substantially and materially to its preparation and that this Agreement has been the subject of negotiations between them and is the product of that negotiation.

## 8.10 Article Headings

8.10.1 The Article headings herein are for purposes of convenient reference only and shall not be used to construe or modify the terms written in the text of this Agreement.

## 8.11 No Agency Relationship and No Joint Venture

8.11.1 The relationship between the Parties is that of independent contractor and contractees. CHEO shall not be construed to be an agent of Transgenomic in connection with the exercise of any rights hereunder, and shall not have any right or authority to assume or create any obligation or responsibility on behalf of Transgenomic. This Agreement does not constitute a partnership or joint venture, and neither Party can be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

#### 8.12 Force Majeure

8.12.1 Neither Party shall be deemed to be in default of any provision of this Agreement for any failure in performance resulting from acts or events beyond the reasonable control of such Party, such as but not limited to, Acts of God, acts of civil or military authority, civil disturbance, war, strikes, fires, power failures, natural catastrophes or other "force majeure" events.

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5.8.1 This Agreement shall be binding upon and shall inves to the benefit of the Parties

9.1 This Agreement shall not be construed more strictly against either Party metely by virtue of the fact that the Agreement may have been duiled or prepared by one Party or its commel, it being recognized that CHEO and Transgenomic have contributed substantially and materially to its preparation and that the Agreement has been the subject of negotiations between them and is the product of that magnitudes.

.10 Article Headings

8.10.1 The Article headings herein are for purposes of convenient reference only and shall not be used to construe or modify the terms written in the text of this Agreement.

Page 15

In witness whereof Transgenomic and CHEO have set their hands and seals, where applicable, by their duly authorized signing officers.

Executed at Ottawa, the <u>8</u> day of March 2016.

Children's Hospital of Eastern Ontario

Un Per:

Name: Alex Munter

Title: President and CEO

Executed at <u>San Diego</u>, the <u>8th</u> day of <u>March</u>, 2016.

Transgenomic, Inc. Pe c/s

Name: Paul Kinnon

Title: Chief Executive Officer & Chairman

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## **Schedule A: Health Authorities**

Health Authorities include but are not limited to the following entities:

- a. the Ministry of Health of British Columbia;
- b. the Medical Services Commission of British Columbia;
- c. the Ministry of Health of Alberta;
- d. Alberta Health Services;
- e. the Saskatchewan Ministry of Health and associated regional health authorities;
- f. Saskatchewan Health Services;
- g. Manitoba Health, Healthy Living and Seniors and associated regional health authorities;
- h. the Ontario Ministry of Health and its Long-Term Care and the Local Health Integration Networks;
- i. the Ministère de la Santé et des Services Sociaux du Québec;
- j. the Régie de l'assurance maladie du Québec;
- k. the New Brunswick Department of Health and associated regional health authorities;
- 1. the Nova Scotia Department of Health and Wellness and associated district health authorities;
- m. Medavie Blue Cross;
- n. the Prince Edward Island Department of Health and Wellness;
- o. Health PEI;
- p. the Newfoundland Department of Health and Community Services and the regional health authorities;
- q. the Yukon Department of Health and Social Services;
- r. the Northwest Territories Department of Health and Social Services;
- s. the Nunavut Department of Health;
- t. Health Canada;
- u. the Federal Public Service Health Care Plan Administration Authority.

## Schedule B: Standard License Agreement

## THIS AGREEMENT is made between:

Transgenomic, Inc., a Delaware corporation providing laboratory services, genetic assays and platforms, with corporate headquarters at 12325 Emmet Street, Omaha, Nebraska, USA 68164 (hereinafter "Transgenomic")

and

(hereinafter "Licensee")

In exchange for good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, Transgenomic and Licensee agree as follows:

## 1. Preliminary Matters

#### 1.1 Background

1.1.1 Transgenomic and Licensee intend that, through this Agreement, Licensee will be permitted to provide Long QT Testing under the Long QT Patents, as herein defined, on a not-for-profit basis to persons entitled to healthcare under the Canadian healthcare system and to carry out not-for-profit patient care and research.

### 1.2 Definitions

- 1.2.1 When used in this Agreement:
- 1.2.2 "at a profit" means any performance for which funding or reimbursement, as the case may be, is not at or below cost;
- 1.2.3 "at or below cost" has the meaning set out in Section 2.2 of this Agreement;
- 1.2.4 "Health Authority" means, in singular or plural usage as required by the context, an agent of the Canadian government or of a Canadian provincial or territorial government that regulates, oversees, funds or reimburses the performance of gene testing or any other medical services, directly or indirectly, by authority of statute, including but not limited to:
  - a. any body administering a "health care insurance plan" within the meaning of the *Canada Health Act*, RSC 1985, c C-6, including but not limited to entities listed in Schedule A;
  - b. any governmental entity that replaces the function of the aforementioned bodies; and

- c. any entity of the Canadian government or of a Canadian provincial or territorial government under the control of any of the aforementioned bodies.
- 1.2.5 "Long QT Patent", in singular or plural usage as required by the context, means:
  - Canadian Patent No. 2 240 737, titled "A LONG QT SYNDROME GENE WHICH ENCODES KVLQT1 AND ITS ASSOCIATION WITH MINK";
  - b. Canadian Patent No. 2 336 236, titled "MUTATIONS IN AND GENOMIC STRUCTURE OF HERG- A LONG QT SYNDROME GENE";
  - c. Canadian Patent No. 2 337 491, titled "HUMAN MINK GENE MUTATIONS ASSOCIATED WITH ARRHYTHMIA";
  - d. Canadian Patent No. 2 369 812, titled "MINK-RELATED GENES, FORMATION OF POTASSIUM CHANNELS AND ASSOCIATION WITH CARDIAC ARRHYTHMIA"; and/or
  - e. Canadian Patent No. 2 416 545, titled "COMMON POLYMORPHISM IN SCN5A IMPLICATED IN DRUG-INDUCED CARDIAC ARRHYTHMIA".
- 1.2.6 "Long QT Genes" means the following genes as embodied in nucleic acids, in a mutated or unmutated state:
  - a. KCNQ1, also called KVLQT1, KCNA9 or KCNA8;
  - b. KCNH2, also called HERG, ERG1 or KV11.1;
  - c. KCNE1, also called MINK or ISK;
  - d. KCNE2, also called MIRP1; and
  - e. SCN5A, also called NAV1.5;
  - 1.2.7 "Long QT Test", in singular or plural usage as required by the context, means any process, machine, manufacture or composition of matter used for:
    - a. research concerning the Long QT Genes or their associated RNAs or polypeptides,
    - b. screening for any mutations within one or more of the Long QT Genes or their functional products (*e.g.*, RNAs or proteins), and/or
    - c. diagnosis relating to the screening set forth,

whether or not the research, screening or diagnosis also involves genes other than the Long QT Genes; 1.2.8 "Party" and "Parties" mean:

a.

- Licensee, and/or
- b. Transgenomic.
- 1.2.9 "Territory" means the whole of Canada; and
  - 1.2.10 "Unexpired Claim", in singular or plural usage as required by the context, means any claim in an unexpired Long QT Patent, which has not been held void or invalid by a decision of a Canadian court or other governmental agency that is unappealable or unappealed within the time allowed for appeal.

#### 2. License

## 2.1 Grant of License

Subject to the terms and conditions of this Agreement, Transgenomic hereby 2.1.1 grants to Licensee, solely to the extent of Transgenomic's legal right to do so, a personal, non-exclusive, non-transferable, non-sublicensable license solely under the Long QT Patents to: (i) undertake or make (but not to have undertaken or made) Long QT Tests in the Territory; (ii) use the Long QT Tests undertaken or manufactured pursuant to Section 2.1.1(i) to (a) conduct internal, not-for-profit research concerning the Long QT Genes or their associated RNAs or polypeptides (provided that, for clarity, such research may not be carried out for any commercial purposes or carried out on behalf of or for the benefit of any third party other than a patient as provided below), (b) screen for any mutations within one or more of the Long QT Genes or their functional products (e.g. RNAs or proteins), and (c) carry out diagnoses based on the screening set forth in Section 2.1.1(ii)(b) hereof; (iii) advertise the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) hereof solely in the Territory; and/or (iv) sell the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) solely in the Territory, in all cases only where all of the following conditions are met:

a.

b.

С.

the Long QT Tests are performed by Licensee and otherwise sold by Licensee at or below cost;

the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) are performed on research subjects or patients who are citizens or residents of Canada, who are refugees in Canada, or who are present in Canada for reasons other than receiving medical services, purchasing medical or pharmaceutical products or services, or otherwise receiving the benefit of the Canadian healthcare system; and

the Long QT Tests are performed pursuant to a healthcare professional's recommendation or direction.

2.1.2 No Exclusivity. The licenses granted herein are non-exclusive, and subject to the terms of this Agreement, Transgenomic reserves all rights to use, commercialize,

license, and otherwise exploit all aspects of the Long QT Patents for any use or purpose.

- 2.1.3 Licensee will not be obliged to pay any fee or royalty to Transgenomic under the license set forth in Section 2.1.1.
- 2.1.4 Licensee shall not commence a legal proceeding challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patents, nor will Licensee assist any other entity in challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patent. In the event Licensee commences a legal proceeding challenging or assists any third party in challenging the validity, enforceability or exclusive ownership by Transgenomic of any Long QT Patent, Transgenomic may terminate this Agreement effective immediately upon notice to Licensee.
- 2.1.5 There are no implied rights or licenses granted under this Agreement, whether by implication, estoppel or otherwise. All rights not expressly granted herein by Transgenomic are reserved by Transgenomic. For emphasis, there are no have made, have used, or similar rights granted hereunder, and, as a part of the foregoing, Licensee shall have no right to have any of its rights exercised by or on its behalf by any third party. Without limiting the foregoing, Licensee acknowledges and agrees that it may not (and that no right or license is granted under this Agreement to) (i) use any third party to undertake or manufacture the Long QT Tests, (ii) perform the Long QT Tests for or on behalf of a third-party testing provider that is not a not-for-profit entity in the Territory, and/or (iii) use or perform the Long QT Tests for any commercial purpose.
- 2.1.6 Transgenomic covenants not to bring a claim of infringement of the Long QT Patents against Licensee alleging infringement of the Long QT Patents based solely on activities coming within the scope of the license granted under Section 2.1.1. If Transgenomic commences a legal proceeding to enforce the Long QT Patents against Licensee in respect of activities not coming within the scope of the license granted under Section 2.1.1, Licensee reserves the right to challenge the validity, enforceability or ownership of the Long QT Patents in such proceeding.
  - 2.1.7 The license granted to Licensee hereunder does not diminish or otherwise affect the rights of Licensee or any third-party to conduct activities exempt from patent infringement in accordance with section 55.2 of the *Patent Act* and/or the common law exemption from patent infringement for non-commercial use of patented inventions.

## 2.2 Determining Use At or Below Cost

- 2.2.1 For the purposes of this subsection only, "Fee" means a payment that reimburses or funds Licensee's performance of a Long QT Test.
- 2.2.2 A Long QT Test is performed at or below cost if the Fee charged by Licensee for the Long QT Test is less than or equal to the sum of all costs it incurs in

association with the Long QT Test. Such costs may include one or more of but are not limited to the following:

- a. payment, direct and indirect, for the labour required to administer and perform the Long QT Test and analyze test results;
- b. the cost of acquiring, storing, and disposing of necessary disposable materials;
- c. the allocable cost of validating the Long QT Test;
- d. the allocable cost of equipment used, directly or indirectly, in the Long QT Test;
- e. the allocable cost of any infrastructure necessary to conduct and validate the Long QT Test; and
- f. reasonably allocable overhead, whether calculated directly or based on a reasonable estimate when assessed in accordance with Generally Accepted Accounting Principles (GAAP).
- 2.2.3 If a Health Authority pays Licensee a Fee for performance of a Long QT Test that is intended to cover only some or all of the costs laid out in the previous paragraph, then the Fee paid is deemed to be less than or equal to the costs incurred, and the Long QT Test is deemed to be at or below cost.
- 2.2.4 Where Licensee has been deemed to provide a Long QT Test at or below cost in accordance with the prior paragraph, subsequent provision of a substantially similar Long QT Test by Licensee for the same or lower Fee shall be deemed to be at or below cost, whether the Fee is paid by a Health Authority or some other person.
- 2.2.5 A Long QT Test is also deemed to be "at or below cost" if Licensee is paid no Fee for that Long QT Test, including but not limited to:
  - a. if Licensee pays for costs out of a publicly-funded operating budget rather than accepting reimbursement at a rate per test, or
  - b. if Licensee or its associated researchers receive grant or other funding to conduct research.
- 2.2.6 If Licensee intends to perform a Long QT Test at a profit, the Parties may negotiate reasonable terms before the Long QT test is undertaken.

## 2.3 No Sublicensing

2.3.1 Licensee will have no right to sublicense any of the rights granted under this Agreement to any third party.

# 3. Accessory Rights and Obligations

#### 3.1 Assignment

- 3.1.1 Licensee may not assign, transfer, or otherwise delegate any of its rights or obligations under this Agreement, in part or in whole, whether directly or indirectly, and whether by operation of law, change of control, acquisition, sale, or any other similar process, to any third party without Transgenomic's prior written consent, which may not be unreasonably withheld.
- 3.1.2 If Transgenomic assigns any of the Long QT Patents, it shall require that the assignee agree to abide by all terms of this Agreement as a condition of the assignment.

#### 4. Representations and Warranties

## 4.1 Representations and Warranties

- 4.1.1 Transgenomic and Licensee each represent and warrant to the other that:
  - a. each is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized;
  - b. each has the legal power and authority to execute, deliver and perform this Agreement;
  - c. the execution, delivery and performance by each of this Agreement has been duly authorized by all necessary corporate action;
  - d. this Agreement constitutes the legal, valid and binding obligation of each, enforceable against each other in accordance with its terms; and
  - e. the execution, delivery and performance of this Agreement will not cause or result in a violation of any law, or of any contract by which each is bound.

## 4.2 Warranty Disclaimers

- 4.2.1 Nothing in this Agreement is or shall be construed as:
  - a. A warranty or representation by Transgenomic as to the validity or scope of any claim or patent within the Long QT Patents;
  - b. A warranty or representation by Transgenomic that the performance of the Long QT Tests or the exercise of any of the license rights under this Agreement is or will be free from infringement of any patent rights or other intellectual property right of any third party;
  - c. A grant by Transgenomic, whether by implication, estoppel, or otherwise, of any licenses or rights under any patents other than the Long OT Patents;

d.

An obligation on Transgenomic to bring or prosecute any suit or action against a third party for infringement of any of the Long QT Patents; or

e. A representation or warranty of the ownership of the Long QT Patents.

4.2.2 TRANSGENOMIC MAKES NO, AND HEREBY DISCLAIMS ANY, WARRANTIES, EXPRESS OR IMPLIED, IN CONNECTION WITH THE LONG QT PATENTS, WHICH ARE LICENSED "AS IS" AND "WITH ALL FAULTS." AND, EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, TRANSGENOMIC, ON BEHALF OF ITSELF AND ITS AFFILIATES, AND THEIR LICENSORS, OFFICERS, DIRECTORS, EMPLOYEES, AND AGENTS, SPECIFICALLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WARRANTIES AS TO VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE.

## 5. Indemnification

- 5.1 Licensee shall defend, indemnify and hold harmless Transgenomic, the Children's Hospital of Eastern Ontario, and their affiliates, and their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys' fees arising out of or relating to: (i) the exercise of the license rights granted to Licensee hereunder, including, without limitation, any claims based on Licensee's manufacture, use, or performance of the Long QT Tests or any diagnoses made using the Long GT Tests, or (ii) the negligence, misconduct, or violation of law by Licensee or any of its officers, directors, employees, or agents with respect to this Agreement or the Long QT Tests.
- 5.2 Transgenomic shall defend, indemnify and hold harmless Licensee and its affiliates, and, their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys' fees arising out of or relating to: (i) the assignment of one or more of the Long QT Patents by Transgenomic in breach of this Agreement, including, without limitation, a failure by Transgenomic to require that the assignee of the Long QT Patents agree to abide by all terms of this Agreement as a condition of the assignment; or (ii) the negligence, misconduct, or violation of law by Transgenomic or any of its officers, directors, employees, or agents with respect to this Agreement.

## 5.3 Governing Law

5.3.1 This Agreement shall be governed in all respects by and construed in accordance with the laws of the Province of Ontario and federal laws of Canada. Transgenomic and Licensee hereby expressly exclude the application of the *United Nations Convention on Contracts for the International Sale of Goods*.

# 5.4 Jurisdiction and Forum

5.4.1 Licensee and Transgenomic submit to the non-exclusive jurisdiction of the courts of Ontario for all disputes under this Agreement. Licensee and Transgenomic

LEGAL\_US\_W # 82943584.15 LEGAL\_1:38652656.1 exclude the jurisdiction of all courts outside Canada for any court action relating to this Agreement or the Long QT Patents. In particular, Licensee and Transgenomic exclude the jurisdiction of the state and federal courts of the United States for any court action relating to this Agreement or the Long QT Patents.

#### 6. General Provisions

#### 6.1 Effective Date

6.1.1 This Agreement is effective on the Effective Date and will, subject to Sections 2.1.4 and 6.2, remain in effect until and terminate upon the expiry of the last-to-expire of the Long QT Patents.

#### 6.2 Termination

6.2.1 If either Party violates any condition of this Agreement (including exceeding the scope of the license granted in Section 2.1.1) and fails to remedy any such violation within forty-five (45) days after written notice thereof by the other Party specifying such violation, then the non-violating Party may, at its option, terminate this Agreement by notice in writing to such effect. Subject to Section 2.1.4, neither Transgenomic nor Licensee may terminate this Agreement for any other reason.

#### 6.3 Survival

6.3.1 Any provision of this Agreement that imposes an obligation after termination of this Agreement shall survive the termination of this Agreement.

#### 6.4 Notices

6.4.1 Any notice, request, report, payment or other communication required or permitted to be given or made under this Agreement to Transgenomic or Licensee shall be given by sending such notice by certified or registered mail, return receipt requested, by email, or by facsimile transmission confirmed by mail, to the address set forth below or to such other address as the recipient Party has specified by written notice given in conformity with this section. Any notice given in accordance with the provisions of this Paragraph shall be effective when mailed, and any notice not so given shall not be valid unless and until actually received.

To Transgenomic:

Transgenomic, Inc.

12325 Emmet Street Omaha, Nebraska, USA 68164 Attn: Kristina Garman Tel: 001 402 452 5416

	Email: kgarman@transgenomic.com
To Licensee:	Name:
	Address:
	Agreenses.
	and all another international states and the factor
	Attn:
	Tel:
	Fax:
	Email:
2	

Fax: 001 402 452 5461

#### 6.5 Further Assurances

6.5.1 Transgenomic and Licensee shall do all things and sign all documents necessary to give effect to this Agreement.

#### 6.6 Severability

6.6.1 In the event that any term, provision or covenant of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove such invalidity, illegality or unenforceability, and the remaining terms, provisions and covenants shall not in any way be affected or impaired thereby.

# 6.7 Entire Agreement and Amendment

- 6.7.1 This Agreement contains the entire understanding of Transgenomic and Licensee with respect to the matter contained herein and replaces any prior oral or written communications between Transgenomic and Licensee.
- 6.7.2 This Agreement may not be amended, modified, released, discharged or otherwise terminated, in whole or in part, except by an instrument in writing, signed by authorized representatives of the Parties hereto.

## 6.8 Successors

6.8.1 This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors.

## 6.9 Construction

LEGAL\_US\_W # 82943584.15 LEGAL\_1:38652656.1 6.9.1 This Agreement shall not be construed more strictly against either Party merely by virtue of the fact that the Agreement may have been drafted or prepared by one Party or its counsel.

#### 6.10 Article Headings

6.10.1 The Article headings herein are for purposes of convenient reference only and shall not be used to construe or modify the terms written in the text of this Agreement.

## 6.11 No Agency Relationship and No Joint Venture

6.11.1 The relationship between the Parties is that of independent contractor and contractees. Licensee shall not be construed to be an agent of Transgenomic in connection with the exercise of any rights hereunder, and shall not have any right or authority to assume or create any obligation or responsibility on behalf of Transgenomic. This Agreement does not constitute a partnership or joint venture, and neither Party can be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

#### 6.12 Force Majeure

6.12.1 Neither Party shall be deemed to be in default of any provision of this Agreement for any failure in performance resulting from acts or events beyond the reasonable control of such Party, such as but not limited to, Acts of God, acts of civil or military authority, civil disturbance, war, strikes, fires, power failures, natural catastrophes or other "force majeure" events.

[--remainder of page intentionally left blank--]

# Signature Page to Standard License Agreement

In witness whereof Transgenomic and Licensee have set their hands and seals, where applicable, by their duly authorized signing officers.

Executed at	, the	day of	, 20
Licensee			
Per:		c/s	
Name:			
Title:			
Executed at	, the	day of	, 20
Transgenom	ic, Inc.		
Per:		c/s	
Name:			
Title:			

#### Signature Page to Standard Lizeine Agreement

In witness whereof Transgenomic and Licensee have set their hands and seals, where applicable, by their solutly authorized signing officers.

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