18-04344-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, May 11, 2018 6:48 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.1 to the 3/31/15 10-Q, filed by Tokai Pharmaceuticals, Inc. (now called Novus Therapeutics, Inc.) on 5/12/2015. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

June 6, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr.
Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04344-E

Dear Mr. Edwards:

This letter is in response to your request, dated May 11, 2018 and received in this office on May 14, 2018, for access to Exhibit 10.1 to the March 31, 2015 10-Q, filed by Tokai Pharmaceuticals, Inc. (now called Novus Therapeutics, Inc.) on May 12, 2015.

The search for responsive records has resulted in the retrieval of 55 pages of records that may be responsive to your request. They are being provided to you with this letter.

As shown on the enclosed invoice, the processing fee is $30.50 in accordance with our fee schedule. You may use our Online Payment option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg., Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me at osbornes@sec.gov or (202) 551-8371. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Sonja Osborne

Sonja Osborne
FOIA Lead Research Specialist

Enclosure

Tokai Pharmaceuticals, Inc.
requests that the marked portions of the exhibit be granted confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

Exhibit 10.1

Execution Copy

Companion Diagnostics

MASTER COLLABORATION AGREEMENT

Between Tokai Pharmaceuticals, Inc.
One Broadway, 14th floor
Cambridge, MA 02142 USA
hereinafter **"Tokai"**

and QIAGEN Manchester Limited
Skelton House, Lloyd Street North
Manchester, M15 6SH,
England
hereinafter **"QIAGEN"**

WHEREAS

(A) Tokai is a world-wide operating pharmaceutical company engaged in the research, development, manufacture and commercialization of pharmaceutical products and methods of treatment of patients with pharmaceutical products.

(B) QIAGEN is a global provider of sample and assay technologies including *in vitro* diagnostics and companion diagnostics in relation to the pharmaceutical industry.

(C) The Parties hereby wish to establish a legal framework for their Project-specific collaborations in the field of development and commercialization of *in vitro* diagnostics and/or companion diagnostics for Tokai Compounds.

NOW, THEREFORE, the Parties agree as follows:

1. Definitions

1.1 Many terms are defined within the provisions of this Agreement. For convenience, the following terms are defined "up-front" for use throughout the Agreement:

"Activities" shall mean the activities set out in a Schedule to be performed by either Party in connection with a particular Project.

"Affiliate" shall mean any entity which, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a Party, as the case may be. As used in this definition, "control" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise.

"Agreement" shall mean this Master Collaboration Agreement.

"Background Intellectual Property" shall mean Intellectual Property, which is in existence and Controlled by a Party at the effective date of the respective Schedule.

"Business Day" means any day other than a Saturday, Sunday, bank holiday or public holiday in Boston, Massachusetts USA.

"Clinical Trial" shall mean a clinical investigation of a Tokai Product undertaken or supported by Tokai as part of the development of such pharmaceutical product to obtain information relating to patient outcome and/or selection for therapy with such pharmaceutical product, which clinical investigation includes the use of the QIAGEN IVD or any prototype of it developed in the respective Project.

"Commercialization" and **"Commercialize"** shall refer to all activities undertaken relating to the manufacture for commercial sale, new product planning, marketing, distribution and sale of a Tokai Product or QIAGEN IVD, and the process of Commercialization, respectively. For clarification, this excludes development and regulatory activities.

"Confidential Information" shall mean any confidential or proprietary information of a Party relating to any assay, diagnostic, biomarker, genetic sequence, compound, research project, work in process, future development, scientific, engineering, launch, manufacturing, marketing, business plan, financial or personnel matter relating to such Party, its present or future products, sales, suppliers, customers, employees, investors or business, including the results arising from this Agreement, whether in oral, written, graphic or electronic form, that is disclosed by or on behalf of a Party to another Party, or becomes known to a Party as a consequence of performing Activities under this Agreement. Notwithstanding the foregoing, Tokai shall be the disclosing Party with respect to Clinical Data, Biomarker Data, Tokai Background Intellectual Property and Tokai Foreground Intellectual Property, and QIAGEN shall be the disclosing Party with respect to Analytical Performance Data, QIAGEN Background Intellectual Property and QIAGEN Foreground Intellectual Property, in each case regardless of the Party that actually discloses such information.

"Control" or "Controlled" or "Controlling" shall mean, with respect to any item of Intellectual Property, the possession (other than by operation of this Agreement) of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or to grant the other Party access or a license or sublicense to, such Intellectual Property as provided for herein without violating the terms of any agreement or other arrangement with a third party.

"Data" shall mean any and all data, results, conclusions, reports, and other information generated by or for Tokai resulting from the activities performed under a Project.

"Deliverables" shall mean the Data and/or materials to be provided to Tokai by QIAGEN in connection with a particular Project.

"Development Project" shall mean a project performed under this Agreement, as agreed between the Parties and set out in a Schedule. Development Projects may include: (i) biomarker identification and validation, (ii) prototype assay development, (iii) companion diagnostic proof of concept, (iv) *in vitro* diagnostic development, (v) enrolment assay

development, (vi) Clinical Trial support and regulatory consultation, or (vii) support of a Regulatory Submission for a Tokai Product; which project ultimately may result in the creation and Commercialization of a QIAGEN IVD in Markets under this Agreement.

"Effective Date" shall mean the date on which this Agreement has been signed by both Parties.

"EU" shall mean the European Union.

"Foreground Intellectual Property" shall mean any and all Intellectual Property arising from work performed under a Project during the Term, whether conceived, discovered, reduced to practice or writing, generated or developed by the employees, consultants, contractors or agents of Tokai and/or its Affiliates and/or by the employees, consultants, contractors or agents of QIAGEN and/or its Affiliates, solely or jointly. For clarification, Foreground Intellectual Property shall exclude Data.

"Governmental Authority" shall mean any court, agency authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

"Indication" shall mean any disease, syndrome or condition for which a product can be used for treatment or prevention of such condition, which use is the subject of a separate Regulatory Approval.

"Intellectual Property" shall mean all intellectual property rights, including patent rights (pending or issued), know-how, materials, methods, processes, protocols, inventions or discoveries (whether or not patentable), utility models, registered designs, design rights, copyrights, copyright registrations, trade secret and other Confidential Information, and similar intellectual property rights.

"IVD" shall mean *in vitro* diagnostic medical device as defined in the European directive 98/79/EC; for the avoidance of doubt the term IVD includes companion diagnostics for a pharmaceutical product as defined in FDA's "Guidance for Industry and Food and Drug Administration Staff - In Vitro Companion Diagnostic Devices" dated August 6, 2014.

"Major Market" shall mean the United States, the EU, Japan, Canada and Australia, unless otherwise agreed in a Project Schedule.

"Market" shall mean any country of the world in which the applicable Tokai Product is Commercialized.

"Materials" shall mean the biological samples, compounds, reagents, supplies, products and other goods that Tokai delivers to QIAGEN, or QIAGEN procures from a third party, for purposes of performing the this Agreement, and all modifications and derivatives of such Materials.

"Party" shall mean Tokai or QIAGEN as the context requires and **"Parties"** shall mean both Tokai and QIAGEN.

"Project" shall mean a Development Project performed under this Agreement and/or subsequent Commercialization of the respective QIAGEN IVD.

"QIAGEN Domain Names" shall mean any Domain Name identical or similar with the QIAGEN Trademarks under any ccTLD (country code Top Level Domain) and gTLD (generic Top Level Domain) address area.

"QIAGEN IVD" shall mean an IVD developed by QIAGEN in the course of a Project including its respective development stages.

"QIAGEN IVD Platform" shall mean a diagnostic instrumentation or device, firmware base software and user interface software, which may include, for example, the RGQ or QIAsymphony instruments.

"QIAGEN Trademarks" shall mean the trademarks which QIAGEN uses for the Commercialization of the QIAGEN IVD to be used in connection with a Tokai Product.

"Regulatory Approval" shall mean with respect to a regulatory jurisdiction, any and all approvals, product and/or establishment licenses, registrations or authorizations of any Governmental Authority, necessary for the commercial manufacture, use, storage, import, export, transport, or Commercialization of a product in such regulatory jurisdiction, including, where applicable, (i) pricing and reimbursement approval in such regulatory jurisdiction, (ii) pre- and post-approval marketing authorisations (including any prerequisite manufacturing approval or authorisation related thereto), (iii) labelling approval and (iv) technical, medical and scientific licences. With regard to an IVD, Regulatory Approval would occur upon FDA approval of a Premarket Approval Application or *de novo* classification or premarket authorization for the IVD, and similar approvals of Governmental Authorities in other jurisdictions.

"Regulatory Submission" shall mean with respect to a regulatory jurisdiction, any and all submissions, which are necessary to obtain a Regulatory Approval.

"Schedule" shall mean an attachment executed by the Parties under this Agreement, as described in Section 2, which details a Project containing a list of Activities, Tokai Compounds, Deliverables, Markets and other terms applicable to a Development Project.

"Tokai Compound" shall mean a single biological or chemical substance identified in a Schedule that Tokai is developing or Commercializing for the prevention, treatment, palliation or cure of a disease, syndrome or condition in humans or animals.

"Tokai Domain Names" shall mean any Domain Name identical or similar with the Tokai Trademarks under any ccTLD (country code Top Level Domain) and gTLD (generic Top Level Domain) address area.

"Tokai Product" shall mean any product containing a Tokai Compound.

"Tokai Trademarks" shall mean the trademarks which Tokai uses for the Commercialization of the Tokai Products with which a QIAGEN IVD will be used.

"Trademark" shall mean the Tokai Trademarks and the QIAGEN Trademarks.

"Valid Claim" shall mean a claim in a granted patent for the Tokai Product that: (a) has not lapsed, expired or been disclaimed and (b) and that has not been revoked, held invalid or otherwise declared unenforceable by a final judgment of a court, tribunal or patent authority of competent jurisdiction from which no appeal has or can be taken; or a claim in a patent application that has not been: (i) abandoned or disclaimed, or (ii) finally rejected or disallowed by an appropriate administrative agency or court of competent jurisdiction from which no appeal has or can be taken, or (iii) pending for more than five (5) years from the date of its first date of nationalization; provided that if a claim that has been pending more than five (5) years shall issue, it shall become a Valid Claim.

1.2 Other Definitional And Interpretative Provisions. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. Any capitalized term used in any Schedule but not otherwise defined therein shall have the meaning as defined in this Agreement. Any singular term in this Agreement shall he deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. Except where the context otherwise requires, the word "or" is used in the inclusive sense connoted by the term "and/or". This Agreement will be fairly interpreted in accordance with its terms and without any strict construction in favor of or against either Party.

2. Projects

2.1 Schedules, Generally. This Agreement shall govern all Projects identified under a Schedule. The period during which Projects may be initiated (hereinafter **"Initiation Term")** under this Agreement is five (5) years as of the Effective Date, or until terminated in accordance with Section 10. QIAGEN shall perform the Activities and provide the Deliverables as set forth in the relevant Schedule and this Agreement in accordance with the highest prevailing standards of care and skill to be reasonably expected in the field of developing and Commercializing *in vitro* diagnostics and companion diagnostics, including adherence to all applicable laws, cGLP (with respect to Tokai Products developed for animals), cGMP, and cGCP practices, and any additional requirements set forth in a Schedule. QIAGEN shall comply with all reasonable and applicable guidelines and instructions that Tokai provides in writing regarding the use, storage or handling of patient samples or the Tokai Product. QIAGEN shall be responsible for the quality, technical accuracy and completeness of all Deliverables to be generated or provided by it under this Agreement or a Schedule. QIAGEN shall be responsible for the professional quality, training and supervision of all of its, its Affiliates' and permitted subcontractors' personnel who are engaged in the performance of any Activities for a Project under a

Schedule. QIAGEN will perform its foregoing obligations in good faith, using commercially reasonable and diligent efforts to meet the milestones set forth in each Schedule.

2.2 Negotiation of Schedules. For each Project conducted under this Agreement, the Parties shall negotiate the specific details and execute a separate written Schedule. Each Schedule shall detail, *inter alia*, the scope of Activities, Tokai Compounds, Deliverables, Project time lines, Markets and compensation terms. Throughout the term of Project each Schedule may be subject to scope changes to be agreed in accordance with section 2.3. Once executed by both Parties, each Schedule and amendment to a Schedule shall be incorporated in its entirety into this Agreement. No Party shall be obliged to enter into any Schedule by virtue of this Agreement. QIAGEN shall not be obligated to perform any Activities for Tokai until the Parties have executed a Schedule for that Project.

2.3 Scope Changes. Each time that the Parties agree that the Activities or Deliverables of a Project should be amended or additional Activities or Deliverables should be added to a Project, the Parties shall prepare a written amendment of the Schedule for such Project. A Party shall not vary from the Activities and Deliverables set out in the original Schedule until the Parties have agreed to do so in writing.

2.4 Conflicting Provisions. In the event there is a specific conflict between the terms or conditions of this Agreement and the terms or conditions of any Schedule, the terms and conditions of this Agreement shall govern, unless the Schedule specifically and expressly supersedes this Agreement on a specific matter and then only with respect to the particular Schedule and the matter so specified.

3. Materials and Records

3.1 Materials Delivery. As more specifically provided in each Schedule, Tokai shall without undue delay provide the relevant Materials free of charge to QIAGEN. If QIAGEN considers that Materials provided by Tokai do not conform to their specifications, then (a) QIAGEN shall provide Tokai a written notice hereof explaining in detail why Materials do not conform and (b) in case the Parties agree on such non-conformance Tokai shall: (i) provide new or replacement Materials or (ii) if that is not possible, propose and discuss with QIAGEN in good faith an alternative, and amend the Schedule in writing to reflect such alternative. In case the Parties disagree on the question of non-conformance of Material, the Parties will discuss this matter and agree in good faith on a solution. To the extent Tokai requests that QIAGEN procure Materials directly from the relevant vendor, such procurement may be subject to a handling charge to be agreed by the Parties in advance.

3.2 Use Restrictions. QIAGEN shall handle the Materials in accordance with any applicable documentation, reasonable handling procedures for similar materials, applicable common scientific standards of care, and Tokai's written instructions. QIAGEN undertakes to use the Materials only in connection with the Activities described in the applicable Schedule and for no other purpose. QIAGEN shall use the Materials in accordance with applicable laws. None of the Materials shall be transferred or sold to third parties except to

subcontractors approved by Tokai. QIAGEN shall not use the Materials for testing in or treatment of human subjects except to the extent described in the applicable Schedule. QIAGEN understands and agrees that the Materials are experimental in nature and that Tokai shall not be liable for any loss, claim, damage or liability which may arise from the use, storage or handling of the Materials by QIAGEN.

3.3 Audits. During and following the Term, Tokai retains the right to audit or have audited QIAGEN's records and any other documentation and facilities in relation to development and regulatory activities for a Project no more than one time per twelve (12) month period during the Term unless there arises a material quality issue that impacts the Project (a "For Cause Audit by Tokai"). QIAGEN agrees to maintain accurate and detailed records of information pertaining to any particular Project and agrees to grant access to Tokai (or its nominees) or the FDA or any other Governmental Authority in a Market at QIAGEN's and any other Project related facility upon request. Such audit(s) will require reasonable prior written notice, no less than 45 days (other than in the case of a For Cause Audit by Tokai and be subject to commercially reasonable security and safety procedures. Should the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") or any other Governmental Authority in a Market conduct or give notice of intent to conduct any inspection at any investigation site, or take any other action with respect to any Project, excluding routine audits of the facility, QIAGEN will promptly give Tokai notice thereof, and supply all information and findings pertinent thereto.

If any audit performed within QIAGEN's internal program results in any critical and major findings concerning a Project, QIAGEN shall provide Tokai with a summary of such findings and proposed corrective actions following the completion of such audit. Should the FDA, EMA or any other Governmental Authority conduct or give notice of intent to conduct any inspection at QIAGEN's offices or other QIAGEN facility relating to the development or regulatory activities for a Project, excluding routine audits of the facility, QIAGEN will promptly (and no longer than 48 hours) give Tokai notice thereof, and supply all information and findings which may have an adverse impact on a Tokai Compound, Tokai Product, a QIAGEN IVD or Project(s) to Tokai, but for clarification, excluding any information relating to a third party's Project or compound. Prior to responding to the findings of any aforementioned inspection, QIAGEN shall review and discuss such response with Tokai. If the inspection relates solely to a QIAGEN IVD or Project for Tokai, and to the extent permitted by law, Tokai shall be entitled to have a representative present for such inspection and all interactions with the FDA, EMA or other Governmental Authority with respect thereto.

3.4 Financial Records. QIAGEN agrees to maintain for a period of seven (7) years after the expiration or termination of this Agreement adequate records of, and copies of all receipts for third party expenses incurred in connection with the performance of the Activities and allow access to Tokai and its authorized representatives to inspect such records and receipts upon reasonable notice during ordinary business hours and subject to QIAGEN's generally applicable security and safety procedures.

4. Interactions with Affiliates and Third Parties

4.1 Subcontractors.

4.1.1 Either Party may involve any of its' Affiliates in the performance of a Project without notice to or consent from the other Party. Any involvement of third party contractors by either Party in performance of a Development Project under a Schedule requires the prior written consent of the other Party, such consent not to be unreasonably withheld. The foregoing shall not be construed as preventing either Party from using individual consultants.

4.1.2 To the extent that a Party utilizes its' Affiliates or third party contractors to perform tasks within the scope of a Project, such Party shall ensure all such Affiliates or third party contractors are obligated to: (i) treat the other Party's Confidential Information in accordance with the provisions of **Section 6**, and (ii) assign rights to any Foreground Intellectual Property, Materials and/or Data so that such rights can be conveyed in accordance with the terms and conditions of **Section 7**, and (iii) with respect to QIAGEN, that its Affiliates or third party contractors grant audits and inspection rights similar to the right set forth in **Section 3.3 and 3.4**; whereas the foregoing shall not limit QIAGEN's audit and inspection responsibilities. Each Party shall be liable and solely responsible for the acts, performance and compensation of its respective third party contractors.

4.2 Contract Laboratories. The Parties may use third party contract laboratories for the performance of certain services such as sample testing pursuant to a Schedule (hereinafter "**Contract Laboratories**"). Tokai and QIAGEN shall cooperate reasonably on a case-by-case basis when contracting with such Contract Laboratories. In the absence of an agreement under a Schedule to the contrary, however, Tokai shall be responsible and authorized to select and contract the Contract Laboratories engaged to assess the clinical utility of a QIAGEN IVD, subject to QIAGEN's prior consent which may only be withheld in case QIAGEN has reasonable quality concerns with respect to the performance of such sample testing by such Contract Laboratory. Tokai and QIAGEN shall ensure that the Contract Laboratories are properly certified to do the clinical utility work according to the applicable Schedule for the Project and this Agreement. QIAGEN shall be solely responsible for the manufacture and supply of a QIAGEN IVD to the Contract Laboratories for clinical utility testing and for sufficient educating and training of the Contract Laboratories personnel as necessary for conducting the clinical utility testing. QIAGEN also shall be responsible for ensuring that each such Contract Laboratory has or is provided the necessary equipment (including any upgrades) needed to perform any assay developed hereunder, all of which shall be at Tokai's expense.

5. Payment

5.1 Fees and Invoices. Tokai shall pay QIAGEN in accordance with the fee/payment provisions set forth in the applicable Schedule. The Parties hereby agree that all Projects shall be performed on the basis of a milestone-based fee structure, unless agreed otherwise. Payments are made in U.S. Dollars by wire transfer to a bank account specified by QIAGEN in the Schedule. QIAGEN shall issue invoices for payments which are milestone

based upon their completion in accordance with this Agreement and the relevant Schedule. In addition, QIAGEN shall issue separate invoices, at the end of each month, for all reimbursable expenses set forth in Section 5.2 which accrued in the relevant month. Invoices shall be sent to the following address:

Tokai Pharmaceuticals, Inc.
One Broadway, 14th floor
Cambridge, MA 02142 USA

mentioning John McBride and of the respective Project in the reference line. Tokai shall pay such invoices within 30 days of receipt of the relevant invoice.

5.2 Reimbursable Expenses. In addition to the fees payable under Section 5.1, Tokai shall reimburse any direct, out-of-pocket costs reasonably incurred by QIAGEN and labelled as "pass-through costs" in the Schedule, without any mark-up or surcharge unless otherwise agreed by the Parties in writing in advance.

5.3 Currency Conversion.

IF USD, use: Any costs to be reimbursed by Tokai in accordance with Section 5.2 which were incurred in a currency other than U.S. Dollars shall be converted into U.S. Dollars using the average of the fixing exchange rates published by Bloomberg under the function "BFIX" for the respective currency at noon New York time for the applicable calendar quarter If, on any business day, no U.S. Dollar foreign exchange fixing rate is determined by Bloomberg for the relevant currency, the last Bloomberg price of such day (data field "PX last") shall be used instead.

http://markets.ft.com/ft/markets/researchArchive. asp?report=WORL.

5.4 Delay: Any payments due under this Agreement shall be due on such date as specified in this Agreement. Any failure by Tokai to make a payment within ten (10) days after the date when due shall obligate Tokai to pay interest on the due payment to QIAGEN. The interest period shall commence on the due date (inclusive) and end on the payment date (exclusive). Interest shall be calculated based on the actual number of days in the interest period divided by 360. The interest rate per annum shall be equal to the 1 month LIBOR rate, fixed two Business Days prior to the due date and reset to the prevailing 1 month LIBOR rate in monthly intervals thereafter, plus a premium of one percent (1%). In addition, if Tokai fails to make an undisputed payment under a Schedule within sixty (60) days after the date due, QIAGEN shall be entitled, in lieu of other remedies hereunder, to suspend its performance under such Schedule until the undisputed payment is made. However, if Tokai fails to make an undisputed payment under a Schedule within one-hundred twenty (120) days after the date due, QIAGEN shall be entitled to treat such failure as a material breach by Tokai and terminate this Agreement immediately so long as advance notice pursuant to Section 10.2.1 had been provided.

5.5 Taxes.

5.5.1 All agreed remunerations/fees are considered to be net of value added tax (hereinafter "**VAT**"). VAT will be due additionally as legally owed to the applicable jurisdiction, payable after receipt of a proper invoice, which meets all legal requirements according to the applicable VAT-law.

5.5.2 To the extent that the goods or services to be provided hereunder are subject to any sales, use, rental, personal property, or any other transaction or indirect taxes under law, payment of said taxes is Tokai's responsibility, subject to any applicable exemption entitlement.

5.5.3 Any Party required to make a payment (hereinafter the "**Paying Party**") to the other Party (hereinafter the "**Payee**") under this Agreement shall be entitled to deduct and withhold from the amount payable the withholding tax for which the Paying Party is liable under any provisions of tax law. Any withheld tax shall be treated as having been paid by Paying Party to Payee for all purposes of this Agreement. Paying Party shall timely forward the tax receipts certifying the payments of withholding tax on behalf of Payee. In case Paying Party cannot deduct the withholding tax due to fulfillment completion of payment obligation by settlement or set-off, Payee will pay the withholding tax to Paying Party separately. If Paying Party failed to deduct withholding tax but is still required by tax law to pay withholding tax on account of Payee to the tax authorities, Payee shall assist Paying Party with regard to all procedures required in order to obtain reimbursement by tax authorities or, in case tax authorities will not reimburse withholding tax to Paying Party, Payee will immediately refund the tax amount.

6. Confidentiality

6.1 Use of Confidential Information. Except for the use in connection with the Activities or the performance of this Agreement, including the permitted use in filings and processes for Regulatory Approval, or as otherwise permitted by either this Agreement or the disclosing Party, each Party shall: (i) not use any Confidential Information of the other Party, (ii) maintain the disclosing Party's Confidential Information in confidence using the same degree of care that it uses for its own Confidential Information of like importance, but in no event using less than reasonable care, and (iii) not disclose or transfer any Confidential Information of the disclosing Party (or any materials which contain such Confidential Information), to any third party; provided, however, that disclosure shall be permitted to the receiving Party's employees, consultants, agents or subcontractors (and those of its Affiliates) who reasonably require such Confidential Information for the purposes of this Agreement and who are bound by obligations of non-use and confidentiality with respect to such Confidential Information equal to those set forth in this Section 6.1. Each Party hereby consents to the disclosure of its Confidential Information by the other Party to any Affiliate of the other Party who reasonably requires such Confidential Information for the purposes of this Agreement, and any such Affiliate shall treat such Confidential Information in accordance with the terms of this Agreement. Tokai shall also be entitled to disclose QIAGEN's Confidential Information, only to the extent directly related to the development and commercialization of the Tokai Product in combination with the QIAGEN IVD and under a binder of confidentiality no less restrictive than the provisions of this Section 6, to: (a) potential or actual commercialization partners for the Tokai Product; and/or (b) potential or actual sources of financing or acquirers of Tokai. Any

disclosures made pursuant to the foregoing Section 6.2(a) or (b) shall not require QIAGEN's prior written consent unless the party to which Tokai is making the disclosure is a competitor of QIAGEN as described in QIAGEN's periodic filings with the Securities Exchange Commission as required by the Securities Exchange Act of 1934.

6.2 Non-Confidential Information. The obligations set forth in Section 6.1 shall not apply to any information that the receiving Party can demonstrate by competent proof: (i) was possessed by the receiving Party or any of its Affiliates prior to disclosure or development under this Agreement, (ii) was developed by the receiving Party or any of its Affiliates independently from disclosure or development under this Agreement, in case of QIAGEN particularly also without use of the Materials, (iii) is now or becomes later publicly available other than by breach of this Agreement by receiving Party or any of its Affiliates, or (iv) is available to the receiving Party or any of its Affiliates from a third party that is not legally prohibited from disclosing such information.

6.3 Compelled Disclosure. Either Party may disclose Confidential Information of the other Party to the extent required to be disclosed by applicable judicial or governmental order, provided, however, that the receiving Party takes reasonable steps to give the disclosing Party sufficient prior notice in order to contest such order at the request and expense of the disclosing Party, such request made in the disclosing Party's reasonable discretion, and, in the event the receiving Party is ultimately required to disclose such Confidential Information, that the receiving Party discloses only such portion of the Confidential Information as is required to be disclosed and seeks, at the disclosing Party's request and expense, a protective order to protect the confidentiality of such Confidential Information.

6.4 Equitable Relief. Each Party agrees that damages may not be an adequate remedy for breach of this Article 6 and that, accordingly, either Party shall be entitled to seek injunctive or other equitable relief to prevent disclosure of its Confidential Information.

6.5 Publicity. Promptly following the Effective Date, the Parties shall issue a press release in the form agreed by the Parties. Following such initial press release, no Party hereto may issue any other press release or other public statement or announcement concerning the terms of this Agreement without the other Party's prior written consent unless such release includes only those facts that were initially released in accordance with the first sentence of this Section 6.5. In addition, no Party hereto shall use the name or any trademarks, logos or trade dress of another Party or its Affiliates in any publicity, press release or other form of public announcement or disclosure without the prior written consent of such other Party. Notwithstanding the foregoing, any Party may disclose the terms or existence of this Agreement if required by law or regulation, including without limitation applicable securities laws and regulations and rules and regulations of securities exchanges. If the terms or existence of this Agreement are required to be disclosed by law or regulation, such Party will give the other Parties' prior written notice of the disclosure requirement and a reasonable opportunity to review and comment on what is intended to be disclosed before disclosure.

6.6 Publications. Each Party shall have the right to publish, present or use Foreground Intellectual Property and/or any portion thereof that it Controls in furtherance of its

publication objectives, or for non-confidential discussions with a Third Party (a "**Publication**"). Tokai will be responsible for and control the timing and scope of any Publication of Clinical Data, Biomarker Data and Tokai Foreground Intellectual Property. QIAGEN will be responsible for and control the timing and scope of any Publication of the Analytical Performance Data and QIAGEN Foreground Intellectual Property. Any Publications of the Joint Foreground Intellectual Property must be agreed and approved by all Parties. Furthermore, Tokai shall not have the right to publish, present or use the Analytical Performance Data, QIAGEN Foreground Intellectual Property or any portion thereof for any Publication without QIAGEN's prior written consent, and QIAGEN shall not have the right to publish, present or use the Clinical Data, Biomarker Data or Tokai Foreground Intellectual Property or any portion thereof for any Publication without Tokai's prior written consent. Such Publication shall be subject to the provisions of this Agreement relating to confidentiality and non-disclosure. At least thirty (30) days prior to submission for publication, the publishing Party shall submit to the other Party for review any proposed Publication. The other Party shall review the proposed Publication and provide its comments to the publishing Party within thirty (30) days of receipt. The Parties agree that the non-publishing Party may request the proposed submission date to be delayed, and the publishing Party agrees to delay, by up to an additional thirty (30) days in order to provide its comments or address concerns regarding the Publication. In addition, upon the other Party's notice to the publishing Party that the other Party reasonably believes that one or more patent applications should be filed which relate to Foreground Intellectual Property Controlled by the other Party or Joint Foreground Intellectual Property prior to any Publication, the publishing Party shall delay the Publication until such patent application(s) have been filed, provided that the other Party will cooperate in expeditiously filing any such patent application(s), and provided further that any such delay of a Publication will not exceed sixty (60) days from the date of such notice by the other Party to the publishing Party. If the other Party believes that any Publication contains Confidential Information or other proprietary information belonging to such Party, such Party will notify the publishing Party, which will remove all references to such Confidential Information or proprietary information prior to publication, presentation or use.

7. Intellectual Property; Licenses

7.1 Background Intellectual Property. Each Party acknowledges and agrees that the other Party Controls certain Background Intellectual Property that relates to that Party's business or operations. Each Party further acknowledges and agrees that Background Intellectual Property Controlled by the other Party shall, as between the Parties, remain the exclusive property of the other Party.

Each Party hereby grants to the other Party during the Term a non-exclusive, worldwide, sub-licensable, non-transferable and royalty-free license under its Background Intellectual Property relevant for a Project solely to the extent such license is necessary for the other Party to carry out its Activities under the respective Project, including subsequent Commercialization by QIAGEN of the QIAGEN IVD developed in the respective Project for use with the respective Tokai Product and subsequent Commercialization by Tokai of the Tokai Product with the QIAGEN IVD under this Agreement. For the avoidance of

doubt, the Parties agree that the foregoing license does not provide QIAGEN any right to promote or Commercialize a Tokai Product. For the further avoidance of doubt, the Parties agree that the foregoing license does not provide Tokai with any right to promote or Commercialize a QIAGEN IVD or a laboratory developed test.

Notwithstanding the foregoing, if Intellectual Property Controlled by a third party is included in the Background Intellectual Property of a Party, such Intellectual Property shall only be included into the license grant of this Section 7.1 paragraph 2, if (i) the other Party has committed in writing to comply with the relevant terms and conditions of the agreement with the third party and (ii) if applicable, the Parties have agreed in writing on the allocation or sharing of any payment obligations towards the third party which may result from the other Party's use of the third party's Intellectual Property. In addition, if the relevant (license) agreement with such third party requires an allocation of Data and Foreground Intellectual Property or licenses deviating from Sections 7.2 and 7.3, (i) the Controlling Party shall inform the other Party hereof and (ii) upon request of the other Party to include such third party's Intellectual Property into the license grant under this section 7.1, (iii) the Parties shall negotiate in good faith provisions deviating from Sections 7.2 and 7.3 and set them forth in writing. For the avoidance of doubt, the foregoing shall also apply to third party Intellectual Property acquired pursuant to Section 7.7.

7.2 Assignment and License Back of Data. All Data supplied to QIAGEN by Tokai, or generated in any Clinical Trial (including, for example, all patient data), or generated by the Contract Laboratories for or on behalf of either or both Parties in the course of the Project under this Agreement, or generated by QIAGEN using the Materials shall be owned as follows:

(a) Tokai shall own all **"Clinical Data,"** which is defined as all data, information, results and reports relating to patients in connection with a Clinical Trial of a Tokai Product; all data, information, results and reports relating to patient populations patient populations genetics, individual patient genetics, therapy and therapeutic efficacy, including clinical outcome data (*i.e.*, any data related to the performance of the Tokai Product (*e.g.*, safety, toxicity, etc.)) derived from any Materials, all as generated by or on behalf of either Party or both Parties during the course of performing the Activities under a Project or Schedule. Tokai shall be free to use the Clinical Data for any purpose. QIAGEN, as far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Clinical Data to Tokai, and if it not in a legal position to so assign, QIAGEN hereby grants to Tokai an exclusive, worldwide, irrevocable, perpetual, fully paid-up license to use the Clinical Data for any purpose. QIAGEN shall promptly provide to Tokai copies of or access to all Clinical Data held by QIAGEN and its Affiliates, and all related supporting documentation, information, results and analyses with respect to QIAGEN's the Aetivities under a Project or Schedule, when and as such Clinical Data become available.

(b) Tokai shall own all "**Biomarker Data**," which is defined as data, information, results and reports relating to biomarkers and genetic mutations including deletions, substitutions, additions, and translocations generated under the Project, all as generated by or on behalf of either Party or both Parties during the course of performing the Activities under a Project or Schedule. Tokai shall be free to use the Biomarker Data for any purpose. QIAGEN, as

far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Biomarker Data to Tokai and if it not in a legal position to so assign, QIAGEN hereby grants to Tokai an exclusive, world-wide, irrevocable, perpetual, fully paid-up license to use the Biomarker Data for any purpose.

(c) QIAGEN shall own all "**Analytical Performance Data**," which is defined as all data, information, results and reports that are related to the analytical performance of the QIAGEN IVD under the Project, which includes but is not limited to: data to support development and optimization of the QIAGEN IVD, data to support the limit of detection, limit of blank, accuracy, cross reactivity, reproducibility and stability (for clarification, Clinical Data and Biomarker Data are specifically excluded from Analytical Performance Data), all as generated by or on behalf of either Party or both Parties during the course of performing the activities under the Project and Schedule for the QIAGEN IVD. QIAGEN shall be free to use the Analytical Performance Data for any purpose. Tokai, as far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Analytical Performance Data to QIAGEN and if it not in a legal position to so assign, Tokai hereby grants to QIAGEN an exclusive, worldwide, irrevocable, perpetual, fully paid-up license to use the Analytical Performance Data for all purposes.

(d) Tokai hereby grants to QIAGEN a non-exclusive, world-wide, royalty-free license and right of reference to the Clinical Data and Biomarker Data, with the right to sublicense to QIAGEN's Affiliates or any third party developing, obtaining Regulatory Approval for, manufacturing or selling the QIAGEN IVD under the Development Project on behalf of QIAGEN, for the sole and limited purpose of, and only to the extent required to carry out its Activities under the Development Project and subsequent Commercialization of the QIAGEN IVD developed within the Development Project for use with the Tokai Product. QIAGEN shall not use the Clinical Data or Biomarker Data for any purpose other than permitted in this Section 7.2 for as long as such Clinical Data or Biomarker Data constitutes Confidential Information.

(e) QIAGEN hereby grants Tokai a non-exclusive license and right of reference to the Analytical Performance Data for the sole and limited purpose of, and only to the extent required to (i) carry out the Activities under the Project and (ii) research, develop and/or obtain Regulatory Approval for, and make, have made, use, sell, offer for sale, import, export and commercialize Tokai Products. The license shall not be sub-licensable except to any of Tokai's Affiliates or any third party researching, developing, obtaining Regulatory Approval for, making, having made, using, selling, offering for sale, importing, exporting or commercializing the Tokai Product, whether alone or in collaboration with Tokai or any of its Affiliates.

(f) As between the Parties, all right, title and interest in and to the Material is and shall remain the property of Tokai.

7.3 Foreground Intellectual Property. Subject to Section 7.1 paragraph 3, the Parties agree that any Foreground Intellectual Property shall be treated as follows:

7.3.1 Tokai Foreground Intellectual Property. Tokai shall exclusively own all right, title and interest in and to any Foreground Intellectual Property relating to (i) biological or chemical substances for the prevention, treatment, palliation or cure of diseases of humans and/or animals and the pharmaceutical use of such substances in human or animals, (ii) the mechanism of action of a Tokai Product, (iii) improvements to the Tokai Background Intellectual Property, and (iv) all Foreground Intellectual Property other than QIAGEN Foreground Intellectual Property that is made or conceived solely by employees, consultants, contractors and agents of Tokai and its Affiliates (hereinafter "**Tokai Foreground Intellectual Property**"). Tokai hereby grants to QIAGEN a non-exclusive, world-wide, royalty-free license, with the right to sublicense, under the Tokai Foreground Intellectual Property solely to carry out the Activities under the applicable Project, including subsequent Commercialization of a QIAGEN IVD developed within a Project for use with the applicable Tokai Product.

7.3.2 QIAGEN Foreground Intellectual Property. QIAGEN shall exclusively own all right, title and interest in and to any Foreground Intellectual Property relating to (i) diagnostic kits and/or diagnostic methods wherein said kits and methods do not comprise therapeutic compounds or products, including Tokai Compounds or Products, or the use thereof, (ii) improvements of QIAGENs Background Intellectual Property concerning the QIAGEN IVD Platform, and (iii) all Foreground Intellectual Property other than Tokai Foreground Intellectual Property that is made or conceived solely by employees, consultants, contractors and agents of QIAGEN and its Affiliates (hereinafter "**QIAGEN Foreground Intellectual Property**"). QIAGEN hereby grants to Tokai an irrevocable, perpetual, non-exclusive, world-wide, fully paid-up license, with the right to sublicense, under the QIAGEN Foreground Intellectual Property for carrying out the Activities under the respective Project and to Commercialize the Tokai Product with (x) a QIAGEN IVD or (y) an IVD solely (1) in the event of a termination of this Agreement by Tokai pursuant to Section 10.2 or (2) in any Market for which QIAGEN declines to seek Regulatory Approval for the QIAGEN IVD.

7.3.3 Joint Foreground Intellectual Property. The Parties shall jointly own an equal, undivided interest in and to any Foreground Intellectual Property, other than Tokai Foreground Intellectual Property and QIAGEN Foreground Intellectual Property, that is made or conceived jointly by employees, consultants, contractors and agents of Tokai and its Affiliates and by employees, consultants, contractors and agents of QIAGEN and its Affiliates (hereinafter "**Joint Foreground Intellectual Property**"). In the event that a jurisdiction requires consent of co-owners for one co-owner to grant license rights under or otherwise exploit Joint Foreground Intellectual Property, each Party hereby grants to the other Party and its Affiliates a sublicensable right and license to exploit such Joint Foreground Intellectual Property without a requirement of accounting other than as set forth in this Agreement.

7.3.4 Protection of Foreground Intellectual Property. The Parties will inform each other about any Foreground Intellectual Property without unreasonable delay after it has been conceived by their employees, agents or consultants. The Parties shall take all legally required steps to ensure and effect the allocation of the Foreground Intellectual Property as provided in Sections 7.3.1 through 7.3.3 at the sole expense of the Party owning the

Foreground Intellectual Property according to Sections 7.3.1 through 7.3.3 and, the other Party shall provide reasonable assistance and all necessary documentation and declarations to perfect the rights in the Foreground Intellectual Property (*e.g.*, documents for proof of chain of title). Each Party will provide the other Party with thirty (30) days prior notice before pursuing patent protection on the Foreground Intellectual Property allocated to it according to Sections 7.3.1 through 7.3.3. Tokai shall be responsible for the preparation, filing, prosecution and maintenance of the Tokai Foreground Intellectual Property and Joint Foreground Intellectual Property. QIAGEN shall be responsible for the preparation, filing, prosecution and maintenance of the QIAGEN Foreground Intellectual Property.

7.4 Defence and Enforcement. Each Party shall promptly notify the other Party in the event it becomes aware of any third party activities that may constitute infringement of any Intellectual Property that is subject to this Agreement, and/or of any third party claims or allegations contesting the validity and/or enforceability of any such Intellectual Property. QIAGEN shall have the right, but no obligation, to control, enforce, and defend worldwide, at its own expense, Intellectual Property rights in QIAGEN Background Intellectual Property and QIAGEN Foreground Intellectual Property. Tokai shall have the right, but no obligation, to control, enforce, and defend worldwide, at its own expense, Intellectual Property rights in Tokai Background Intellectual Property and Tokai Foreground Intellectual Property. With respect to any Joint Foreground Intellectual Property, the Parties will promptly thereafter consult and cooperate to determine a course of action, which may include, without limitation, the commencement of legal action by any or all of the Parties to terminate or otherwise address such infringement, misappropriation or misuse, and/or to defend the Joint Foreground Intellectual Property.

7.5 Patent Term Restoration. The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for United States patents and patent applications. The Parties shall cooperate with each other, including without limitation to provide necessary information and assistance as another Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Foreground Intellectual Property.

7.6 Trademarks.

7.6.1 Tokai shall have the sole right to select, register and maintain the Tokai Trademarks at its own expense, and shall own and retain all right, title and interest in and to such Tokai Trademarks, and all goodwill associated with or attached to the Tokai Trademarks arising out of the use thereof by Tokai, its Affiliates and third party licensees shall inure to the benefit of Tokai. Only Tokai will be authorized to initiate at its own discretion legal proceedings against any infringement or threatened infringement of the Tokai Trademarks. Tokai shall be responsible for the registration, hosting, maintenance and defence of the Tokai Domain Names. For the avoidance of doubts, Tokai is allowed to register such Domain Names in its own name, to host on its servers, maintain and defend these Domain Names and use them for websites.

7.6.2 QIAGEN shall have the sole right to select, register and maintain the QIAGEN Trademarks at its own expense, and shall own and retain all right, title and interest in and to such QIAGEN Trademarks, and all goodwill associated with or attached to the QIAGEN Trademarks arising out of the use thereof by QIAGEN, its Affiliates and third party licensees shall inure to the benefit of QIAGEN. Only QIAGEN will be authorized to initiate at its own discretion legal proceedings against any infringement or threatened infringement of the QIAGEN Trademarks. QIAGEN shall be responsible for the registration, hosting, maintenance and defence of the QIAGEN Domain Names. For the avoidance of doubt, QIAGEN is allowed to register such Domain Names in its own name, to host on its servers, maintain and defend these Domain Names and use them for websites.

7.6.3 The Parties recognize the exclusive ownership of each other Party's Trademarks, logotype or trade dress furnished by such Party for use in connection with the marketing, sale or distribution of the Product as defined in this Agreement. The Parties shall not, either while this Agreement is in effect, or at any time thereafter, register, use or challenge or assist others to challenge the other Party's Trademarks, logotype and trade dress furnished by each Party for use in connection with the marketing of the products as defined in this Agreement or attempt to obtain any right in or to any such name, logotype, trademarks or trade dress confusingly similar for the marketing of the products as defined in this Agreement or any other goods and products, notwithstanding that such goods or products have a different use or are dissimilar to the products as defined in this Agreement.

7.6.4 Each Party hereby grants to the other Party a non-exclusive, world-wide, sub-licensable, non-transferable and royalty-free license under its Trademarks relevant for a Project to the extent such license is necessary for the other Party to carry out its Activities under the respective Project, including subsequent Commercialization by QIAGEN in accordance with Section 8 of this Agreement of the QIAGEN IVD developed in the respective Project for use with the respective Tokai Product and subsequent Commercialization by Tokai of the Tokai Product with the QIAGEN IVD under this Agreement.

7.7 Third Party Intellectual Property Licenses

7.7.1 Licenses relevant for the Tokai Product

For the avoidance of doubt, Tokai shall be solely responsible, at its own discretion and expense, for obtaining and maintaining any licenses or other rights to access or use any other third party Intellectual Property that is necessary for the development, manufacture, use or Commercialization of any Tokai Product, including but not limited to treatment decisions derived from a diagnostic result and/or patient selection and/or stratification and/or biomarkers. QIAGEN agrees to cooperate reasonably with Tokai to assist Tokai's acquisition of any licenses that it is obligated to obtain pursuant to Section 7.6.1; provided, however, that such cooperation shall not include the undertaking of any financial obligations such as the payment of royalties, milestones or the like, unless otherwise agreed between the Parties.

7.7.2 Licenses relevant for the QIAGEN IVD.

QIAGEN shall be solely responsible, at its own discretion and expense, for obtaining and maintaining any licenses or other rights to access or use any third party Intellectual Property related to:

(i) circulating tumor cell assays, if applicable for a particular Project;

(ii) the QIAGEN IVD Platform, and

(iii) the use of the QIAGEN IVD for sample preparation, amplification and detection,

to the extent necessary for the development, manufacture, use or Commercialization by QIAGEN of such QIAGEN IVD pursuant to this Agreement.

8. Commercialization of the QIAGEN IVD as Companion Diagnostic; Supply of IVDs

8.1 General Principles. The Parties agree that the ultimate goal of each Project conducted under this Agreement is the Commercialization of a QIAGEN IVD used in connection with the Tokai Product. The determination of whether and to which extent and in which countries or territories the Tokai Product shall be Commercialized shall be within Tokai's sole discretion. To the extent Tokai Commercializes a Tokai Product in certain countries or territories, QIAGEN shall Commercialize the corresponding QIAGEN IVD in each Major Market, and may Commercialize such QIAGEN IVD in such other markets included in the Project Schedule.

8.2 QIAGEN's Commercialization Obligations. QIAGEN shall be responsible to Commercialize or have Commercialized by a subcontractor the QIAGEN IVD according to the terms and conditions herein. Within the timeframe set forth in the relevant Schedule, QIAGEN shall prepare and the Parties (acting through the JSC) shall agree upon a commercialization plan ("**Commercialization Plan**") for launch, marketing and sale of the QIAGEN IVD in the Markets in accordance with its customary commercial practices. For clarity, any activities that are: (a) outside the scope of QIAGEN's customary commercial practices; or (b) that are tailored to, or necessarily connected to the same activities for, the Tokai Product, the Parties shall mutually agree on the plan and funding for such activities in the Commercialization Plan. Each Commercialization Plan shall, among other things, detail launch strategies for the Markets, sales force activities, marketing strategies, alignment of package inserts, instructions for use, data sheets, marketing material, publications, training activities, reimbursement strategies, sharing of market research information and use of advisory boards/key opinion leaders. Without limiting the foregoing, QIAGEN shall use commercially reasonable and diligent efforts to: (a) ensure the availability of the QIAGEN IVD for purchase in the Markets for use in connection with the initiation and ongoing treatment of patients with the Tokai Product and (b) collaborate with Tokai to seek any necessary reimbursement approvals for the QIAGEN IVD from Governmental Authorities and other third party payors in each of the Major Markets. In addition, while QIAGEN shall be entitled to establish the price to be charged for the QIAGEN IVD, it shall price the QIAGEN IVD in a manner consistent with market norms for the pricing of companion diagnostic products.

8.3 Regulatory Approvals. QIAGEN shall be responsible for obtaining and maintaining, at its own expense, Regulatory Approvals for the QIAGEN IVD in any Major Markets identified by Tokai in a Project Schedule, as well as any other Markets that are mutually agreed by the Parties in a Project Schedule. Tokai shall be responsible for obtaining Regulatory Approvals for the Tokai Product. Without limiting the foregoing, QIAGEN shall use commercially reasonable and diligent efforts to: (a) prepare Regulatory Submissions for QIAGEN IVDs, (b) solicit and obtain Tokai's approval of any such Regulatory Submission, but only the portion of such Regulatory Submission that includes discussion of the Tokai Product, Clinical Data or Biomarker Data, (c) file such Regulatory Submissions with the appropriate Governmental Authority, (d) solicit Tokai's input for scheduled meetings with Governmental Authorities in each Major Market to the extent such meetings involve discussion of the Tokai Product, Clinical Data or Biomarker Data, (e) at Tokai's request, permit Tokai to participate in scheduled meetings with Governmental Authorities in each Major Market regarding development of the Tokai Product for use with the QIAGEN IVD, (f) obtain Regulatory Approval of the QIAGEN IVD in each Major Market and (g) support any efforts of Tokai to obtain Regulatory Approval for the Tokai Product for use with the QIAGEN IVD in each Major Market.

8.4 Manufacture and Supply of IVDs. QIAGEN shall be solely responsible for, and shall use commercially reasonable and diligent efforts to, manufacture QIAGEN IVDs. QIAGEN shall manufacture the QIAGEN IVDs in compliance with cGMP requirements. Until commercial launch of a QIAGEN IVD, QIAGEN shall ensure that adequate supplies of QIAGEN IVDs (or prototypes), are made available to Tokai, any Contract Laboratories and any Clinical Trial sites according to the terms set forth in the Schedule. Subject to receiving sufficient notice of required quantities from Tokai, QIAGEN shall ensure that it maintains sufficient inventories of each QIAGEN IVD as is necessary for the complete conduct of the Clinical Trials of the applicable Tokai Product and Tokai shall pay costs of all remaining quantities which cannot be used for commercialization by QIAGEN. QIAGEN shall be responsible for the transfer of the QIAGEN IVD or the prototypes thereof to the Contract Laboratories involved in the Clinical Trials. Within a commercially reasonable time prior to launch of a Tokai Product, with reasonable advance written notice by Tokai of such launch, QIAGEN will build up and maintain at its own cost an inventory of QIAGEN IVDs which shall be sufficient to satisfy the Commercialization requirement.

8.5 Commercialization Term and Viability of the QIAGEN IVD.

(a) Once Tokai commercially launches the Tokai Product in a Market that is a Major Market, QIAGEN shall make the QIAGEN IVD commercially available in that Major Market and use commercially reasonable and diligent efforts to Commercialize the QIAGEN IVD in that Major Market. QIAGEN shall also Commercialize the QIAGEN IVD in any Market other than Major Markets that were agreed in a Project Schedule and for which Tokai funded the applicable Regulatory Approvals.

(b) QIAGEN shall be responsible for Commercializing the QIAGEN IVD in each Market for as long as there are Valid Claims in that particular Market (the "**Commercialization Term**"). However, QIAGEN may be sooner released from this obligation on a Market by Market basis as follows. In the event QIAGEN reasonably determines that it is not

commercially reasonable to Commercialize a QIAGEN IVD in a Market other than a Major Market (it being understood that QIAGEN shall at all times keep the QIAGEN IVD commercially available in a Major Market if the labelling for the Tokai Product in such Major Market requires that an IVD be administered to a potential patient prior to a physician prescribing the applicable Tokai Product), QIAGEN shall provide Tokai with twelve (12) months' written notice, which notice shall include a detailed summary of the basis therefor. During such twelve (12) month period, QIAGEN shall use commercially reasonable efforts to procure alternative channels of distribution and make available or procure the making available of the QIAGEN IVD in such quantities and upon commercially reasonable terms in each case as necessary to reasonably enable Tokai to market the Tokai Product in conjunction with the QIAGEN IVD. If QIAGEN is unable to procure an alternative distribution channel or make available such QIAGEN IVD at the end of such twelve (12) month period, or sooner if mutually agreed by the Parties, QIAGEN shall be obligated to supply Tokai's requirements for such QIAGEN IVD kit (in the relevant Markets, based on reasonable forecasts) to Tokai, its Affiliates and/or third party distributors of Tokai in such Market at a price of 125% of the cost of goods therefor. Such supply obligation shall expire upon expiration of the Commercialization Term.

9. Management

9.1 Joint Steering Committee. Within thirty (30) days after the Effective Date, the Parties shall form a Joint Steering Committee (the "**JSC**") to facilitate the transfer of information and coordinate processes related to the development, Regulatory Approval and Commercialization of the Tokai Products and the QIAGEN IVDs being the subject of this Agreement. The JSC shall be composed of three (3) representatives appointed by each Party. Each representative shall be appointed (and may be replaced at any time) by a Party upon prior written notice to the other Party. These representatives shall have appropriate experience, knowledge, and ongoing familiarity with the Projects in their then current phases. Each Party shall bear its own expenses for participation in the JSC, provided that the Parties shall use commercially reasonable efforts to hold in-person meetings in Manchester, England.

9.2 Responsibilities. The JSC's responsibilities shall include, but not be limited to, the following functions:

- Facilitating the transfer of information and data related to the Commercialization and Regulatory Approval process;
- Facilitating the cooperation of the Parties, when requested, to provide information and support;
- Facilitating coordinated interpretation of data;
- Establishing the JCC and determine how the JCC shall operate;
- Approving each Commercialization Plan (subject to execution of the Commercial Plan by authorized signatories of the Parties); and

- Taking such other actions as may be specifically allocated to the JSC by the Parties from time to time.

9.3 Meetings. The JSC shall meet (either in person, telephonically or via video conference) not less than once per calendar quarter or at such greater frequency as agreed by the respective committee members. Meetings of the JSC shall be at such locations as the Parties agree. Additional representatives of the Parties may from time to time be invited to attend JSC meetings, subject to the other Party's prior consent which shall not be unreasonably withheld. The chair of the JSC shall alternate between a representative of Tokai and a representative of QIAGEN. All decisions of the JSC require the approval of a majority of each Party's representatives to the JSC.

9.4 Joint Project Team.

Within 30 days after last signature of this Agreement the Parties will, in addition to the JSC, form a joint project team (the "**Joint Project Team**" or "**JPT**"), which shall be responsible for facilitating the operational tasks and providing updates on the status of the Development Project. Members of the JPT can include but shall not be limited to representatives with expertise in research biology, translational medicine, clinical, regulatory, and/or product development. Each Party will designate a representative as JPT Lead. Such JPT shall meet, either in person, via telephone or video conferences, on a regular basis, however, at least once per month. Each Party shall bear its own expenses for participation on the JPT, provided that the Parties shall use commercially reasonable efforts to hold in-person meetings in Manchester, England.

9.5 Joint Project Team Responsibilities.

The JPT's primary responsibilities shall include, but shall not be limited to, the following functions or roles:

- Serving as technical lead and principal point of contact for all matters set forth in the Schedules;
- Overseeing project planning and progress and coordinating all activities set forth in the Schedules;
- Recommending updates to the Schedules including tactics and risk mitigation to the JSC;
- Leading meetings (at least monthly) to facilitate review and coordinated interpretation of data, information sharing, and timeline monitoring;
- Facilitating issue resolution at the Team level and escalating issues to the JSC; and
- Coordinating with the Alliance Managers to provide input to the agenda, preparing thoroughly for meetings, attending meetings and ensuring follow up on action items.

9.6 Alliance Manager.

To manage the Activities under the Agreement, an alliance manager for each Party (the "**Alliance Manager**") shall be appointed by each Party. The Alliance Manager will be an associated member of the JSC and:

- Serve as central point of contact;
- Manage the administrative aspects related to the Agreement;
- Manage and coordinate the different Activities under the contract and ensure appropriate communication and information among the Parties;
- Ensure, together with the JPT, JCC and JSC, that timelines and milestones are defined appropriately and linked with respective payment schedules; and
- Support the resolution of conflicts.

9.7 Joint Commercialization Committee. At least one (1) year prior to the date on which the first Regulatory Approval of a Tokai Product is expected, the Parties will form a joint commercialization team (the "**JCC**"), which shall be responsible for:

- Facilitating the transfer of information and coordination of processes related to the Commercialization of the Tokai Product and QIAGEN IVD;
- Reviewing each Commercialization Plan prior to submission to the JSC for approval;
- Coordinating planned sales and marketing activities, including launch strategies for the Markets, sales force activities, marketing strategies, alignment of package inserts, instructions for use, data sheets, marketing material, publications, training activities, reimbursement strategies, sharing of market research information and use of advisory boards/key opinion leaders; and
- Forecasting and measuring sales and distribution data to ensure adequate supply of the QIAGEN IVD in each Market.

The JCC shall be constituted and shall operate as the JSC determines. Each Party shall bear its own expenses for participation on the JCC, provided that the Parties shall use commercially reasonable efforts to hold in-person meetings in Manchester, England.

10. Term and Termination

10.1 Term. This Agreement shall come into force on the Effective Date and shall continue until the expiration or termination of any and all Projects that have been executed within the Initiation Period, or until this Agreement terminated in accordance with this Article 10 ("Term").

10.2 Termination for Cause

10.2.1 Material Breach

(a) This Agreement

Either Party may terminate this Agreement immediately upon sixty (60) days' prior written notice if the other party commits a material breach of the Agreement and fails to cure such breach within the notice period. For clarity, a breach that is specific to a Project shall not serve to terminate this Agreement, but shall be addressed as set forth below. Any termination of this Agreement shall automatically terminate any Project Schedules, Commercialization Plans, or related agreements that may be in effect, unless the Parties agree otherwise in writing.

(b) A Project

Either Party may terminate a Project (Schedule or Commercialization Plan, as the case may be) immediately upon sixty (60) days' prior written notice if the other party commits a material breach of the Schedule and fails to cure such breach within the notice period.

10.2.2 Insolvency or Bankruptcy. Either Party may terminate this Agreement and any Schedules immediately by written notice to the other Party, if the other Party becomes insolvent, makes or has made an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against it (except for involuntary bankruptcies which are dismissed within ninety (90) days) or has a receiver or trustee appointed for substantially all of its property.

10.3 Termination without Cause. Tokai may terminate this Agreement or a Schedule for any Project, for any reason or no reason, at any time upon one hundred eighty (180) days' prior written notice to QIAGEN.

10.4 Effects of Termination. In the event of a termination for cause under Section 10.2 or without cause under Section 10.3, with regard to the terminated Project(s):

(i) the Parties shall promptly meet to prepare a close-out Schedule,

(ii) Tokai shall make a final payment to QIAGEN for: (A) a pro rata portion of any future milestone payments where work was properly performed toward the agreed milestone(s) prior to the date of the termination notice; (B) any project-specific inventory of the QIAGEN IVD maintained in accordance with this Agreement; (C) any pass-through costs that were already paid, or ordered and unable to be cancelled, by QIAGEN pursuant to the Schedule or as otherwise authorized by Tokai;

(iii) upon settlement of all financial obligations of Tokai to QIAGEN, Tokai shall have the right to issue a last order within 14 calendar days as of the effective date of termination and QIAGEN shall transfer to Tokai, within the normal lead time for the quantity ordered after receipt of such last order from Tokai, the quantities of QIAGEN IVDs as ordered by Tokai to enable Tokai to complete the respective Clinical Trial(s), whereas Tokai shall pay for such QIAGEN IVDs the price

equalling the market price QIAGEN offers to its third party customers for such types of IVDs;

(iv) all licenses to Background Intellectual Property granted by either Party under this Agreement shall terminate (for the terminated Project, or this Agreement, if terminated in its entirety) upon the effective date of such termination; and

(v) finally, **only in the event of a termination by Tokai for material breach of this Agreement by QIAGEN under Section 10.2 (and specifically not where Tokai terminates this Agreement without cause) or for the hankruptcy or insolvency of QIAGEN under Section 10.2**, all licenses to Data and Foreground Intellectual Property granted by either Party under Sections 7.2 and 7.3 shall survive any expiration or termination of this Agreement.

10.5 Wind-down Costs

In the event of a termination for cause by QIAGEN under Section 10.2 or termination without cause by Tokai under Section 10.3, with regard to the terminated Project(s), Tokai shall reimburse QIAGEN's costs in winding down the Project, which shall be calculated as follows: An amount equal to the number of QIAGEN personnel who were actively engaged in performing Activities in support of the Development Project at the time of termination, multiplied by the percentage of their time allocated to the Development Project at that time, multiplied by a daily FTE rate of US$1,634 for the period of Business Days from the date of notice of termination until the date the QIAGEN personnel are reallocated to other activities or projects, not to exceed ninety (90) days.

10.6 Return of Materials and Confidential Information. At the earlier of completion or termination of a particular Project (or this Agreement as a whole), and except as otherwise permitted herein, each Party shall destroy, or return at the other Party's expense and election, Materials and Confidential Information of the other Party. A Party may retain one copy of Confidential Information of the other Party for the purpose of evidence. The return or destruction of Materials and Confidential Information will not affect the receiving Party's obligation to observe the confidentiality and non-use restrictions set out in this Agreement. The provisions of this Section 10.5 shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the receiving Party according to provisions of mandatory law.

10.7 Survival. Termination or expiration of this Agreement will not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation arising hereunder. Sections 3 [Materials and Records], 5 [Payment], 6 [Confidentiality], 7.2 [Assignment and License Back of Data], 7.3.2 [QIAGEN Foreground Intellectual Property], 7.3.3 [Joint Foreground Intellectual Property], 10.4 [Effects of Termination], 10.5 [Wind-down Costs], 10.6 [Return of Materials and Confidential Information], 10.7 [Survival], 11.4.3, 11.5 [Disclaimers] 12

[Indemnification, Liability and Insurance], and 13 [Miscellaneous], shall survive any termination or expiration of this Agreement. In addition, any other provisions which by their nature are understood to survive the termination or expiration of this Agreement shall so survive.

11. Warranties and Disclaimers

11.1 General Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date that: (i) it is a corporation duly organized, validly existing, and in good standing under applicable laws, rules and regulations, (ii) it has obtained all necessary consents, approvals and authorizations of all governmental authorities (both inside and outside the Markets) and other persons required to be obtained by it in connection with this Agreement, (iii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part, and (iv) it has, to its knowledge, the right to grant the applicable rights and licenses provided for under this Agreement.

11.2 No Inconsistent Agreements. Each Party hereby represents, warrants and covenants to the other Party that during the Term of a Project it will not grant or convey to any third party any right, license or interest in any Intellectual Property that is inconsistent with the rights and licenses expressly granted to the other Party under this Agreement with respect to the relevant Project.

11.3 No Debarment Nor Prohibited Payments. Each Party hereby certifies that it will not employ or otherwise use and has not employed or used in any capacity the services of any person (i) debarred by, or (ii) to the best of the respective Party's knowledge, currently subject to a debarment procedure by US Food and Drug Administration (FDA) under Title 21 United States Code Section 335a or any other competent authority in performing any activities under this Agreement. Each Party further represents and warrants that in connection with the subject matter of this Agreement: (i) none of its employees, agents, officers or directors is a Foreign Official as defined in the U.S. Foreign Corrupt Practices Act, (ii) it will not make, accept or request any payment, either directly or indirectly, of money or other assets to any third party where such payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010, (iii) regardless of legality, it shall neither make, accept nor request any such payment for the purpose of improperly influencing the decisions or actions of any third party, and (iv) it shall report any suspected or actual violation of this Section 11.3 to the other Party upon becoming aware of the same.

11.4 Compliance.

11.4.1 Each Party shall perform all work performed as part of the contractual relationship with the other Party in a manner consistent with all applicable laws and regulations, including, but not limited to, all applicable anti-bribery and antitrust laws. To the extent related to this Agreement, each Party represents and warrants that it has not made or provided, and will not make or provide, any payment or benefit, directly or indirectly, to government officials, customers, business partners, healthcare professionals or any other person in order to

secure an improper benefit or unfair business advantage, affect private or official decision-making, affect prescription behaviour, or induce someone to breach professional duties or standards.

11.4.2 Each Party will immediately report to the other Party in writing any suspected or detected violation of the above principles in connection with the other Party's business and, in such cases, will cooperate fully with the other Party in reviewing the matter. In the event that a Party believes, in good faith, that the other Party has violated any of the above principles; then such Party shall have the unilateral right to terminate the contractual relationship with the other Party with immediate effect.

11.4.3 During the Term and for the one (1) year period following the termination or expiration of this Agreement, each Party through a mutually agreeable, independent third-party auditor, upon reasonable advance notice to and at the auditing Party's sole expense, shall have the right during normal business hours to examine and review such books, records, and other documents and materials, except individual salary information, for the sole purpose of verifying whether the other Party has complied with the compliance obligations stated in this Section 11.4.

11.5 Disclaimers. THE REPRESENTATIONS AND WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ANY AND ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, OR STATUTORY, AND EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES OR REPRESENTATIONS, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS.

12. Indemnification, Liability and Insurance

12.1 Indemnification by QIAGEN. QIAGEN shall defend, indemnify and hold harmless each of Tokai, its Affiliates and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "**Tokai Indemnitee**") from and against any and all third party claims, suits, actions, demands or judgments (collectively, "**Claims**") to the extent that such Claims arise, directly or indirectly out of or in connection with this Agreement, and any and all resultant liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees) ("**Liabilities**") to the extent that such Claims and Liabilities arise out of, or in connection with: (i) a QIAGEN Indemnitee's negligence or willful misconduct, (ii) a QIAGEN Indemnitee's violation of applicable law, rule or regulation, (iii) the breach by QIAGEN of any of its representations, warranties and/or covenants under Article 11, (iv) personal injury or death caused by QIAGEN's use, storage or handling of the Materials in violation of this Agreement, (v) personal injury or death caused by the use or administration of a QIAGEN IVD hereunder and (vi) the infringement of third party Intellectual Property as a result of the Commercialization of any QIAGEN IVD (other than third party Intellectual Property covering biomarkers); provided, however, that QIAGEN's obligations under this Section 12.1 shall be excused to the extent that such Liabilities arise

out of a Claim to which a QIAGEN Indemnitee is entitled to indemnification under Section 12.2.

12.2 Indemnification by Tokai Pharmaceuticals. Tokai shall defend, indemnify and hold harmless each of QIAGEN, its Affiliates, and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "**QIAGEN Indemnitee**") from and against any and all Claims to the extent that such Claims arise, directly or indirectly out of or in connection with this Agreement, and any and all resultant Liabilities, to the extent that such Claims and Liabilities arise out of, or in connection with: (i) a Tokai Indemnitee's negligence or willful misconduct, (ii) a Tokai Indemnitee's violation of applicable law, rule or regulation, (iii) the breach by Tokai of any of its representations, warranties and or covenants under Article 11, and (iv) personal injury or death caused by the use or administration of a Tokai Product, (v) medical malpractice occurring in connection with the Clinical Trials of a Tokai Product, and (vi) the infringement of third party Intellectual Property as a result of the Commercialization of any Tokai Product alone, or third party Intellectual Property covering biomarkers as a result of the Commercialization of the QIAGEN IVD; provided, however, that Tokai's obligations under this Section 12.2 shall be excused to the extent that such Liabilities arise out of a Claim to which a Tokai Indemnitee is entitled to indemnification under Section 12.1.

12.3 Procedure. A Party seeking indemnification under Section 12.1 or Section 12.2 (an "**Indemnitee**"), shall notify the other Party (the "**Indemnitor**") upon becoming aware of any Claim that may be subject to indemnification under this Article 12. Failure to provide such notice shall not constitute a waiver or release of the Indemnitee's rights to indemnification, except to the extent that such delay or failure materially prejudices the Indemnitor. The Indemnitor shall have the right, (but not the obligation) to control the defense and disposition (including, without limitation, settlement, litigation or appeal) of any such claim. The Indemnitee shall cooperate reasonably with the Indemnitor and its legal representatives in connection with the investigation and defense of any Claim and/or Liability covered by this Article 12. Indemnitor shall not settle any indemnified claim hereunder in a manner that establishes liability on the part of any Indemnitee, without the express written consent of such Indemnitee. The Indemnitor shall have no obligation to indemnify any Indemnitee with respect to any claim settled without the prior written consent of the Indemnitor.

12.4 Limitation of Damages. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER SIMILAR DAMAGES (INCLUDING ANY CLAIMS FOR LOST PROFITS OR REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT; PROVIDED, HOWEVER, THAT THIS SHALL NOT LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO ANY THIRD PARTY CLAIMS UNDER THIS ARTICLE 12.

12.5 Insurance. During the Term and until completion of the last Project conducted under this Agreement, each Party shall maintain a comprehensive commercial general liability

insurance program as is customary for diagnostic or pharmaceutical companies (as the case may be), including product liability insurance with coverage limits not less than US$5,000,000 for each occurrence and in the aggregate. Tokai also will maintain clinical trials liability coverage with limits not less than US$5,000,000 for each occurrence and in the aggregate, and will name QIAGEN as an additional insured. All insurers utilized to confirm coverage within Section 12.5 shall be rated A, Class VII or better by A.M. Best Company in a form satisfactory to both Parties. Upon request, each Party will provide to the other Party respective insurance certificates. For clarification, the insurance coverage required herein may be provided through any reasonable structure of local and global insurance programs.

13. Miscellaneous

13.1 Force Majeure. Neither Party shall be liable for failure or delay in performance under this Agreement due to causes such as an act of God, strike, lockout or other labor dispute, civil commotion, sabotage, fire, flood, explosion, acts of any government, any other similar causes not within the reasonable control of the Party affected (a "**Force Majeure Event**"). In the event either Party is unable to perform any of its obligations hereunder due to a Force Majeure Event, such Party shall promptly notify the other Party. Performance hereunder shall be promptly resumed after the applicable Force Majeure Event has been remedied.

13.2 Notice. All notices under this Agreement shall be in writing and shall be sent by registered or certified mail, postage prepaid, or by overnight courier service, to the attention of the Legal Department in the case of QIAGEN, and to the attention of the Chief Operating Officer in the case of Tokai, in each case at the addresses of the respective Parties set forth in the first paragraph of this Agreement.

13.3 Governing Law and Disputes.

13.3.1 Law. The formation, existence, performance, validity and all aspects of this Agreement shall be governed by and construed in all respects in accordance with the laws of the State of the New York, USA without regard to its rules on conflicts of laws.

13.3.2 Dispute Resolution. Prior to arbitration, the parties shall seek informal resolution of disputes. The process shall be initiated with written notice of one party to the other, describing the dispute with reasonable particularity followed with a written response within ten (10) calendar days of receipt of notice. Each party shall promptly designate an executive with requisite authority to resolve the dispute. The informal procedure shall commence within 10 calendar days of the date of response. If the dispute is not resolved within 10 business days of the date of commencement of the procedure, either party may proceed to binding arbitration without recourse to the ordinary courts of law according to the American Arbitration Association (the "**Rules**"). The seat of arbitration shall be New York, New York USA. The number of arbitrators shall be three (3). The arbitrators shall be appointed in accordance with the Rules. The language to be used in the arbitration proceedings shall be English. If any arbitration is brought for the enforcement of this Agreement, or because of any alleged dispute, breach, default or misrepresentation in connection with any of the provisions of this Agreement, the successful or prevailing party

shall be entitled to recover reasonable attorneys' fees and other costs incurred therein, in addition to any other relief to which it or they may be entitled. Notwithstanding anything to the contrary in this Section, if either Party in its sole judgment believes that any such breach of this Agreement could cause it irreparable harm, such Party (i) will be entitled to seek equitable relief in order to avoid such irreparable harm, and (ii) will not be required to follow the procedures set forth in this Section 13.3.2 with respect to seeking such relief.

13.4 Entire Agreement. This Agreement sets out the entire agreement and understanding between the Parties regarding the subject matter of this Agreement and supersedes all prior discussions, arrangements and agreements, whether oral or in writing or which may be inferred from the conduct of the Parties, including without limitation the Initiation Agreement dated October 29, 2014 between the Parties.

13.5 Validitv/Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision which shall remain in full force and effect. The Parties undertake to replace such invalid or unenforceable provision by a valid and enforceable provision which accomplishes as far as possible the purpose and the intent of the invalid or unenforceable provision.

13.6 Assignment. This Agreement may be freely assigned by either Party to any of its' Affiliates. This Agreement shall not be assigned by either Party to a third party, except (i) with the other Party's prior written approval, which approval shall not be withheld unreasonably, or (ii) by reason of any merger, acquisition, reorganization, or consolidation to any successor in interest of the business to which this Agreement relates. Other than as provided by this Section 12.6, any attempt by either Party to effect an assignment without the consent of the other Party will be void and without effect.

13.7 Waiver; Modification of Agreement. No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances. Any amendments to this Agreement shall be made in writing; the same applies for any waiver or amendment of this written form clause.

13.8 Relationship of the Parties. The relationship of the Parties is that of independent contractors.

13.9 Independent Development. Nothing in this Agreement will be construed as restricting either Party's ability to acquire, license, develop, manufacture or distribute for itself, or have others acquire, license, develop, manufacture or distribute for such Party, similar technology performing the same or similar functions as the technology contemplated by this Agreement, or to market and distribute such similar technology in addition to, or in lieu of, the technology contemplated by this Agreement, provided, however, that such activities of such Party comply with all provisions herein.

13.10 Execution In Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.

13.11 No Third Party Beneficiaries. No person other than Tokai or QIAGEN (and their respective affiliates and assignees) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[*signature page follows*]

IN WITNESS WHEREOF, QIAGEN and Tokai, intending to be legally bound, have executed this Agreement at the dates indicated below by their respective duly authorized representatives.

Tokai Pharmaceuticals, Inc.	**QIAGEN Manchester Limited**
By: /s/ John McBride	By: /s/ Douglas Liu
Name: John McBride	Name: Douglas Liu
Title: CEO	Title: Senior VP Global Operations
Date: January 12, 2015	Date:

Companion Diagnostics

PROJECT WORK PLAN

Between TOKAI PHARMACEUTICALS, INC.

One Broadway, 14th Floor

Cambridge, MA 02142

hereinafter " **TOKAI** "

and QIAGEN Manchester Limited

Skelton House, Lloyd Street North

Manchester, M15 6SH,

England

hereinafter **"QIAGEN"**

This Project Schedule 1 (this "**Schedule**") is dated March 13, 2015 (the "Schedule Effective Date"), and is incorporated into the Master Collaboration Agreement dated January 12, 2015 by and between TOKAI and QIAGEN (for the purposes of this Schedule, the "**MCA**"), and describes a Project to be conducted under the terms of the MCA, including, without limitation, a list of Activities, the TOKAI Compound ("Galeterone") and the QIAGEN IVD development timelines, Deliverables, Markets and other terms applicable to a Development Project. The Project was initiated under an Initiation Agreement dated October 29, 2014 ("Initiation Agreement"), which shall be superseded by this Schedule. All capitalized terms used and not expressly defined in this Schedule will have the meanings given to them in the MCA.

This Schedule is divided into the following seven (7) sections:

1. Background
2. Activities
3. Deliverables
4. Timeline
5. Key Assumptions and Requirements
6. Compensation
7. Additional Terms

1. BACKGROUND

The party's MCA establishes a legal framework for their collaborations in the field of development and commercialization of *in vitro* diagnostics and/or companion diagnostics for TOKAI Compounds.

TOKAI wishes to have QIAGEN develop and commercialize a companion diagnostic to identify patients carrying Androgen Receptor Exon 9 Xq12 (AR-V7) splice variant in Castration Resistant Prostate Cancer (CRPC) for treatment with the TOKAI Compound (for purposes of this Schedule, the "**QIAGEN IVD**").

The scope of this Project is for development of the QIAGEN IVD necessary for co-development and clinical validation together with the TOKAI Compound, designated for approval and Commercialization in the US, EU, Canada and Australia. While Japan is not included within the scope of this Project due to an evolving regulatory landscape in this country, at TOKAI's request the Parties shall negotiate diligently and in good faith the terms under which the scope of this Project would be expanded to include potential Commercialization of the QIAGEN IVD together with the TOKAI Compound in Japan.

2. Activities

TOKAI responsibilities

In relation to the development of the QIAGEN IVD, TOKAI shall be responsible for the following:

- TOKAI shall solely be responsible for the clinical testing of Galeterone and proper use of the QIAGEN IVD by the central laboratories in connection with such clinical testing.
- TOKAI shall provide QIAGEN clinical data, including sample and patient demographic data, regarding the use of the QIAGEN IVD as well as patient outcome data to the extent such data is available and necessary, as reasonably determined by QIAGEN, for QIAGEN regulatory filings for the QIAGEN IVD and for planning of further QIAGEN IVD development activities at QIAGEN in the performance of the Development Project. TOKAI will be responsible for contracting out the clinical sample testing to and providing oversight of a suitable GCP-compliant central laboratory clinical testing site ("**Laboratory Site**") and QIAGEN will support the selection, training and qualification of this vendor. For clarification, notwithstanding any provision in the MCA, the parties expressly agree that Tokai shall be responsible for the Milestone Payments set forth below and costs set forth in Attachment 3 which relate to applications for Regulatory Approval of the QIAGEN IVD.

- TOKAI will make reasonable efforts to provide any clinical samples necessary for QIAGEN IVD development and verification/validation. QIAGEN will work with its approved procurement service providers to source appropriate samples. Sample costs will be passed through to TOKAI.

QIAGEN responsibilities

Subject to and without limiting the terms and conditions of the Agreement, QIAGEN shall be responsible for the development of the QIAGEN IVD as follows.

- QIAGEN shall lead the development and PMA submission with FDA's Center for Devices and Radiological Health (CDRH) for the QIAGEN IVD. QIAGEN shall inform and coordinate with TOKAI on all CDRH-related matters and support TOKAI in discussions with FDA's Center for Drug Evaluation and Research (CDER) for Galeterone.
- Subject to the involvement of TOKAI as described above, QIAGEN shall be responsible for the design, development and regulatory approval of the QIAGEN IVD in accordance with this Schedule, including the development of suitable and necessary protocols for the QIAGEN IVD.
- QIAGEN shall be responsible for manufacturing, supply and delivery of the QIAGEN IVD, including all components for the QIAGEN IVD, subject to any intellectual property considerations set forth in Section 7 below.
- QIAGEN shall be responsible for the preparation of the PMA documentation and site readiness required for submission of the PMA for the QIAGEN IVD.
- QIAGEN shall be responsible for the intended use and applicable package insert, and the pricing, reimbursement and market access of the QIAGEN Kit, subject to the applicable terms of the MCA.

3. DELIVERABLES

Stage 1 Feasibility

The first stage of the AR-V7 project covers technology transfer and feasibility testing required to establish a prototype assay for CRPC samples; i.e. design and testing or primer and probe sets to detect AR-V7. Stage 1 of development is covered under the initiation agreement between QIAGEN and TOKAI which was executed on October 29, 2014.

Stage 2 Clinical Trial Assay labelled Investigational Use Only ("IUO")

The second stage of the project will involve generation of data and documentation necessary to apply to CDRH for a potentially required Investigational Device Exempt ("IDE") assay for prospective patient selection for TOKAI's clinical trial. An IUO labelled Clinical Trial Assay ("CTA") (with or without and IDE) is required in H1 2015. The preparation of the IDE application (US) will be started in advance of this requirement. In addition to the provision of an CTA, QIAGEN will also facilitate the preparedness of TOKAI's chosen testing labs by carrying out the following key tasks:

- Establishment and Training of Clinical Testing Labs Site initiation visits

Stage 3 Pre-Analytical Comparisons between the Adnagen and PAXgene Blood RNA extraction Device

The third stage of development will overlap with stage 2 and will cover the feasibility activities required to identify if PAXgene Blood RNA System may be substituted for the current methodology of Circulation Tumor Cells ("CTC") collection and isolation.

Stage 4 CDx Development and Validation

The fourth stage of development will cover all of the activities needed for the development and approval of a CDx assay in the USA, Canada, EU and Australia. This stage will include all Design Verification and Clinical Validation Studies

Stage 5 CDx Approval and Product Implementation

Product Implementation into the US will follow approval of the PMA approval and agreement on the device labelling with CDRH

For the EU development data used to support the US PMA application will be used to generate a technical file in compliance with the Essential Requirements Checklist. The MHRA shall be notified of the new product under the self-certification scheme. Appropriate labeling and translations will be prepared as necessary for EU countries accepting the CE Mark.

For Canada it is also assumed that data used to support the US PMA application will be used to complete the necessary requirements as established by Health Canada for successful

submission and approval. Product Implementation will follow and establish the product in the Canadian market with appropriate labelling and translations as necessary.

For Australia it is also assumed that data used to support the US PMA application will be used to complete the necessary requirements as established by the Australian Therapeutic Goods Administration (TGA) for successful submission and approval. Product Implementation will follow.

Contractual Milestone Description

The Project Agreement will be delivered on a completed milestone based model. The following descriptions provide a high level overview of the work package and the deliverable for acceptance and completion.

Milestone 1: Assessment of Technology for Transfer

This milestone will involve site-visit preparation, evaluation and assessment of the existing work undertaken by Dr. Jun Luo and associates at Johns Hopkins University ("JHU") for information exchange.

Evidence of Milestone Achievement: Short report on findings and recommendations for technology transfer.

Note: This Milestone 1 was completed under the Initiation Agreement.

Milestone 2: Design Control Planning (CDx)

This milestone represents the initial activities associated with the Companion Diagnostic Development process for the AR-V7 splice variant [inclusive of AR-FL] assay.

For this milestone, the following design control documents will be signed off and provided as evidence of Milestone achievement:

- Customer Requirements

- Includes all important aspects of the product.
- Inputs to this document include, but are not limited to, stakeholder needs and requirements, market analysis and market needs and technical analysis.
- The customer requirements which the project team and stakeholders agree, shall be documented in the Customer Requirements Document.

- Intended Use Statement
  - Describes the how and by whom the device is to be used, e.g. target condition, target population and purpose.
  - Created by a cross functional team consisting at a minimum global product management, Regulatory affairs, Medical affairs and Product development
  - The statement may be changed during external discussions with regulatory authorities but this change will be conducted under document or Design Change Control.

- Product description
  - Description of the product detailing product configuration, main functionalities, product users and use conditions.
  - Description of market segments in which the product will be marketed.
  - Created by a cross functional team consisting of global Product management, Regulatory affairs, Medical affairs and Product development.

- These activities will require
  - Establishment of a Design History File (DHF)
  - A cross functional team comprising global product management, regulatory affairs, medical affairs, product development and project management

Evidence of Milestone Achievement: Design control documents as specified above.

NOTE: This Milestone 2 was completed under the Initiation Agreement.

Milestone 3: Feasibility; Conversion of AR-V7 [inclusive of AR-FL] splice variant assay to a QIAGEN format & formulation for use on the Rotor-Gene Q MDx

Where possible QIAGEN will use its own suppliers and technologies for the development of the AR-V7\AR-FL splice variant assay.

- Assessment of suitability of existing assay primers designs
- Testing of primers using QIAGEN reaction mix formulation
- Design, testing and selection of probes for real time PCR detection.
- Design and testing of additional novel primer & probe designs required to support assay formats.
- Multiplex testing of selected Primer\Probe Combinations.
- AR-V7 assays based on *TOKAI* requirements for the RGQ MDx platform.
- Sample Processing feasibility[1]

Evidence of Milestone Achievement; Feasibility testing summary report

NOTE: This Milestone 3 was started under the Initiation Agreement and is estimated to be completed by January 30, 2014.

Milestone 4: Delivery of the CE Technical File for Adna Test Prostate Cancer Select and AdnaTest Prostate cancer detect product demonstrating compliance of the medical devices to the European Community - Essential Requirements Checklist (Annex I, 93/42/EEC as amended by Directive 2007/47/EC)

Evidence of Milestone Achievement; CE Technical File and Signed Declaration of Conformity for Adna Test Prostate Cancer Select and AdnaTest Prostate Cancer Detect products.

Milestone 5: Clinical Trial Assay Build Completion (Including CTA QC and Control Specifications)

This milestone entails activities required to complete development of the Clinical Trial Assay for use in Phase III Clinical Trial. The assay is planned to be presented to CDRH under an Investigational Device Exemption application. The following work packages will be competed;

[1] Sample processing feasibility will be dependent on the availability of samples.

- Preparation for batch manufacture of CTA assay (including ordering of raw materials)
- Robustness study using research grade primers but GMP grade Taq, dNTPs, PCR Buffer and $MgCl_2$.
- Clinical Trial Assay batch manufacture for specification setting and performance studies. (x3 Batches)
- Positive control specifications complete
- QC Release Methods developed
- Start small scale stability study
- Performance Studies to support planned IDE application

Evidence of Milestone Achievement: Summary Report presenting activities\data associated with clinical trial assay build as specified above.

Milestone 6: Lab Set-up for Clinical Trial Testing (6a,6b, & 6c US, EU & Asia)

QIAGEN will provide subject matter expert support for the establishment of AR-V7 testing at Clinical Testing Sites using the QIAGEN IVD; this will include the following activities:

- On-site training of test lab operators.
- Provision of training records for site operators.
- Support for local validation requirements of assay prior to sample testing (CLIA validation).
- Completion of site initiation visits to all test sites.
- Data collection and data transfer – identification of data required for the PMA from the clinical trial. QIAGEN will stipulate what specific information needs to be collected relating to samples and analysis that will be required to support a pre-market application of the diagnostic

Evidence of Milestone Achievement: Clinical Site Initiation Reports

Milestone 7: Method Comparison between the Adnagen and PAXgene pre-analytical methodologies in conjunction with AR – FL & V7 assays

Evidence of Milestone Achievement: Method Comparison Report

Decision Point: Determination of pre-analytical methodology based on method comparison data

Milestone 8: Completion of Design Inputs; Design Input Lock and Design & Development Plan (CDx)

The aim of this milestone is to have all of the information and design inputs that the product development and software development teams need to progress the kit through the development process.

For this milestone, the following design control documents will be signed off:

- User Needs
- Design and Development Plan
- Product Requirements and Specifications
- Traceability Matrix
- Risk Management Plan
- Verification Master Plan
- Validation Master Plan
- Software requirements and specifications

Some of these documents may be updated as development proceeds, but the first versions are signed off at this stage. Analysis parameters will be developed and this information will be passed to the software team to allow their development activities to proceed.

Evidence of Milestone Achievement: Design Control Documents as specified above.

Milestone 9: Completion of Assay Optimization and Specification Setting for CDx

Robustness testing will be completed for the CDx assay development. Robustness testing is carried out in order to ensure that the QIAGEN IVD assay can be reliably manufactured. Following robustness positive control and QC specifications will be established for the CDx assay.

- Positive control specifications complete (CDx)
- QC release methods developed (CDx)

On completion of the assay optimization a comparative analysis will be carried out between the CTA and CDx Assays. While the primer & probes sequences and run parameters of the CTA and CDx assays will be identical, minor modifications to the manufacturing specifications may be required at this stage.

Evidence of Milestone Achievement: Design Output Reports for Assay Robustness and CDx positive control and QC release methodology. Comparative Analysis report: CTA verses CDx.

Milestone 10: Prototype Batch Manufacturing (CDx) – needed for assay performance studies
For this milestone, Prototype batches will be manufactured and QC released. Manufacturing operatives will be fully trained in the procedures for their manufacture. These prototype batches will be used to characterize the AR-V7 assay and generate relevant acceptance criteria for the subsequent verification and validation studies.

Evidence of Milestone Achievement: Final QC release documentation for Prototype Batches

Milestone 11: PMA RGQ Module Submission
QIAGEN will initiate a Modular PMA submission starting with the platform and software module.

Evidence of Milestone Achievement: Acknowledgement of Receipt of Module by Document Control Centre at CDRH

Milestone 12: CDx Assay Performance Studies Complete
For this milestone, the Prototype batches will be used to characterize the assay and to generate acceptance criteria for the verification and validation studies:

- Performance studies
- In-Use Performance (User Guard-band studies)

Evidence of Milestone Achievement: CDx Performance Study Reports

Milestone 13: Assay Software Available

Automated calling software for AR-V7 expression analysis will be developed and verified.

Evidence of Milestone Achievement; AR-V7 expression analysis software release documentation.

Milestone 14: Completion of Verification Batches (Pilot Batches)

For this milestone, the Pilot (Verification) AR-V7 batches will be manufactured and QC released and manufacturing operatives will be fully trained in their manufacture. These pilot batches will be used for design verification (Analytical Validation).

Evidence of Milestone Achievement: Final QC release documentation for Pilot Batches

Milestone 15: System Design Lock;

This milestone represents the stage of the project at which all development activities have been completed and verification of the AR-V7 assay can proceed. The following design control documents will be required for this milestone;

- Risk management Documentation
- Product requirements and specifications (revised based on development outputs)
- Verification Master Plan (design verification plan)
- Verification protocols

Evidence of Milestone Achievement: Design Control Documents as specified above.

Milestone 16: PMA Facilities Module Submission;

This module will contain the following information;

- Executive summary
- Design Controls
- Production Controls

- Quality System Procedures
- Manufacturing Processes
- Establishment Description

Evidence of Milestone Achievement: Acknowledgement of Receipt of Module by Document Control Centre at CDRH

Milestone 17: Design Output and Design Verification Lock (Completion of Verification)

For this milestone all verification studies will have been completed, data analyzed and reports generated. The final list of verification reports will be dependent on regulatory interactions with CDRH during the course of assay development

Evidence of Milestone Achievement: Verification Summary Report

Milestone 18: PMA Analytical Module Submission

- Executive summary
- Summary Device Description and Principles of Operation
- Declaration of Conformance to Standards
- Non-clinical Laboratory Studies (Final list of studies will be subject to feedback from CDRH pre-submission)

Evidence of Milestone Achievement: Acknowledgement of Receipt of Module by Document Control Centre at CDRH

Milestone 19: PMA Clinical Validation Module Submission

- Bridging Study Report
- Summary of Safety and Effectiveness Document
- Clinical Reproducibility
- Clinical Data (including Protocols, Results and Analyses)
- Financial Disclosure Information

- Proposed Labelling
- References for the Final Module
- Bibliography

Evidence of Milestone Achievement: Acknowledgement of Receipt of Module by Document Control Centre at CDRH

Milestone 20: PMA Approval

This milestone will be triggered upon successful approval of the companion diagnostic

Evidence of Milestone Achievement; Receipt of successful notification letter by CDRH

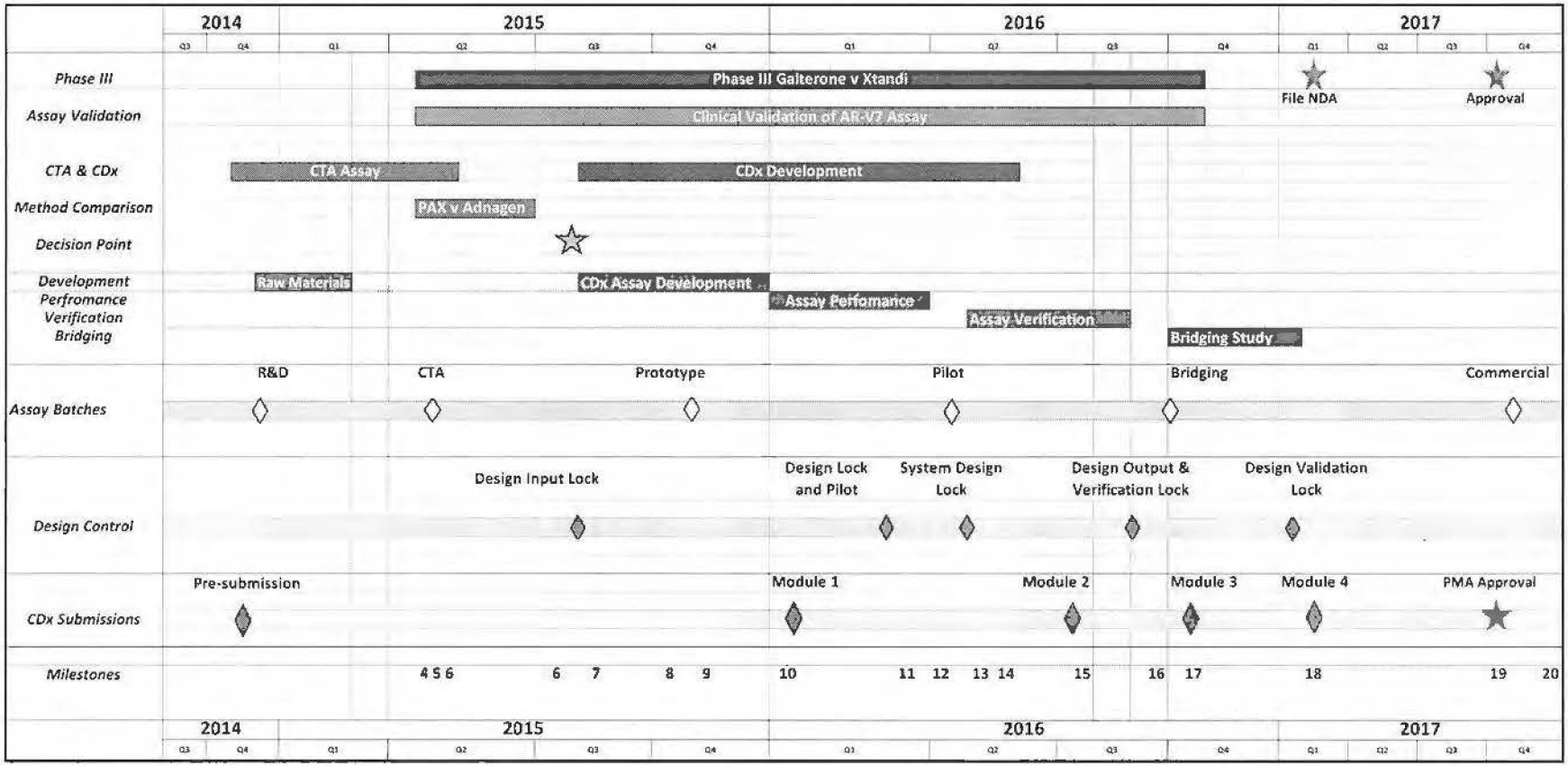
Milestone 21: Product Implementation

Following CDRH review and agreement QIAGEN will finalize the product handbook. The final labelling of the product will be approved. Commercial Batches of product will be manufactured and packed ready for sale. The products will be uploaded onto the QIAGEN Global Supply Chain Management system with SAP integration and full distribution to global supply centers.
Evidence of Milestone Achievement; Provision of Final Product Labelling (Handbook) and Final QC release documentation for Commercial Batch of product.

4. **TIMELINE**

TOKAI - Updated Gantt Chart Based on start date of 28th October 2014

Chart to be redacted in its entirety.



5. KEY ASSUMPTIONS AND REQUIREMENTS

Tokia and QIAGEN each recognize that this Schedule has been prepared on the basis of a number of Key Assumptions as described in this Section 5. During the course of the Development Project, a change in an assumption upon which this Schedule is based may require a change to modify the scope of the project, and the Parties agree to address such changes in good faith pursuant to the process provided under Section 2.3 of the MCA.

Regulatory

An IDE may be required by FDA. This shall be dependent on FDA's response to the Risk Determination Document.

Study Estimates

Tokia estimates screening approximately 1500 patients to enroll a total of 150 AR-V7 positive patients into the clinical trial. Patient screening and selection is planned to begin as soon as possible in H1 2015

Clinical Samples

TOKAI will work with Johns Hopkins University and other parties to supply QIAGEN with clinical samples to support the development and verification of the AR-V7 assay

- QIAGEN will make all best efforts to procure representative samples for development and analytical validation of the assay. However, the availability of samples containing specific splice variants cannot be guaranteed.
  (1) QIAGEN shall not be held responsible for any delays caused by insufficient supply or other issues with the third party sample providers.

  (2) Any such samples shall be considered "pass-through costs" and shall be paid in full by *TOKAI* upon invoice from QIAGEN.

- The development of any specialized sample material *e.g.* cell lines containing specific splice variants are not included in this project plan and costing. The development of specialized sample material would be considered as pass through costs to TOKAI. These pass through costs are outlined as estimated in Attachment 2.

- Samples from the AR-V7 trial need to be retained for the purposes of any bridging studies.

Territory

The Territory for this Development Project shall include the Markets listed on Attachment 1 to this Schedule.

6. MILESTONE PAYMENTS

The following Milestones and Deliverables shall be completed by QIAGEN to the satisfaction of TQKAI in accordance with the terms of Section 2 of the MCA. Payment for completed Milestones will be made in accordance with Section 5 of the MCA and with the additional process as follows: (1) Tokai shall approve or dispute milestone completion within fifteen (15) business days of receiving QIAGEN's report; (2) Tokai agree to review milestone four within five (5) business days of receiving QIAGEN's report; (3) if Tokai fails to approve or dispute the milestone completion within such time period, the milestone completion shall be considered approved; (4) if Tokai disputes the milestone completion, the parties shall work in good faith to timely resolve the dispute.

Milestone	Description	Completion Date (Est)	Payment (USD)
1	Assessment of Technology for Transfer	complete	$25,000
2	Design Control Planning	complete	$311,032
3	Feasibility Testing for AR-V7	Jan-14	$153,800
Full CDx Milestones			
4	CE Technical File for Adna Test	Mar -15	$1,000,000
5	Clinical Trial Assay Build Complete (Controls and QC)	May-15	$394,243
6a	Lab set up for IUO Testing – US	May-15	$75,000
6b	Lab set up for IUO Testing – EU	tbc	$75,000
6c	Lab set up for IUO Testing – Australia	tbc	$75,000
7	Method Comparison between the Adnagen and PAXgene pre-analytical methodologies	Aug -15	$60,000
8	Design Input Lock & DDP	Sep-15	$240,933
9	Completion of Assay Optimization and Specification Setting for CDx	Oct-15	$130,026
10	Prototype Batch Manufacture	Nov-15	$196,938
11	PMA RGQ Module Submission	Jan-16	$231,501

12	CDx Performance Studies Complete	Mar-16	$500,000
13	Assay Software Available	Apr-16	$232,722
14	Completion of Verification Batches (Pilot Batches)	May-16	$200,000
15	System Design Lock	May-16	$204,046
16	PMA Facilities Module Submission	Jul-16	$204,046
17	Design Output and Verification Lock Completion of Assay Verification	Sep-16	$243,752
18	PMA Analytical Module Submission	Oct-16	$239,706
19	PMA Clinical Validation Module Submission	Feb-17	$244,855
20	PMA Approval	Q4 2017	$1,000,000
21	Product Implementation	Q4 2017	$56,602
Total			**$6,094,202**

[1] In the event the CTC Technology is not acquired by QIAGEN, then QIAGEN shall not be obligated to deliver Milestone 4 and Tokai shall not be obligated to make a Milestone Payment for Milestone 4.

7. ADDITIONAL TERMS

7.1 Project Term

The Project Term of this Project shall commence on the Schedule Effective Date and continue until all commercialization obligations expire under Section 8 of the MCA, unless sooner terminated by either Party under the terms of the MCA.

7.2 Technology and Intellectual Property Considerations

(a) Circulating Tumor Cells Technology Access Fee

(i) Acquisition of Technology

The Parties have identified a potentially useful technology for the isolation and detection of circulating tumor cells from patients, known as the *AdnaTest Prostate Cancer Select* and *AdnaTest Prostate Cancer Detect* (hereinafter referred to as the "CTC Technology"). As a result, QIAGEN has agreed to make an offer to acquire the CTC Technology from Adnagen on the express condition that TOKAI would pay QIAGEN a "Technology Access Fee" for the right to have QIAGEN utilize such technology in this Project. The Parties understand and agree that this Section 7.2(a) is contingent upon QIAGEN's successful acquisition of the CTC Technology.

(ii) Scope of Technology Access

In exchange for the Technology Access Fee described above and notwithstanding anything in Section 7 of the to the contrary, QIAGEN will grant, and hereby does grant, TOKAI the exclusive right to have QIAGEN utilize the CTC Technology in the field of companion diagnostics for the TOKAI Compound. For clarity, the CTC Technology shall be considered the "Background Intellectual Property" of QIAGEN under the MCA.

(iii) Technology Access Fee

The Technology Access Fee shall be US $1.25 Million. QIAGEN shall invoice Tokai for this amount promptly upon acquiring the CTC Technology from Adnagen. The invoice will include a representation that the purchase price is equal to or greater than $4.5M. TOKAI shall pay the invoice within ten (10) days of receipt. This fee is both non-refundable and non-cancelable

(b) JHU Sublicense

(i) **"JHU License"** shall mean that certain Exclusive License Agreement dated January 9, 2015 between The Johns Hopkins University ("JHU") and TOKAI, a copy of which is attached hereto as Attachment 4.

(ii) The Licensed Patents and Licensed Know-How (each as defined in the JHU License) shall be considered TOKAI's Background Intellectual Property.

(iii) QIAGEN specifically acknowledges and agrees that, in accepting the grant of certain of the licenses under the MCA, it shall be sublicensed under the Licensed Patents and Licensed Know-How and, as such, QIAGEN shall be subject to and shall assume certain terms and conditions of the JHU License (as such agreement may be amended from time to time and communicated to QIAGEN) as if those terms and conditions were imposed on QIAGEN itself. These terms and conditions include, without limitation, due diligence, reporting and recordkeeping, indemnification, maintenance of insurance non-use of JHU's name, and audit rights. In addition, QIAGEN may not sublicense the Licensed Patents and Licensed Know-How sublicensed to QIAGEN without TOKAI's and JHU's consent. QIAGEN shall also have no right to prosecute the Licensed Patents or to defend or enforce the Licensed Patents. In the event of any conflict or inconsistency between any applicable provision of this Agreement and the provisions of the JHU License, the provisions of the JHU License shall prevail. Without limiting the foregoing, QIAGEN shall be subject

to Sections 7, 8, 10.3 and 12.2 of the JHU License, which terms are incorporated by reference herein.

(iv) QIAGEN acknowledges and agrees that TOKAI may provide JHU an unredacted copy of the sections within the MCA and this Project Agreement which are strictly related to the sublicensing of third party intellectual property, and to disclose such information related to the conduct of the Project to the extent reasonably necessary for TOKAI to fulfil its reporting obligations to JHU under the JHU License. In the event TOKAI is required to disclose QIAGEN's Confidential Information to JHU in order to fulfil its obligations under the JHU License, TOKAI shall provide QIAGEN with advance notice of any such disclosures. TOKAI will reasonably consider any comments that QIAGEN may have on the scope of such disclosure.

(v) For so long as QIAGEN is commercializing a QIAGEN IVD, it shall provide TOKAI, within thirty (30) days following completion of each calendar quarter, a written report detailing, on a country by country basis, aggregate Net Revenues (as defined in the JHU License) of each QIAGEN IVD during the preceding calendar quarter in sufficient detail for TOKAI to calculate and remit royalties due to JHU under the JHU License. Such reports shall be considered the highly confidential information of QIAGEN and shall not be disclosed or used for any purpose other than calculating the royalty obligation under the JHU License. Without limiting the foregoing, such reports shall include Net Sales Revenues (as defined in the JHU License) and all deductions and adjustments that may be applicable to a calculation of Net Revenues. QIAGEN shall make itself reasonably available to answer any questions that TOKAI may have on the foregoing royalty reports in sufficient time for TOKAI to fulfill its reporting and payment obligations to JHU.

(vi) TOKAI shall be responsible for the timely payment of all royalty obligations to JHU under the JHU License. TOKAI shall defend, indemnify and hold harmless QIAGEN for any third party costs, claims, or liabilities directly resulting from TOKAI's failure to make royalty payments under the JHU License (except to the extent such failure is the result of QIAGEN failing to fulfil its reporting obligations to TOKAI under this Agreement).

(vii) TQKAI shall at all times comply with the JHU License to maintain such license in full force and effect during the term of this Agreement. TOKAI shall defend, indemnify and hold harmless QIAGEN for any third party costs, claims or

liabilities directly resulting from TOKAI's failure to comply with the JHU License (except to the extent such failure is the result of QIAGEN failing to fulfil its obligations to TOKAI under this Agreement).

IN WITNESS WHEREOF, QIAGEN and TOKAI, intending to be legally bound, have executed this Agreement at the dates indicated below by their respective duly authorized representatives.

TOKAI Pharmaceuticals, Inc.		**QIAGEN Manchester Limited**	
By:	_____	By:	/s/ Douglas Liu
Name: Title:		Name: Title:	Douglas Liu Senior VP Global Operations QIAGEN
Date:	_____	Date:	12 March 2015

Attachment 1

Territory

United States

European Union

Canada

Australia

Attachment 2

Name	Description	Payment (USD)
Sample Procurement	Procurement of CRPC samples for development and verification; may require customized project to be established with a procurement service provider to prospectively collect and ship samples	$250,000
Non GMP Raw materials	Non GMP oligos, Extraction Kits, PCR reagents	$50,000
Adnagen CTC Enrichment and RNA extraction	AlereTM AdnaTest (ProstateCancerSelect & Detect) Cost of 1 test is approximately $170. This includes Adnaselect and Adnatest. Approx. 1800 test required for clinical trial testing Approx. 1500 required for development verification and validation	$TBD
PAX gene tubes and extractions	PAXgene tubes may be used instead of the Adnagen technology. The cost of PAXgene will not exceed that of Adnagen costs above	$TBD
GMP Raw materials	GMP reagents for the completion of assay feasibility, development, verification and validation. A total of 7 batches of oligonucleotides will be required over the course of the project	$100,000
Long oligonucleotides	GMP long oligonucleotide will be used as positive controls if Adnagen technology is used for pre analytical step in commercial kits . A total of 7 batches of long oligonucleotides will be required over the course of the project.	$50,000
In vitro transcripts	In vitro transcripts will be used as positive control materials in the event that PAXgene blood collection tubes are used in the development of the commercial assay. A total of 7 batches of in vitro transcripts will be required over the course of the project	$100,000
Cell Line Control Materials	Procurement and culture of AR–V7 cell lines for development.	$100,000
Development of reference method for accuracy	A comparator method may be required to determine the Sensitivity and specificity of the assay. The requirements will be determined by discussions with CDRH	$250,000
IP	Analyze third party rights for freedom-to-operate of the assay. Does not include licensing fees.	$TBD
Materials Management Fee	Covers the development of specifications for any incoming materials such as: samples, goods receipt, labelling, database entry for internal tracking and storage Final amount is dependent on final PTEs costs.	$125,000
Total (Estimate)		$1,856,000

Attachment 3

Registration:

The parties expressly agree that Tokai shall fund all regulatory filings set forth in this Project Agreement, despite any conflicting terms in the MCA.

Territory	Requirements	Costs	Preparation	Review Clock
Canada	Product implementation together with IVD registration activities and submission fees for Health Canada (Assumes no additional data generation)	$112,484	3 Months	4-5 Months according to Health Canada Guidance
EU- CE Mark	Product implementation with IVD registration activities for self-certification and updated filing with notified bodies (Assumes no additional data generation)	$191,103	1 month	n/a – products currentl y self-certified* * Subject to existing requirements and subject to change with new updates as they materialize.
Australia	Product implementation with IVD registrational activities and submission fees for Australian Therapeutic Goods Administration (TGA) (Assumes no additional data generation)	$114,184	3 Months	7-12 months according to TGA Guidance

Attachment 4

JHU License

Incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014