MASTER AGREEMENT

 # VCU-R&D-5372

This MASTER AGREEMENT ("Agreement" or "MA"), effective as of the last date executed ("Effective Date"), is between Virginia Commonwealth University, a corporation and an institution of higher education of the Commonwealth of Virginia, whose address is 912 West Grace Street, Richmond, VA 23298 ("VCU", or "University"), and WuXi AppTec (HongKong) Limited, a Hong Kong corporation, with offices located at Unit C, 20/F., OfficePlus @ Mong Kok, No. 998 Canton Road, Kowloon, Hong Kong ("WuXi" or "Contractor"). VCU and WuXi are sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, VCU issued a Request For Proposals to solicit proposals for Investigational New Drug Guided Advanced Pre-Clinal Studies for IND Application to the FDA, RFP # 184115372AZ issued June 5th, 2024 (the RFP); and

WHEREAS, WuXi AppTec (HongKong) Limited submitted its proposal dated July 4th, 2024, (the "Proposal") wherein it wished to be considered, inter alia, for the Investigational New Drug Guided Advanced Pre-Clinal Studies for IND Application to the FDA as more fully specified therein (the "Services"); and

WHEREAS, VCU considered all proposals submitted, including the WuXi AppTec (HongKong) Limited's Proposal, and VCU now desires to award to WuXi AppTec (HongKong) Limited, as set forth in greater detail below; and

WHEREAS, WuXi AppTec (HongKong) Limited desires to perform the Investigational New Drug Guided Advanced Pre-Clinal Studies for IND Application to the FDA Services as set forth herein.

NOW THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

I. **CONTRACT DOCUMENTS:** The contract documents are integrated and shall consist of: (A) MSA, (B) Price Proposal, (C) RFP#184115372AZ- IND-Guided Advanced Preclinical Studies, (D) Contractor's proposal dated July 4th, 2024 (all of the foregoing, together, the "Contract"). Should a conflict arise among the foregoing (A) MSA, (B) Price Proposal, (C) RFP#184115372AZ- IND-Guided Advanced Preclinical Studies, (D) Contractor's proposal dated July 4th, 2024, and this MSA, this MSA shall control.

II. **SERVICES/GOODS:** Contractor shall perform the following Services: Investigational New Drug Guided Advanced Pre-Clinal Studies for IND Application to the FDA identified as more fully described in Exhibit B of this Contract. Furthermore, various terms specific for Services that involve toxicology studies in animals housed in facilities in Suzhou ("Toxicology Services") are provided in Exhibit C. For clarity of doubt, this Agreement specifically excludes oligo/peptide services from Contractor TIDES.

III. **TERM and RENEWAL OF CONTRACT:** This Agreement shall have a three (3) year initial term (the "Initial Term") and may be renewed by the Parties upon mutual written agreement of authorized representatives of both Parties for two (2) successive three (3) year periods (the "Renewal Term") under the terms and conditions of this original Agreement or as otherwise agreed in writing by the Parties at such time.

If VCU elects to exercise the option to renew the contract for an additional three (3) year period, the contract price(s) for the additional three (3) year shall not exceed the contract price(s) for services

identified herein increased/decreased by more than the percentage increase/decrease of the Services category of the CPI-U section of the Consumer Price Index of the United States Bureau of Labor Statistics for the latest twelve months for which statistics are available.

IV. **FEES:** VCU shall pay Contractor a fee consistent with the pricing provided in Exhibit B.

V. **PAYMENT METHOD AND PAYMENT TERMS:**

A. VCU shall pay Contractor within the net days specified below following receipt of a proper invoice for services rendered, or goods delivered, whichever is later pursuant to and in accordance with §§ 42-45 of the *Rules Governing Procurement of Goods, Services, Insurance and Construction by a Public Institution of Higher Education of the Commonwealth* (similar to the Virginia Prompt Payment Act.

B. All payments will be made based on the net terms agreed upon in this Agreement, starting from after receipt of invoice or delivery, whichever occurs last. This shall not affect offers for early payment discounts, however. If this Agreement includes a payment for completion of a project stage or other kind of milestone, then Contractor shall notify VCU promptly after the milestone is achieved. Each milestone payment is designed to reflect fair value of the corresponding Services, and is not dependent on any other milestone unless otherwise specified in the Agreement or applicable Quotation. Payment must be made without set-off or other deduction of any nature.

C. **No Clawbacks**. Service fees and other payments under this Section are non-cancelable and non-refundable for services properly performed and validated.

D. Fees appearing to be incorrect will be researched and challenged in good faith, and that portion of the invoice held in abeyance until a settlement can be reached. In the event of an overdue payment (a "Payment Default"), (a) interest of 0.21‰ will be accrued daily (8% per annum) of the overdue payment as of the date of the Payment Default (or to the maximum extent permitted by applicable law) and (b) Contractor may suspend the provision of the Services until the Payment Default is rectified by VCU. If the Payment Default is not rectified within 30 days, then it will be deemed an incurable material breach of the Agreement, and Contractor may terminate the Agreement

E. **Specific Terms:**

1. **Payment Method**: Wire Transfer
2. **Payment Terms:** Net 30

VI. **INVOICING:** All invoices will reflect the VCU Purchase Order number and will be emailed to VCU.Invoices@trustflowds.com or mailed to Accounts Payable, Box 3985, Scranton, PA 18505.

For additional information regarding proper invoicing practices follow the link below.

https://procurement.vcu.edu/for-suppliers/vendor-invoicing--payment/

VII. **ACCEPTANCE OF VCU PURCHASE ORDERS:** The Contractor will provide a detailed statement of work prior to any project summarizing specific services, deliverables, delivery dates, and cost. The Contractor will do so without introducing additional terms or conditions and will not require VCU to sign any separate agreements. Notwithstanding the foregoing, VCU agrees that it shall first provide Contractor with written confirmation to Contractor (including but not limited to an email confirmation) confirming acceptance as Contractor is not obligated to perform any of the services until such time as the written confirmation is provided. VCU further agrees that the written confirmation is binding.

VIII. CONTRACTOR RESPONSIBILITIES: Contractor will, as mutually agreed upon, support comprehensive drug discovery, design, and development programs here at VCU by conducting Investigational New Drug (IND)-guided advanced preclinical studies that are required by the US Food and Drug Administration (FDA) prior to starting clinical trials in patients. Services may include studies such as ADME (Absorption, Distribution, Metabolism, and Excretion), DMPK (Drug Metabolism and Pharmacokinetics), pre-formulation, formulation, non-GLP (Good Laboratory Practice) dose range finding, maximally tolerated dose, GLP chronic toxicology studies in rodents, and non-rodent, chemistry, manufacturing and control studies.

IX. GENERAL TERMS AND CONDITIONS:

A. APPLICABLE LAW AND COURTS: This Agreement shall be construed, governed, and interpreted pursuant to the laws of the Commonwealth of Virginia without regard to choice of law principles. The Parties agree that all disputes arising under this Contract shall be brought in the state or federal courts located in Richmond, Virginia. To the extent any provision of the Agreement is prohibited by Virginia law, or is otherwise not authorized by Virginia law, due to VCU's status as an agency of the Commonwealth of Virginia, such provision is null and void. Each Party shall be responsible for its own legal fees and costs unless otherwise ordered by a court of law.

B. ARBITRATION: Neither Party shall be compelled to arbitrate any matter or otherwise be subject to any form of alternative dispute resolution, but may request and/or opt to participate in alternative dispute resolution in its sole discretion.

C. WAIVER OF CLAIMS: Notwithstanding anything contained herein to the contrary, VCU is an agency of the Commonwealth of Virginia and as such, pursuant to § 2.2-514 of the *Code of Virginia* (*Virginia Code*), cannot waive or settle legal claims that VCU may have against another party nor may VCU bestow any right or obligation that is beyond the duly granted authority of the signatory to bestow or incur on behalf of the Commonwealth of Virginia. The waiver by either Party of any breach of any term of this Agreement will not constitute a waiver of any other breach of the same or any other term. Failure or delay on the part of either Party to fully exercise any right under this Agreement will not constitute a waiver or otherwise affect in any way the same or any other right.

D. ANTI-DISCRIMINATION: To the extent applicable to Contractor and to the extent permitted under applicable law, Contractor certifies to VCU that it will conform to the provisions of the Federal Civil Rights Act of 1964, as amended, as well as the Virginia Fair Employment Contracting Act of 1975 (VFECA), as amended, the Virginians With Disabilities Act (VDA), the Americans With Disabilities Act (ADA) and § 9 of the *Rules Governing Procurement of Goods, Services, Insurance and Construction by a Public Institution of Higher Education of the Commonwealth.* If the award is made to a faith-based organization, the Contractor shall not discriminate against any recipient of goods, services, or disbursements made pursuant to the contract on the basis of the recipient's religion, religious belief, refusal to participate in a religious practice, or on the basis of race, age, color, gender or national origin and shall be subject to the same rules as other organizations that contract with public bodies to account for the use of the funds provided; however, if the faith-based organization segregates public funds into separate accounts, only the accounts and programs funded with public funds shall be subject to audit by the public body. ((§ 36 of the *Rules Governing Procurement of Goods, Services, Insurance and Construction by a Public Institution of Higher Education of the Commonwealth*). In every contract over $10,000 the provisions in 1. and 2. below apply:

1. During the performance of this Contract, to the extent applicable to

Contractor, the Contractor agrees as follows:

a. VCU is an equal opportunity/affirmative action institution providing access to education and employment without regard to age, race, color, national origin, gender, religion, sexual orientation, veteran's status, political affiliation or disability. As such, the Contractor will not discriminate against any employee or applicant for employment because of age, race, color, national origin, gender, religion, sexual orientation, veteran's status, political affiliation or disability or any other basis prohibited by state law related to discrimination in employment, except where there is a bona fide occupational qualification reasonably necessary to the normal operation of the Contractor. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this nondiscrimination clause.

b. The Contractor, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, will state that such Contractor is an equal opportunity employer.

c. Notices, advertisements, and solicitations placed in accordance with federal law, rule or regulation shall be deemed sufficient for the purpose of meeting these requirements.

2. To the extent applicable, the Contractor will include the provisions of a. above in every subcontract or purchase order over $10,000 so that the provisions will be binding upon each subcontractor or vendor who performs work relative to this RFP.

E. IMMIGRATION REFORM AND CONTROL ACT OF 1986: to the extent applicable to Contractor, Contractor certifies that it does not and will not during the performance of this contract employ illegal alien workers or otherwise violate the provisions of the Federal Immigration Reform and Control Act of 1986.

F. ANTITRUST: By entering into a contract, Contractor conveys, sells, assigns, and transfers to the Commonwealth of Virginia all rights, title and interest in and to all causes of the action it may now have or hereafter acquire under the antitrust laws of the United States and the Commonwealth of Virginia, relating to the particular goods or services purchased or acquired by the Commonwealth of Virginia under this Contract.

G. ASSIGNMENT OF CONTRACT: The Agreement shall not be assignable by Contractor in whole or in part without the written consent of the University.

H. TESTING AND INSPECTION: To the extent applicable, VCU reserves the right to conduct any testing/inspection it may deem advisable to assure goods and services conform to the specifications/Contract.

I. TERMINATION OF CONTRACT:

1. Either Party may terminate this Agreement if the other Party materially breaches this Agreement and such breach is not cured within thirty (30) days after written notice to the breaching Party.

2. University reserves the right to terminate this Agreement, in part or in whole,

without penalty, upon sixty (60) days written notice to the Contractor.

3. Except as otherwise provided in this Agreement or as otherwise mutually agreed upon in writing by the Parties, either Party may terminate this Agreement after the initial twelve (12) months following the Effective Date of this Agreement upon sixty (60) days written notice to the other Party.

J. CHANGES TO THE AGREEMENT: Changes may be made to the Agreement:

1. The Parties may agree to modify the scope of the Agreement. An increase or decrease in the price of the Agreement resulting from such modification shall be agreed by the parties as a part of their written amendment to modify the scope of the Agreement.

2. VCU may order changes within the general scope of the contract at any time by written notice to the Contractor. Changes within the scope of the contract include, but are not limited to, things such as services to be performed, the method of packing or shipment, and the place of delivery or installation. The Contractor shall comply to the extent mutually agreed upon. The Contractor shall be compensated for any additional costs incurred as the result of such order and shall give the VCU a credit for any savings.

3. Material, substantive modifications, changes, and amendments to the Agreement must be in a writing executed by authorized representatives of each Party.

K. NOTICE: All notices provided hereunder in regard to default, claims, actions, or similar events shall be in writing and delivered personally, or sent by registered or certified mail, return receipt requested, postage prepaid, to the respective Party at the following addresses:

For VCU:
Director, Procurement Services
912 West Grace Street, 5th Floor
Richmond, Virginia 23298-0327

For WuXi AppTec (HongKong) Limited:
WuXi AppTec
Building 1, 288 Fute Zhong Road
Waigaoqiao Free Trade Zone
Shanghai, China 200131
Attn: Legal Department
Email: wuxilegalnotices@wuxiapptec.com

With a copy to:
WuXi AppTec (HongKong) Limited
Unit 826, 8/F, Ocean Centre, Harbour City,
5 Canton Road, Tst, Kowloon,
Hong Kong

Any notice sent by any other means shall not be considered duly given or delivered unless the receiving Party affirmatively acknowledges receipt. Notices with respect to any services and communications specifically for day-to-day servicing purposes shall be sent to the designated points of contact as specified by each Party.

L. TAXES: To the extent permitted under applicable law, and VCU shall pay, any applicable taxes (other than taxes on Contractor's income) and other fees of any nature imposed by or under the authority of any appropriate government authority.

M. FAILURE TO DELIVER GOODS OR SERVICES: Subject to the limitations set forth in Section O, in the event that the Contractor does not comply with Section VI above solely due to Contractor's failure to perform its obligations under this Agreement (and not attributable to any process, method or VCU Materials provided by VCU), VCU has the discretion to accept Contractor's performance or conformance at Contractor's cost and expense, the affected work or portion of the Services affected by the non-conformance to the relevant specifications as a remedy..

N. MATERIALS/VCU MATERIALS:

1. Materials. At the expense of VCU, Contractor shall purchase all materials necessary for the Services (the "Materials"). If a Material is not commercially available, then VCU may elect to (a) supply, at its expense, the Material to Contractor or (b) amend the Agreement to permit the use of a commercially available substitute.

2. VCU Materials. If a Material is to be supplied by VCU (a "VCU Material"), then VCU shall provide the VCU Material at its expense in a timely manner and provide such information as may be required by Contractor or applicable law concerning the stability, storage and safety requirements. Contractor shall ensure that the VCU Material will be (a) used solely for the purpose of providing the Services, (b) only distributed to Personnel on a need-to-know basis for the provision of the Services and (c) preserved and protected in a manner consistent with the specifications of the Agreement and any relevant standard operating procedures or other instructions provided by VCU. For clarity of doubt reasons, VCU shall provide such information as may be required by Contractor or applicable law concerning the stability, storage and safety requirements of any materials, including without limitation any VCU Materials, target molecules, and any isolated or potentially isolated intermediates, necessary for the performance of the Services in a timely manner and shall promptly and clearly inform Contractor of the hazardous characteristics of any such materials or the wastes generated during their preparation (the "**Hazardous Information**") known to VCU including but not limited to high potency, allergenicity, reproductive toxicity, cytotoxicity, genotoxicity, flammability and explosive characteristic of such materials. VCU shall also provide Contractor with complete supporting documentation of the Hazardous Information in VCU's possession (such as a safety data sheet (the "**SDS**"), toxicology reports issued by authoritative third parties, internal toxicology evaluation reports and other supporting documents). If the aforesaid Hazardous Information changes during the performance of the Services, VCU shall promptly and accurately inform Contractor of such changes and provide relevant information and supporting documentation thereof.

3. Unused VCU Materials and Other Materials. Contractor shall, at VCU's option and expense, return, destroy or otherwise dispose of unused VCU Materials promptly after the earlier of (a) completion of the Services for which the VCU Materials were

provided, (b) termination of the Agreement, or (c) receipt of written instructions from VCU pertaining to their disposition. Contractor may dispose of other unused Materials at its sole discretion

O. SHIPPING:

1. All materials to be provided by Contractor to VCU, VCU shall arrange the shipment of the Packaged Products with Client Carriers and choose the shipping method acceptable by VCU Policy. DDP (Incoterms 2020) for foreign shipments, and FOB Destination for Domestic Shipments. Client will schedule freight pickup and pay outbound freight delivery costs, customs clearance and duties. Client shall be responsible for investigating any incoming and outgoing in-transit product losses.

2. All materials to be provided by VCU to Contractor will be delivered DDP (site designated by Contractor) (Incoterms 2020), including Materials provided by VCU and VCU Materials. For the avoidance of doubt, DDP (site designated by Contractor) means VCU is responsible for delivery to and unloading at the site designated by Contractor and pays all costs including import duties and taxes.

P. INSURANCE: Contractor confirms it will have the following insurance coverages, and any insurance otherwise required by applicable law, throughout the entire term of the Contract, as well as renewal terms.. Contractor further confirms all insurance coverage will be provided by commercially reputable insurance companies:

Q. Commercial General Liability - $1,000,000 per occurrence. Commercial General Liability is to include bodily injury and property damage, personal injury and advertising injury, products, and completed operations coverage.

R. Cyber Security Liability - $1,000,000

S. DRUG-FREE WORKPLACE: To the extent applicable to Contractor, during the performance of this contract, the Contractor agrees to (i) provide a drug-free workplace for the contractor's employees; (ii) post in conspicuous places, available to employees and applicants for employment, a statement notifying employees that the unlawful manufacture, sale, distribution, dispensation, possession, or use of a controlled substance or marijuana is prohibited in the contractor's workplace and specifying the actions that will be taken against employees for violation of such prohibition: (iii) state in all solicitations or advertisements for employees placed by or on behalf of the Contractor that the Contractor maintains a drug-free workplace: and (iv) includes the provisions of the foregoing clauses in every subcontract or purchase order of over $10,000, so that the provisions will be binding upon each subcontractor or vendor providing services under this Contract. For the purposes of this section, "drug-free workplace" means a site for the performance of work done in connection with a specific contract awarded to a contractor, the employees of whom are prohibited from engaging in the unlawful manufacture, sale, distribution, dispensation, possession or use of any controlled substance or marijuana during the performance of the Contract.

T. NONDISCRIMINATION: to the extent applicable to Contractor, federal law requires compliance with the following:

1. 41 CFR § 60-1.4(a). Equal Opportunity Clause prohibiting discrimination on the basis of race, color, religion, sex, sexual orientation, gender identity or national origin, and require affirmative action to employee and advance in employment qualified individuals without regard to race, color, religion, sex, sexual orientation, gender identity or national origin.

2. 41 CFR § 60-300.5(a) and 41 CFR§ 60-741.5(a). These regulations prohibit discrimination against qualified individuals on the basis of disability (41 CFR § 60-741.5(a)) and protected veteran status (41 CFR§ 60-300.5(a)), and require affirmative action to employ and advance in employment qualified individuals with disabilities and qualified protected veterans.

U. FERPA: To the extent that University provides to Contractor any identifiable student information, including student address, phone number and email address, the University hereby designates Contractor as a school official with a legitimate educational interest in using such student information, and Contractor agrees to use such information only for the purpose of fulfilling its obligations under this Contract. Contractor further agrees not to disclose any such student information to any individual other than the student except as required by applicable law, rule or regulation or court or governmental order or as authorized in writing by the University or the individual student. Contractor acknowledges that this protection of student information is necessary for the University's compliance with the *Virginia Code* § 23.1-405(C) and the federal Family Educational Rights and Privacy Act (FERPA).

V. CONFIDENTIAL INFORMATION:

1. "Confidential Information" means all information of a Party ("Disclosing Party") disclosed or made available to the other Party ("Receiving Party") or any of its Representatives that (i) is clearly marked or identified as such at the time of disclosure or within a reasonable time thereafter; or (ii) should be reasonably known by the Receiving Party to be confidential due to the nature of the information disclosed and the circumstances surrounding the disclosure. Confidential Information of VCU shall include, but not be limited to information about VCU personnel and students of VCU to the extent such information is not available to the public domain in accordance with the laws of the Commonwealth of Virginia and FERPA. Receiving Party shall use its reasonable efforts to prevent and protect Confidential Information from unauthorized use or disclosure, with at least the same degree of care that Receiving Party uses to protect its own confidential and proprietary information, but in no event less than a reasonable degree of care under the circumstances. Receiving Party will only disclose the Disclosing Party's Confidential Information to its Representatives only on a need-to-know basis, provided that such Representatives are subject to confidentiality obligations no less restrictive than those contained herein.

2. Upon the expiration or termination of this Agreement or upon the written request of the Disclosing Party, the Receiving Party shall return all Confidential Information received in written format, including copies or reproductions or other media containing Confidential Information within thirty (30) calendar days of such written request; provided, however, that (a) the Receiving Party may retain a single secure copy of any Confidential Information for legal archival purposes and (b) electronic back-up files that have been created by routine archiving and back-up procedures need not be deleted.

3. Exceptions to Confidentiality. The obligations of Section N(1) do not apply to Confidential Information if (a) the Confidential Information is public knowledge or becomes public knowledge after disclosure through no fault of

the Receiving Party or any of its Representatives, (b) the Confidential Information can be shown by the Receiving Party to have been in its or any of its Representatives' possession prior to disclosure, (c) the Confidential Information was received from a third party that was not obligated to the Disclosing Party or any of its Representatives to maintain the Confidential Information in confidence, or (d) the Receiving Party can show that equivalent information was developed independently by the Receiving Party or any of its Representatives without recourse to the Confidential Information

W. VA FOIA: Nothing contained herein is intended to limit VCU's compliance with the Virginia Freedom of Information Act ("VFOIA"). For clarity and subject to confidentiality obligations no less stringent than this Agreement, contracts and pricing between VCU and its vendors are not considered to be exempt from VFOIA requests.

X. INDEMNIFICATION: To the extent permitted by applicable law, each party shall be responsible for the negligent acts or omissions of its officers, employees, agents and students. Nothing contained herein shall constitute a waiver of the sovereign immunity of VCU or the Commonwealth of Virginia.

Y. LIMITATION OF LIABILITY: Except for Losses arising from breach of confidentiality obligations, either Party's maximum aggregate total liability in connection with this Agreement will not exceed the total payments received under the Agreement.

Z. STATUTORY DAMAGES: VCU is not authorized to waive damages granted or otherwise available by statute.

SOVEREIGN IMMUNITY: VCU is an agency of the Commonwealth of Virginia and is afforded the protection of sovereign immunity under Virginia law. Any claims against VCU or the Commonwealth are subject to the requirements established under Virginia law for bringing such claims against VCU or the Commonwealth, including the Virginia Tort Claims Act (Virginia Code §§ 8.01-195.1 et seq.) and other applicable statutes relating to claims against the Commonwealth or its agencies. Notwithstanding any other provision, nothing in this Contract shall be deemed to be or construed as a waiver of VCU's or the Commonwealth's sovereign immunity, or any other applicable requirements under Virginia law for bringing claims against VCU or the Commonwealth. The total cumulative liability of the University, its officers, employees, and agents in connection with this contract or in connection with any goods, services, actions or omissions relating to this contract, shall not under any circumstance exceed payment of the maximum purchase price.

AA. INTELLECTUAL PROPERTY:

1. **Ownership**.

a. Except as otherwise provided in this Agreement, (i) Contractor has no rights in any Intellectual Property that is owned by or licensed to VCU or any of its Affiliates ("**VCU IP**") and (ii) VCU has no rights in any Intellectual Property that is owned by or licensed to Contractor or any of its Affiliates ("**Contractor IP**").

b. Contractor shall ensure that each of the Personnel vests in Contractor any and all rights that such person might otherwise have in the Intellectual Property created or developed in connection with the provision of the Services ("**Project IP**"). Contractor hereby assigns and shall assign all right, title and interest in Project IP to VCU. VCU will, at its expense, have sole control of filing

and prosecuting applications for, and maintenance and enforcement of, patents for Project IP. Contractor shall, at VCU's expense, use reasonable efforts to assist VCU to obtain, maintain and enforce the patents. VCU shall promptly notify Contractor of any patents granted for Project IP. Contractor is responsible for all payments to be made to Personnel in accordance with applicable law requiring remuneration for inventions.

c. Notwithstanding the foregoing, Intellectual Property created or developed in connection with the provision of the Services that does not rely on, use or incorporate VCU Confidential Information or VCU Materials and that: (i) is derivative of Contractor IP, (ii)that relates to new manufacturing technologies, methods, processes or techniques or improvements to existing manufacturing technologies, methods, processes or techniques and are broadly applicable to pharmaceutical products in general or (iii) that relates to experimental methods is, in each case, Contractor IP and not Project IP.

d. Unless otherwise provided for in this Agreement, Project IP and Records may only be used for research purposes. Other uses such as in connection with regulatory filings are prohibited.

2. **Licenses.**

a. VCU hereby grants, and shall ensure that each applicable Affiliate will promptly grant, to Contractor and its Affiliates the limited right to use VCU IP and Project IP for the purpose of providing the Services. Contractor hereby grants, and shall ensure that each applicable Affiliate will promptly grant, to VCU and its Affiliates the limited right to use Contractor IP for the purpose of using Project IP.

BB. FORCE MAJEURE: Neither Party will be responsible for any losses resulting from delay or failure in performance resulting from any cause beyond either Party's reasonable control, including without limitation, war, strikes or labor disputes, civil disturbances, fires, national security mandates, natural disasters, pandemics, including if VCU, in its sole discretion, must close a campus location or take other restrictive actions due to concerns related to the COVID-19 pandemic or acts of God. If the delay or failure in the performance of the Party claiming Force Majeure continues for thirty (30) days or more, then the Party not claiming Force Majeure may terminate this Agreement by written notice to the other Party without penalty. Any funds paid will be reimbursed pro rata based on Services not provided

CC. RECORDS:

1. Storage. All materials, data and documentation obtained or generated by VCU in the course of providing the Services, including all computerized records and files ("Records"), will be maintained in a secure area in accordance with industry standards. The Records are the sole and exclusive property of VCU.

2. Retention. Upon termination of the Agreement, Contractor shall, at VCU's option, (a) destroy the Records, (b) deliver the Records to VCU, or (c) retain the Records for three years and then destroy them. If the Records are to be destroyed, then Contractor shall give 30-days' written notice to VCU, and VCU may elect during the 30-day period to have the Records transferred to it. Notwithstanding the foregoing, the Records may be retained as required by

applicable law or as otherwise necessary for regulatory or insurance purposes. Terms for retention of Records for Toxicology Services are provided in Exhibit C.

DD. AUDIT: The Contractor shall retain all books, records, and other documents directly relating to the Services for three (3) years after final payment, or until audited by the Commonwealth of Virginia, whichever is sooner. The University, its authorized agents, and/or State auditors shall have reasonable access to and the right to examine any of said materials during said period visits; provided, however, that any financial records reviewed by VCU shall only be reviewed by VCU's professional accountants, or if applicable, Commonwealth of Virginia authorized auditors and/or accountants who are first bound by confidentiality agreements or obligations no less stringent than this Agreement.

EE. AVAILABILITY OF FUNDS: It is understood and agreed between the parties herein that VCU shall be bound hereunder only to the extent the funds are appropriated, or otherwise made available, from the Virginia General Assembly or other funding source, or which funds may hereafter be provided for the purpose of this Contract.

FF. ADDITIONAL GOODS AND SERVICES: The University may acquire other goods or services that the supplier provides than those specifically solicited. The University reserves the right, subject to mutual contract, for Contractor to provide additional goods and/or services under the same pricing, terms and conditions and to make modifications or enhancements to the existing goods and services. Such additional goods and services may include other products, components, accessories, subsystems, or related services newly introduced during the term of the Contract.

GG. REALSOURCE REGISTRATION: This Contract shall result in a purchase order or purchase orders issued via VCU's source-to-pay platform, RealSource. Contractor shall register in RealSource upon award of contract. For information on registering, visit realsource.vcu.edu. Registration is free, and registered vendors shall have access to purchase order, invoice, and payment information. Contractor is responsible for the security of its RealSource portal account, including restricting access to it, maintaining the confidentiality of login information, and taking any other actions necessary to protect the security of the Contractor's account. VCU will not be responsible for a third party's fraudulent collection of VCU payments due to the Contractor's failure to update or protect its account information. If this is a cooperative procurement, this clause shall apply to orders placed by VCU only.

HH. eVA REGISTRATION AND FEES: Contractor agrees to self-register with the Commonwealth of Virginia's electronic procurement system, eVA (information on eVA can be found at http://www.eva.virginia.gov), and agrees to maintain self-registered status for the duration of this Contract. The Commonwealth shall assess eVA transaction fees as specified below for each order resulting from this Contract. The Vendor Transaction Fee is:

1. DSBSD-certified Small Businesses: 1%, capped at $500 per order.
2. Businesses that are not DSBSD-certified Small Businesses: 1%, capped at $1,500 per order.

The specified Vendor Transaction Fee will be invoiced by the Commonwealth of Virginia Department of General Services, approximately 30 days after the corresponding purchase order is issued and the invoice is payable 30 days after the invoice date.

Contractor is responsible for the security of its eVA account, including restricting access to it, maintaining the confidentiality of login information, and taking any other actions necessary to protect the security of Contractor's account. VCU will not be responsible for a third party's fraudulent collection of VCU payments due to Contractor's failure to update or protect its account information.

II. SWAM REPORTING: Contractor will submit a quarterly SWAM business report to the University by the 8th of the month following each calendar quarter, specifically the months of April, July, October, and January.

Contractor will submit the quarterly SWAM business reports, based upon the Contractor's proposed commitment to:

VCU SWaM Reporting

E-mail: swamreporting@vcu.edu

The quarterly SWAM business reports will contain the following information:

1. SWAM firms' name, address and phone number with which Contractor has contracted over the specified quarterly period.
2. Contact person at the SWAM firm who has knowledge of the specified information.
3. Type of goods and/or services provided over the specified period of time.
4. Total amount paid to the SWAM firm as it relates to the University's account.

X. SPECIAL TERMS AND CONDITIONS:

A. SENSITIVE FOREIGN NATIONS CONTROLS: In connection with any activities in the performance of this agreement, WuXi AppTec (Hong Kong) Limited and its affilaties/ subsidiaries agrees to comply with any applicable laws related to "Sensitive Foreign Nations Controls" requirement, relating to those countries which may from time to time, be identified by the United States Secretary of State, as a foreign country of concern by written notice. Upon receipt of any written notice, Client shall communicate such notice to WuXi AppTec (Hong Kong) Limited promptly. WuXi AppTec (Hong Kong) Limited and its affilaties/ subsidiaries shall not release to anyone outside it and its Affiliates' respective organization's any proprietary or confidential data provided by Client, regardless of medium, pertaining to any part of this agreement without the expressed consent of the Client.

B. ADVERTISING/TRADEMARKS/LOGOS: Each Party shall not, and shall ensure that its Representatives will not, use the name, symbols or marks of the other Party or any of its Affiliates in any advertising or publicity material or make any form of representation or statement that would constitute an express or implied endorsement by the other Party or any of its Affiliates of any commercial product or service without the other Party's or Affiliate's prior written consent.

C. EXTRA CHARGES NOT ALLOWED: The Contract price shall reflect all fees to be incurred for the performance of the Contract, including all applicable freight and installation charges, as well as other fees and expenses provided under this Agreement. Any additional fees that arise during the performance of the Contract shall only be paid if approved by the University in writing prior to incurring such fees.

D. ADDITIONAL USERS OF CONTRACT: It is the University's intent to allow for cooperative

procurement. Accordingly, any public body, public or private health or educational institution, or any University-related foundation (Additional Users) may access this Agreement if authorized by Contractor.

E. To that end and if agreeable with the Contractor, upon written request from Additional Users the Contractor may allow access to the contract. Although the University desires to provide access on such contract to Additional Users, the Contractor is not required to provide such access. A Contractor's willingness to provide this access to Additional Users, will not be a consideration in awarding this contract. Although the Additional Users have access to any resulting contract,

F. Additional Users and Contractor are not bound to use the contract and any use of the contract is strictly optional. If the Additional Users choose to access the contract and the Contractor agrees to such access, the terms and conditions of the contract will be in full force and effect as between the Additional Users and the Contractor. VCU will have no responsibility for the resolution of any contractual disputes, or for payment for services rendered which may arise from an Additional User accessing the contract. The Contractor understands and agrees that it shall not have any recourse against VCU with respect to any claim it may have against another Additional User that accessed this contract.

G. GRAMM-LEACH-BLILEY ACT: The Contractor shall comply with the Act by implementing and maintaining appropriate safeguards to protect and prevent unauthorized release of student, faculty and staff nonpublic information. Nonpublic information is defined as social security numbers, or financial transactions, bank, credit, and tax information.

H. SUBCONTRACTS: Contractor may delegate or subcontract the Services to an Affiliate. If the Services are provided by an Affiliate, then references to Contractor in this Agreement will be deemed to be references to the Affiliate with the necessary modifications. Contractor shall be liable for the performance of the Affiliate to the same extent as if the performance was that of Contractor. However, no portion of the work shall be subcontracted to any non-Affiliated third-parties without prior written consent of VCU.

I. CRIMINAL BACKGROUND INVESTIGATION: to the extent applicable to Contractor, if Contractor employees and agents will be on the VCU campus, or have access to protected data as defined herein, Contractor must comply with the following: Contractor shall ensure that its employees, full-time or part-time, including newly hired, re-hired, seasonal, and/or temporary, who may have access to VCU confidential or proprietary information, or data about VCU personnel or students, have passed a criminal background check pursuant applicable law and to its internal standard operating procedures.

J. IDENTIFICATION CARDS: To the extent applicable to Contractor, all Contractor employees authorized to work at VCU must obtain a VCU identification card. Information on obtaining a card is available at http://vcucard.vcu.edu/. Contractor's employees must wear their VCU identification when they are on VCU property.

K. REPRESENTATIONS AND WARRANTIES: All representations and warranties made by a Party are made to the best of its knowledge at the time the representation or warranty is made. University will use its best efforts to comply with all conditions and restrictions on its accounts and the services provided hereunder.

L. WARRANTY:

1. **Infringement**. Each Party represents and warrants that, to the best of its knowledge, the Services will not infringe the Intellectual Property rights of

any third party.

2. **Debarment.** Contractor represents and warrants that neither it nor any of the Personnel has been debarred, or, to the best of its knowledge, is under consideration for debarment, by the United States Food and Drug Administration from working in or providing services to any pharmaceutical or biotechnology company pursuant to the Generic Drug Enforcement Act of 1992 or any other governmental authority pursuant to analogous laws.

3. **Compliance with Law**. Each Party (a) represents and warrants that neither it nor any of its Affiliates violated any applicable law in connection with actions leading up to entry into this Agreement and (b) shall, and shall ensure that each applicable Affiliate will, comply with all applicable law in connection with performance of this Agreement. Each Party shall immediately notify the other Party upon becoming aware of a breach of this Section.

M. COUNTERPARTS: This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together constitute one and the same instrument. Executed counterparts may be exchanged by facsimile or e-mail in PDF or similar electronic format.

XI. FEDERAL TERMS AND CONDITIONS:

A. For Contracts funded by a U.S. Government grant or contract, VCU is deemed a state pursuant to 2 C.F.R. 200.90 and is subject to the provisions of 2 C.F.R. 200.317. The following provisions found in Appendix II of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule (2 CFR Part 200, et al) shall be incorporated and made a part of this Contract to the extent applicable to the Services.

B.

1. Equal Employment Opportunity (Executive Order (E.O) 11246 as amended by E.O. 11375 and supplemented by 41 CFR Part 60).

2. For construction with Federal funds: the Davis-Bacon Act (40 U.S.C. §§ 3141-3148) as supplemented by 29 CFR Part 5

3. Copeland "Anti-Kickback" Act (40 U.S.C. § 3145 and 29 CFR Part 3).

4. Where applicable, the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 3701-3708) as supplemented by 29 CFR Part 5.

5. For non-profit organizations and small business, patent rights will be governed by 37 CFR Part 401, "Rights to Inventions Made by Non-Profit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Contracts."

6. The Clean Air Act (42 U.S.C. §§ 7401-7671q.) and the Federal Water Pollution Control Act (33 U.S.C. §§ 1251- 1387.), as amended.

7. Mandatory standards and policies relating to energy efficiency contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act (42 U.S.C. § 6201).

8. When applicable, this Contract is subject to Debarment and Suspension (E.O.

12549 and E.O.12689) as provided in 2 CFR Part 180.

9. The Byrd Anti-Lobbying Amendment (31 U. S. C. §1352): awards of $100,000.00 or more will file the required certification.

10. This contractor and subcontractor shall abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity, national origin, and for inquiring about, discussing or disclosing compensation. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability or veteran status.

IN WITNESS WHEREOF, the Parties have executed this Contract on the dates designated below.

VIRGINIA COMMONWEALTH UNIVERSITY

Signed by:
By: Michael Rao
A5F198A1803A4CD...

Name: Michael Rao, Ph.D.

Title: President, Virginia Commonwealth University

Date: 8/28/2025

WUXI APPTEC (HONGKONG) LIMITED

By: for

Name: Bill Harrison

Title: VP. Head of Toxicology Services

Date: 2025-01-16

DS
Seen/Agreed: MW
Meredith Weiss, Senior Vice President
Finance and Administration and CFO Division of Finance and Administration
5/30/2025

Initial
Seen/Approved: JM
John McHugh, Executive Director
VCU Office of Procurement Services
5/30/2025

DS
Seen/Agreed:
Jay Bonfili,Senior Associate Vice President for Health Sciences - Finance and Administration
Health Sciences
2/23/2025

Initial
Seen/Agreed: RW
Dr. Robert Winn, Director, Massey Cancer Center
Massey Comprehenisive Cancer Center
2/21/2025

EXHIBIT B

Price Proposal

Price Proposal

a) Quotation A: Laboratory Testing Service (LTD)

- WuXi Project ID: W05-VCU-20240606
- PRICE SUMMARY:
  The total price of this quote is US$1,487,050. Additional price details may be provided in attachment and are subject to change based on scope requirements.

b) Quotation B: STA

Manufacture of 1 kg API under GMP.
Stability study under GMP.

- PRICE SUMMARY:
  Timing: 6 - 8 weeks but TBD when technical documents are being prepared Cost: $30,000 - $200,000+ varies on batch size requirements, based on general estimations only and subject to change,
  Regulatory Affairs 30K USD for DS IND sections, 30K DP IND sections

c) Quotation C: Research Chemistry Services (RCS)

- PRICE SUMMARY
- Timing: TBD on scope of project
- Cost: $~80,000.00+ varies on batch size requirements, based on general estimations only and subject to change.

PROJECT
WIND Package
PRICE SUMMARY
The total price of this quote is **US$1,487,050.** Additional price details may be provided in attachment.

PRICE OUTLINE & ASSUMPTIONS

No.	Study Description【FDA】	FDA-Price (US$)	Note
PART A【DMPK】			
List of bioanalysis components with method development and qualification		**$64,735**	
A1	LC-MS/MS methods in mouse, rat and dog plasma will be developed at WuXi.	$10,055	

A2	Method qualification in mouse, rat and dog plasma, including: Calibration standards, Within-run precision and accuracy, Carryover Dilution and Suitability of analytical run. Acceptance criteria: An LC-MS/MS method for the quantitative determination of test compound in biological matrix will be developed under non-GLP compliance. For qualification run, at least one set of calibration curve will be applied with 6 non-zero calibration standards. at least three sets of QCs consisting low, middle and high concentrations and LLOQ will be applied. For sample analysis, study samples will be quantified against calibration curve with matched matrix. At least one set of calibration curve will be applied with 6 non-zero calibration standards. At least two sets of QC samples consisting low, middle and high concentrations will be applied. The STDs and QCs should be prepared from different stock solutions. Linearity: ≥75% STDs are back calculated to be within ±20% of their nominal values (±25% for LLOQ) in plasma and within 25% of their nominal values (30% for LLOQ) in tissue homogenate samples. Precision: ≥ 67% all QCs are back calculated to be within ±20% of their nominal values (±25% for LLOQ) for plasma and within 25% of their nominal values (30% for LLOQ) for tissue homogenate	$6,600	

	samples. At least 50% (1/2) of the replicates at each concentration level must be no more than 20% (25% for tissue homogeante sample) of their respective nominal values. Specificity: The peak area of test compound in the blank sample should be less than 0.5 times of the LLOQ. Sensitivity: the LLOQ will target 1 – 5 ng/mL for plasma and 1-5 ng/ml for tissue homogenate. Carryover: the carryover peak area of test conpound in the blank sample immediately after the highest standard injection should be less than the LLOQ. If the carryover criteria cannot be met then the percent of carryover will be estimated following WuXi Bioanalytical SOP.		
A3	Formulation screen and Microscopy inspection with the PLM (no more than 10 vehic) • Identify appropriate formulation for in vivo study • Microscopy inspection for rough particle size determination for the suspension with the PLM • Determination of the solubilized fraction and homogeneity for the suspension • Result report in Excel summary	$2,500	
A4	Formulation Screening PK Study-Rat (total 5 formulations) -n=3/vehicle, Administration at several vehicles. -Serial bleeding at: 15, 30 min, 1, 2, 4, 7, 24 hr post dosing per animal. -PK calculation. Conc., PK parameters, BA data reported in MS Excel report format.	$5,380	
	Option: MS Word report can be available with additional charge	$1,100	
A5	LC-MS/MS method development in 11 tissues, urine, feces and bile of rat.	$10,100	

A6	Partial method validation in 2 representative tissues, urine, feces and bile of rat, including: Calibration standards, Within-run precision and accuracy, selectivity for each batch, carryover and suitability of each analytical run.	$10,000	
A7	LC-MS/MS method development in 11 tissues, urine, feces and bile of mouse.	$10,100	
A8	Partial method validation in 2 representative tissues, urine, feces and bile of rat, including: Calibration standards, Within-run precision and accuracy, selectivity for each batch, carryover and suitability of each analytical run.	$10,000	
A9-Optional	Option 1: Bench-top stability for plasma (2 QC levels, n≥ 3). 2) Freeze/thaw stability for plasma (2 cycles, 2 QC levels, n≥3).	$2,650	
List of *in vivo* studies		**$115,290**	
A10	Single dose SD rat PK, intravenous and oral – Total 6 male animals, single dosing, IV and PO dose levels, n=3/route – Serial bleeding at: 5, 15, 30 min, 1, 2, 4, 6, 8, 24 hr post dosing per animal. – PK calculation. Conc., PK parameters, BA data reported in MS Excel report and Word report format.	$3,516	
A11	Single rising dose PK (Dose Proportionality) in rat – n=3/dose group, 3 dose levels, total 9 SD rats. – Serial bleeding at: 15, 30 min, 1, 2, 4, 7, 24 hr post dosing per animal. – Plasma samples preparation. – PK calculation. Conc., PK parameters, BA data reported in MS Excel report and Word report format.	$4,220	

A12	Single dose CD-1 mouse PK, intravenous and oral – Total 12 male animals, single dosing, IV and PO dose levels, n=6/route – Alternating bleeding at: 5, 15, 30 min, 1, 2, 4, 6, 8, 24 hr post dosing per animal. Total 54 mouse plasma samples. – PK calculation. Conc., PK parameters, BA data reported in MS Excel report and Word report format.	$4,740	
A13	Single rising dose PK (Dose Proportionality) in mice – n=6/dose group, 3 dose levels, total 18 CD-1 mice. – Alternating bleeding at: 15, 30 min, 1, 2, 4, 7, 24 hr post dosing per animal. Total 63 mouse plasma samples. – Plasma samples preparation. – PK calculation. Conc., PK parameters, BA data reported in MS Excel report and Word report format.	$5,950	
A14	Single rising dose dog PK, intravenous and oral – Total 12 non-naive male animals, single dosing, IV and 3 PO dose levels, n=3/group. – Serial bleeding at: 5, 15, 30 min, 1, 2, 4, 6, 8, 24, 48 hr post dosing per animal. – PK calculation. Conc., PK parameters, BA data reported in MS Excel report and Word report format.	$15,015	
A15	Rat tissue distribution, cold compound – Total 9 male animals, single PO dose, n=3/time point. – LC-MS/MS method development in rat 11 tissues. – 9 rats sacrificed at 3 time points (0.5, 2, 8 hr). – 11 tissues (brain, liver, spleen, lung, heart, kidney, stomach, small intestine, large intestine, muscle, fat) and blood collected from each animal.at each time point. – Data reported in MS Excel report and Word report format.	$10,250	

A16	Mouse tissue distribution, cold compound – Total 9 male animals, single PO dose, n=3/time point. – LC/MS/MS method development in mouse 11 tissues. – 9 mice sacrificed at 3 time points (0.5, 2, 8 hr). – 11 tissues (brain, liver, spleen, lung, heart, kidney, stomach, small intestine, large intestine, muscle, fat) and blood collected from each animal.at each time point. – Data reported in MS Excel report and Word report format.	$10,250	
A17	Rat Mass balance, single oral, cold compound – Group1, total 3 male (bile duct cannulated) rats, one dose level. – The bile samples will be collected from the bile duct cannula at periods of 0-72 hours post dosing, 7 intervals, 3 male /interval. – Group 2, total 3 intact male rats, one dose level. – The urine and feces samples were collected at periods of 0-168 hours post dosing, 9 intervals, 3 male /interval – PK calculation. Conc., PK parameters, BA data reported in MS Excel report format and MS Word report format.	$6,050	
A18-Optional	Option: – Group 3, total 3 male rats, one dose level. – Serial bleeding at: 5, 15, 30 min, 1, 2, 4, 6, 8, 24, 48 hr post dosing per animal.	$1,450	

A19	Mouse Mass balance, single oral, cold compound – Group1, total 3 male (bile duct cannulated) mice, one dose level. – The bile samples will be collected from the bile duct cannula at periods of 0-72 hours post dosing, 7 intervals, 3 male /interval. – Group 2, total 3 intact male mice, one dose level. – The urine and feces samples were collected at periods of 0-168 hours post dosing, 9 intervals, 3 male /interval – PK calculation. Conc., PK parameters, BA data reported in MS Excel report format and MS Word report format.	$6,200	
A20-Optional	Option: – Group 3, total 6 male mice, one dose level. – Alternating bleeding at: 5, 15, 30 min, 1, 2, 4, 6, 8, 24, 48 hr post dosing per animal. Total 30 mouse plasma samples.	$2,110	
A21	In vivo Metabolite profiling/identification in urine, feces, bile and plasma samples – Sample provided from male rat mass balance or other studies. – Metabolite profiling and identification in plasma, urine, feces and bile (4 samples). – MS Word report	$24,550	
A22	In vivo Metabolite profiling/identification in urine, feces, bile and plasma samples – Sample provided from male mouse mass balance or other studies. – Metabolite profiling and identification in plasma, urine, feces and bile (4 samples). – MS Word report	$24,550	
List of *in vitro* ADME, Met ID studies-These studies will be performed and invoiced in New Jersey		**$285,580**	
A23	Plasma stability	$4,300	

	1. Frozen plasma from 5 species (human, CD-1 mouse, SD rat, Beagle dog and Cyno monkey); 2. Test compound at one conc. (n=3); 3. Incubation for 5 time points; 4. Semi-Quantitation; 5. Experimental conditions and deliverables (%remaining, t1/2, CLint) will be reported in MS Excel report and (eCTD compatible) word report.		
A24	Plasma protein binding (HTD)	$9,300	
	1. Frozen plasma from 5 species (human, CD-1 mouse, SD rat, Beagle dog and Cyno monkey); 2. Test compound at 3 conc., (n=3), one incubation time; 3. Samples will be quantitated with calibration Curve; 4. Experimental conditions and deliverables (fb, fu, %recovery) will be reported in MS Excel report and (eCTD compatible) word report.		
A25	Blood to plasma partitioning (direct method) assay	$6,300	
	1. 3 species (human and two preclinical species); 2. Test compound at 3 conc., (n=3), one incubation time; 3. Semi-Quantitation; 4. Experimental conditions and deliverables (B/P partition ratio) will be reported in MS Excel report and (eCTD compatible) word report.		
A26	Liver Microsomes metabolic stability	$4,300	
	1. 5 species (human, CD-1 mouse, SD rat, Beagle dog and Cyno monkey); 2. Pooled liver microsomes, protein concentration at 0.5 mg/mL; 3. Test compound at 1 conc. (n=3); 4. Incubation for 6 time points;		
	5. Semi-Quantitation; 6. Experimental conditions and deliverables (%remaining, t1/2, CLint) will be reported in MS Excel report and (eCTD compatible) word report.		
A27	Hepatocyte metabolic stability	$10,300	

	1. 5 species (human, CD-1 mouse, SD rat, Beagle dog and Cyno monkey); 2. Pooled (N>=3) male hepatocytes for mice, rats, dogs, and monkeys and mixed genders for human hepatocytes, at 1.0 million cells/mL; 3. Test compound at 1 conc. (n=3); 4. Incubation for 6 time points; 5. Semi-Quantitation; 6. Experimental conditions and deliverables (%remaining, t1/2, CLint) will be reported in MS Excel report and (eCTD compatible) word report.		
A28	CYP inhibition (DI+TDI)	$24,500	
	1. Pooled human liver microsomes; triplicate assay; - Pre-study: Solubility confirmation (at the highest testing conc.) in assay buffer by LC/MS 2. Test compound at 7+1 (VC) concentrations; 3. 7 CYPs (1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 3A4/5), 8 individual substrates (two for 3A4/5) discrete incubations. VC, PC (1 conc); 4. Direct and time-dependent inhibition (± 30-min pre-incubation) in the presence of NADPH; 5. Quantitative bioanalysis of metabolite of each CYP-specific probe substrate in human liver microsomes by LC-MS/MS. 6. Reporting: • Study protocol with experimental designs in WuXi protocol template; • Full data QC; • Detailed experimental conditions and deliverable (% activity remaining, IC50 values† and IC50 shift when applicable) will be in CRO standard format (eCTD compatible) MS Word report. Report conforming to Sponsor report template may require additional charges. *Note: .Approximate Ki values or Ki values and inhibition mechanism are available as follow up.		
A29	CYP induction	$29,370	

	1. CYP1A2 (AhR mediated), CYP2B6 (CAR mediated) and CYP3A4 (PXR mediated). CYP2C may be evaluated as a follow-up assay when positive results for CYP3A4 (see details below). 2. Pre-study assay: Solubility confirmation (the highest testing concentration) in culture medium. 3. Plateable cryopreserved human hepatocytes (CYP induction qualified) from three (3) donors 4. TA at 3 concentrations, triplicate measurements. Additional TA concentrations options available for request. 5. Positive (known inducers), negative (known non- inducer), vehicle controls. 6. 48-72 hr incubation (72 hr as default, adjustable based on pre-study viability optional assay see below details) 7. mRNA expression levels of CYP1A2, 2B6 and 3A4 (CT method using GAPDH as the reference gene and vehicle control samples as the base line) and viability measurement at the end of induction incubation. Concentration of TA in incubation medium on last dosing day. Reporting: 8. Study protocol with experimental designs in WuXi protocol template 9. Full data QC 10. Experimental conditions and deliverables (CT values, induction fold, % of PC, % viability, etc. as applicable) will be in CRO standard format (eCTD compatible) MS Word report. Option 1: Pre-study: cell viability Option 2: Enzyme activity endpoint for CYP1A2, 2B6 and 3A4/5 at 3 Concentrations		
A30	CYP phenotyping study (substrate Depletion or metabolite formation)	$31,460	

	1. CYP panel (1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 3A4/5). Triplicate; 2. Linearity conditions (protein concentration and incubation time) determination (PC & NC); 3. Use of Chemical Inhibitors (1 inhibitor conc.) for CYP Phenotyping (PC & VC) under linear condition at one TA conc; 4. Recombinant CYPs (8 CYP isozymes, 1 protein conc.) to evaluate TA (1 conc.) metabolism (5-6 time points) (PC & NC); 5. Substrate depletion or metabolite formation monitoring by LC/MS; 6. Formal LC-MS/MS method qualification for parent or metabolite and report Reporting: 7. Study protocol with experimental designs in WuXi protocol template, Full data QC 8. Detailed methodology and deliverables (% remaining, linear conditions, Michaelis-Menten parameters, % inhibition, elimination rate, t1/2, fm, CYP, etc, as applicable) will in CRO standard format (eCTD compatible) MS Word report. Note: optional enzyme kinetics can be requested with additional cost		
A31	Metabolite profiling/identification in liver microsomes	$25,450	

	1. Pooled liver microsomes; 2. 5 species (human, CD-1 mouse, SD rat, Beagle dog and Cyno monkey); 3. Test compound at 1 conc. (e.g. 10 µM) (n=1), 2 time points (0 and 60 min); 4. Positive control; 5. LC-UV/HRMS metabolite analysis; 6. Metabolites (>1% of parent based on UV or MS in each species and report no more than 8 metabolites in general); 7. Relative abundance by MS peak area for all species; 8. Cross species comparison; 9. Metabolic pathways; 10. Experimental conditions and deliverables (metabolism profile/ID, % by UV) will be reported in study summary and (eCTD compatible) word report.		
A32	Metabolite Identification in Hepatocytes	$35,500	
	1. Five species (mouse, rat, dog, monkey, and human, all males); 2. Pooled (N>=3) male hepatocytes for mice, rats, dogs, and monkeys and mixed genders for human hepatocytes; 3. Incubation for 0 and 4 hr at 10 uM in singlet; 4. Positive control; 5. LC-UV/HRMS metabolite analysis in hepatocytes; 6. Metabolites (>1% of parent based on UV or MS in each species and report no more than 8 metabolites in general); 7. Relative abundance by MS peak area for all species; 8. Cross species comparison; 9. Metabolic pathways; 10. Experimental conditions and deliverables (metabolism profile/ID, % by UV) will be reported in study summary and (eCTD compatible) word report		
A33	Permeability and Efflux Potential Evaluation in Caco-2 Cells	$7,900	

	1. Human Caco-2 cells; 2. Triplicate measurements at 3 non-zero concentrations; 3. Both A to B and B to A directions with and without GF-120918, an efflux inhibitor; 4. 120 min incubation; • Lyse monolayer cells at the end of incubation and measure test article in lysate 5. Sample will be quantified using a calibration curve; 6. Papp, efflux ratio, recovery, experimental conditions will be reported in MS Excel report and (eCTD compatible) word report.		
A34	Transporter Inhibition on Transfected Cell Line (Full FDA panel, MDR1/BCRP/7 SLCs) (EMA Panel available)	$34,400	
	1. Triplicate assays; Solvo Cell Lines - Pre-study: Solubility confirmation (at the highest testing conc.) in assay buffers used in permeation and cellular uptake transport assays 2. Cellular (permeation) efflux assays for MDR1, BCRP: Bi-directional permeability (efflux ratio) of probe substrates ± TA (2 conc.) in MDCKII-MDR1 & - BCRP cells. PC, VC, background controls (MDCKII), monolayer integrity controls (during and post assay), and recovery of probe substrates; 3. SLC Cellular uptake inhibition assays (IC50) for OATP1B1, OATP1B3 (30-min pre-incubation for OATP1B1/3), MATE1, MATE2-K, OAT1, OAT3, OCT2. PC, VC, and NC (background control); 4. Experimental conditions and deliverables (% activity remaining, inhibition, recovery, monolayer integrity, IC50), will be reported in (eCTD compatible) Word report. Note: BSEP, OCT1 and other transporters are available upon request		
A35	Transporter Substrate on Transfected Cell Line (cold TA) (Full FDA Panel, MDR1/BCRP/7 SLCs) (EMA Panel available)	$62,500	

	1. Triplicate assays; Solvo Cell Lines - Pre-study: Solubility confirmation (at the highest testing conc.) in assay buffers used in permeation, cellular uptake and vesicular transport assays, if conducted 2. Cellular (permeation) efflux assays for MDR1/BCRP: • Bi-directional permeability (efflux ratio, net flux ratio) of TA (3 TA conc.) in MDCKII, MDCKII-MDR1 and MDCKII-BCRP cells. Functional, positive and background (MDCKII) controls, monolayer integrity controls (during and post assay), substrate recovery. 3. Cellular uptake substrate assays for OATP1B1, OAT1B3, MATE1, MATE2-K, OAT1, OAT3, OCT2 : Transporter-mediated uptake of TA (4 conc.). Functional, positive and background controls, protein measurements. Transporter-mediated uptake of TA ± reference inhibitor will be performed In case of a ≥ 2-fold of transporter-mediated TA uptake.		
	4. LC-MS/MS method qualification (calibration curves with QC) in in vitro matrices: permeation buffer and cell lysates (Additional tests and details below); will be reported in CRO standard format (eCTD compatible) MS Word report. Note: BSEP, OCT1 and other transporters are available upon request		
Total for DMPK (excluding the optional)		**$465,605**	
PART B【Toxicology】			
Formulation analysis		**$15,500**	**Note**

B1	Method development and verification of an HPLC method for the determination of test article in dose formulation (1 vehicle 1 analyte 1 method)	$7,000	$1,000 per day, if longer than 7 days
B2	Method validation of an HPLC method for the determination of test article in dose formulation (1 vehicle 1 analyte 1 method)	$8,500	
Bioanalysis		**$221,725**	
B3	Rat: Bioanalysis of an LC-MS/MS method transfer for the determination of test article concentration in plasma-GLP-MT (1 analyte 1 method)	$9,450	
	Mouse: Bioanalysis of an LC-MS/MS method transfer for the determination of test article concentration in plasma-GLP-MT (1 analyte 1 method)	$9,450	
	Dog: Bioanalysis of an LC-MS/MS method transfer for the determination of test article concentration in plasma-GLP-MT (1 analyte 1 method)	$9,450	
	1. Optimize LC and MS method, sample extraction method, calibration curve, 2. Sensitivity, specificity and selectivity (endogenous interference and interference between analytes), 3. Extraction recovery, matrix effect, matrix effect in hemolyzed matrix, dilution integrity, carryover, 4. Stability (solution, matrix, whole blood, freeze/thaw, reinjection, and processed sample), 5. Two Accuracy and precision (two sets of standard curve, six sets of quality control), batch size.		
B4	Rat: Bioanalysis of an LC-MS/MS method validation for the determination of test article concentration in plasma (MV) (1 analyte 1 method)	$27,825	

	Mouse: Bioanalysis of an LC-MS/MS method validation for the determination of test article concentration in plasma (MV) (1 analyte 1 method)	$27,825	
	Dog: Bioanalysis of an LC-MS/MS method validation for the determination of test article concentration in plasma (MV) (1 analyte 1 method)	$27,825	
	1. Calibration curve, at least 3 accuracy and precision runs (two sets of standard curve, six sets of quality control), batch size, 2. Sensitivity, specificity and selectivity (endogenous interference of blank matrix and hemolyzed matrix, interference between analytes), 3. Extraction recovery, matrix effect (blank matrix and hemolyzed matrix) 4. Dilution effect, 5. Carryover in analytical runs, 6. Processed sample stability under auto-sampler storage conditions, 7. Reinjection stability under auto-sampler storage conditions, 8. Short term stability in matrix: 3 or 5 cycles freeze/thaw and bench-top stability, 9. Solution stability: bench-top and 1 month stability, 10. Whole blood stability (DQC, HQC, LQC): 1 time point. 11. Long-term stability (1 species, 1 analyte, 2		
	timepoints) 12. Method validation report		

B5	TK Sample Analysis for MTD+14 days in rat plasma (276+28 samples (10% reassay sample))-non-GLP SA (1 analyte 1 method)	$14,400	
	TK Sample Analysis for MTD+14 days in mouse plasma (study sample+ (10% reassay sample))-non- GLP SA (1 analyte 1 method) 276+28 samples	$14,400	
	TK Sample Analysis for MTD+14 days in dog plasma (184+20 samples (10% reassay sample))-non-GLP SA (1 analyte 1 method)	$9,600	
	1. two sets of calibration curve (each batch), two sets of quality control (each run) 2. DQC*3 3. None report, provide Excel version BA data 4. None QA		
B6	TK Sample Analysis for 28-day in rat plasma (276+56 samples (10% reassay sample +10% ISR sample)) -GLP SA (1 analyte 1 method)	$22,200	
	TK Sample Analysis for 28-day in mouse plasma (study sample+ (10% reassay sample +10% ISR sample)) -GLP SA (1 analyte 1 method) 276+56 samples	$22,200	
	TK Sample Analysis for 28-day dog plasma (348+70 samples (10% reassay sample +10% ISR sample)) - GLP SA (1 analyte 1 method)	$27,100	
	1. two sets of calibration curve (each batch), two sets of quality control (each run) 2. DQC*3 3. GLP sample analysis report		
General Toxicology		**$606,220**	
B7	Acute Maximum Tolerated Dose and 14-Day Repeated Oral Dose Range Finding Toxicity Study in Rats (Non-GLP)	$49,090	

	1. SD rat from certified supplier 2. Phase I:3/sex/group,total 5 escalating groups; 3. Phase II:Main Study: 5/sex/group, TK: 6/sex/group for low, mid, high dose group and 3/sex/group for control group, total 4 groups. 4. Phase II slides (control and high group) read by WuXi staff pathologist 5. 276+28 TK samples 6. SEND data		
B8	Acute Maximum Tolerated Dose and 14-Day Repeated Oral Dose Range Finding Toxicity Study in Mice (Non-GLP)	$49,820	
	• CD-1 mouse from certified supplier • Phase I: 5/sex/group, total 5 escalating groups; Phase II: Main Study: 5/sex/group, TK: 6/sex/group for low, mid, high dose group and 3/sex/group for control group, total 4 groups. • Phase II slides (control and high group) read by WuXi staff pathologist • 276+28 TK samples • SEND data		
B9	A Maximum Tolerated Dose and 14-Day Range Finding Oral Gavage Toxicity Study in the Beagle Dog (Non-GLP)	$99,510	
	1. Dogs from certified supplier 2. Phase I:2/sex/group,escalating doses; 3. Phase II:2/sex/group for low, mid, high dose group and control group.		

	4. Phase II slides read by WuXi staff pathologist 5. 184+20 TK samples 6. SEND data		
B10	28-Day Repeated Oral Dose Toxicity and Toxicokinetics Study in Rats with a 14-Day Recovery Period (GLP)	$115,850	
	1. Rats from certified supplier 2. 4 groups. Main Study: 10/sex/group, recovery: 5/sex/group (control and high group), TK: 6/sex/group for low, mid, high dose group and 3/sex/group for control group 3. Slides (control and high group) read by ACVP board certified pathologist. Photo will be at additional cost 4. 276+56 TK samples 5. SEND data		
B11	28-Day Repeated Oral Dose Toxicity and Toxicokinetics Study in Mice with a 14-Day Recovery Period (GLP)	$113,720	
	• CD-1 Mouse from certified supplier • 4 groups. Main Study: 10/sex/group, recovery: 5/sex/group (control and high group), TK: 6/sex/group for low, mid, high dose group and 3/sex/group for control group • Slides (control and high group) read by ACVP board certified pathologist. Photo will be at additional cost • 276+56 TK samples • SEND data		
B12	28-Day Repeated Oral Dose Toxicity and Toxicokinetics Study in Dogs with a 14-Day Recovery Period (GLP)	$178,230	

	1. Dogs from certified supplier 2. 4 groups. Main Study: 3/sex/group, recovery: 2/sex/group (control and high group) 3. Slides read by ACVP board certified pathologist. Photo will be at additional cost 4. Dogs ECG read by US board certified vet 5. 348+70 TK samples 6. SEND data		
Total for Toxicology		**$843,445**	
Part C【Dossier preparation and submission】			
Pre-IND Meeting		**$27,000**	
C1	**Pre-IND Meeting-FDA filing** 1) Registration strategy supports 2) Pre-IND meeting planning 3) Be the representative for pre-IND meeting 4) Meeting request preparation 5) Briefing document preparation (Briefing document will be provided by client if the dossier is not prepared by wuxi) 6) Meeting minutes 7) Response to the agency's recommendations	$27,000	
Dossier Preparation-FDA filing		**$131,000**	
C2	1. Regional administrative information (Module 1, exclude 1.14 and 1.20 for FDA)-FDA filing	$35,000	
C3	4. Non-clinical Sections and related regulatory issue analysis (Module 2.4)-FDA filing	$23,500	
C4	5. Non-clinical Sections (Module 2.6)-FDA filing	$23,500	
C5	6. Clinical study synopsis (First in human)-FDA filing	$3,000	
C6	7. Clinical Sections (Module 2.5(clinical overview) and Module 5 (protocol, ICF), include IB and clinical investigational for FDA)	$46,000	
Regulatory Submission-FDA filing		**$20,000**	
C7	**Regulatory Submission-FDA filing** 1) Manage and overall review of dossier 2) eCTD submission (eCTD/file compilation, validation and submission) 3) Help to address the information request and comments from the authorities	$20,000	

Sub Total for Dossier preparation and submission	**$178,000**	
Total Price (excluding the optional)	**$1,487,050**	

Exhibit C—Toxicology Services

1. **Animal Facility.** Contractor shall (a) provide space that is sufficient for an appropriate number of animal cages to be maintained in accordance with standard laboratory practice and applicable law (the "**Animal Facility**") and (b) house the animals in the Animal Facility, and use and dispose of them in accordance with applicable law.

2. **Records Retention.** Upon termination of the Agreement, Contractor shall, at VCU's option, (a) destroy the Records, (b) deliver the Records to VCU, or (c) retain the Records. If the Records are to be destroyed, then (x) Contractor shall give 30-days' written notice to VCU, and VCU may elect during the 30-day period to have the Records transferred to it and (y) Contractor may require VCU to provide a waiver reasonably satisfactory to Contractor prior to the destruction. If the Records are to be retained, then the Records will be retained at no cost to VCU for the first year, and for a fee thereafter. Notwithstanding the foregoing, the Records may be retained as required by applicable law or as otherwise necessary for regulatory or insurance purposes.

3. Postponement

3.1. For a postponement before animals are ordered, VCU will not be charged other than, to the extent applicable, for non-cancellable obligations in accordance with section 6 below.

3.2. For a postponement after animals are ordered, if Contractor is unable to cancel the animal vendor delivery, charges may be assessed at a rate of USD 10,000 per room per week for Toxicology Services. Charges may also be assessed for technical work such as surgical preparation or other scientific procedures that are required to maintain the integrity of the study, as well as, to the extent applicable, for non-cancellable obligations in accordance with section 6 below.

4. Termination

4.1. For termination prior to animal arrival, Contractor shall make commercially reasonable efforts to repurpose the animals. If Contractor is unable to repurpose the animals, charges will be assessed for such animal costs.

4.2. For termination after animal arrival but prior to initiation of dosing, Contractor shall make commercially reasonable efforts to repurpose the animals. If Contractor is unable to repurpose the animals, charges will be assessed for such animal costs as well as the room charge of USD10,000 per room per week from the date of animal arrival until the notice of termination was provided to Contractor.

4.3. For termination after initiation of dosing, charges will be assessed for the prorated protocol price plus the animal cost.

5. **Non-cancellable obligations.** In the event of postponement, suspension or termination, additional charges may be assessed for non-cancellable obligations incurred prior to postponement or termination, which may include items procured specifically for the study

such as dedicated equipment and perishable or non-reusable supplies, and for non-recoverable expenses such as equipment lease payments, subcontractor charges and consultant fees. Notwithstanding the foregoing, Contractor shall make commercially reasonable efforts to reallocate such resources and mitigate the above-noted expenses.

6. Contractor shall credit VCU for amounts paid by VCU in excess of any service charge or expense incurred.

Exhibit D—GMP Services

This Exhibit D and only applies in respect of the provision of GMP Services (as defined below).

1 Definitions. For purposes of this Exhibit D, the following terms will have the following meanings:

1.1 "**API/Drug Substance**" means the active pharmaceutical ingredient or drug substance identified in the Agreement.

1.2 "**Batch**" means a specific quantity of the Product produced during the same cycle of Manufacture and intended to be of uniform character and quality as defined by the Master Batch Record, and memorialized in a Batch Record.

1.3 "**Batch Record**" means the final documented record prepared in accordance with cGMP for the Manufacture and disposition of a Batch of Product.

1.4 "**Certificate of Analysis**" means a document signed by an authorized representative of Contractor, describing Specifications for, and testing methods applied to, Product, and the results of testing.

1.5 "**cGMP**" means current good manufacturing practices and regulations applicable to the Manufacture of Product that are enacted or promulgated by any competent government authority including statutory and regulatory requirements, and guidance of a competent government authority published from time to time interpreting such requirements.

1.6 **"GMP Services"** means the Manufacturing of Product in compliance with cGMP, as applicable, as described in the Agreement.

1.7 **"Manufacture"** and **"Manufacturing"** means any steps, processes and activities necessary to the production of the Product in final form, including purchasing component materials, subcontracting or performing services, manufacturing, processing, formulating, quality control testing, stability testing, quality assurance release, cleaning, maintenance, storage and other facility-related activities, labeling, packaging, handling and shipping.

1.8 "**Manufacturing Process**" means any and all processes and activities (or any step in any process or activity) used or planned to be used by Contractor to Manufacture Product.

1.9 "**Master Batch Record**" means the documents that specify the complete set of formal instructions and procedures for the Manufacturing Process, as mutually developed and approved by the Parties.

1.10 "**Product**" means any API/Drug Substance or drug product comprised of API/Drug Substance in each case as specified in the Agreement, including, if applicable, bulk packaging and/or labeling as provided in the Agreement.

1.11 "**Quality Agreement**" means the agreement entered into by the Contractor and VCU, with respect to the quality-control related activities, including but not limited to compliance with cGMP, analytical test methods, Product release procedures, and acceptance criteria applicable in connection with the Product.

1.12 **"Reprocess"** and **"Reprocessing"** means introducing a Product back into the process and repeating appropriate manipulation steps that are part of the established Manufacturing Process, and for clarity, does not include the continuation of a process step after an in-process control test showing the process to be incomplete.

1.13 **"Rework"** and **"Reworking"** means subjecting Product to one or more processing steps that are different from the established Manufacturing Process.

1.14 **"Specifications"** means the specifications of the Product, along with the set of analytical test methods and acceptance criteria applicable thereto, as set forth in the Agreement or the Quality Agreement, as may be amended from time to time in accordance with this Agreement and the change control procedures in the Quality Agreement.

2 Manufacturing and Compliance.

2.1 **Specifications and Manufacturing Process.** Contractor shall Manufacture each Product in accordance with (a) all mandatory governmental licenses and permits relating to the Manufacturing of the Product in material aspects; (b) all applicable law; and (c) the written Specifications for the Product and the Manufacturing Process. VCU may modify the Specifications and Manufacturing Process; provided, however, that Contractor's consent is required for any modification to the Specifications and Manufacturing Process. VCU shall pay the increased costs as a result of the modification made to Specifications and Manufacturing Process.

2.2 **Conflict Between Documents.** If, with respect to GMP Services, there is any conflict, discrepancy, or inconsistency between the terms of this Exhibit D and the Agreement, the terms of this Exhibit D will control. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement or the Quality Agreement, or other document or form used by the Parties, the terms of this Agreement will control; provided, however, that if the Quality Agreement contains provisions that are more specific with respect to technical and quality matters, such terms in the Quality Agreement will supersede the more generalized provisions in this Agreement.

2.3 **Regulatory Assistance.** To the extent applicable, Contractor shall, at VCU's cost, provide VCU with all supporting data and information relating to Manufacturing that is reasonably necessary for applying for and maintaining regulatory approvals relating to a Manufacturing.

3 Quality Release.

3.1 **Contractor Quality Release.** Product may not be delivered to VCU until a person authorized by Contractor having the necessary qualifications, experience and authority to oversee quality assurance of the Manufacture and review and determine the suitability of individual Batches for release under applicable law has (a) conducted analyses using the analytical methods agreed to in writing by the Parties, (b) executed the Certificate of Analysis applicable to the Product and such other Batch documentation that may be requested by VCU and (c) completed any other certifications or documents and other activities that may be required to release the Product under applicable law and the Quality Agreement.

3.2 **Storage.** Prior to delivery, all Product at the facility will be stored in a clean, secured, segregated area. For each Product that has been stored for more than three (3) months after the execution of the Certificate of Analysis for such Product, Contractor will charge VCU storage fees ("**Storage Fees**") at a monthly rate of USD200 per 1200*1200 mm pallet in normal storage condition. Rates for special storage condition will be defined in the Agreement. The Storage Fees are subject to periodic review and adjustment by Contractor. VCU agrees that it is responsible to insure such Products against damage or loss and shall purchase appropriate insurance to cover its Products stored in Contractor facilities.

4 Warranty; Non-Conforming Product.

4.1 **Warranty.** Contractor warrants to VCU that each Product supplied will have been Manufactured in accordance with, and will comply with, this Agreement, the Specifications and applicable law (the "**Warranty**"); provided, that the Warranty is not applicable to any non-conformance attributable to reasons other than Contractor's failure to perform its Manufacturing obligations in accordance with this Agreement, and the Quality Agreement.

4.2 **Non-Conformance.** VCU may only reject a shipment of a Product if, within thirty (30) days after receiving the shipment, (a) VCU conducts a quality inspection and reasonably determines that the Product does not conform to the Warranty, (b) notifies Contractor in writing that the Product does not conform and (c) provides supporting documentation. A shipment that is not rejected pursuant to the preceding sentence will be deemed accepted by VCU.

4.3 **Disputes.** If the Parties are unable to agree as to whether a Product conforms to the Warranty, VCU shall send a sample of the Product for testing at an independent quality control laboratory chosen by Contractor and reasonably acceptable to VCU. The findings of the laboratory will be binding on the Parties. The cost of inspections and testing by the laboratory will be shared equally by each Party.

4.4 **Reimbursement and Refund.** Except to the extent attributable to defects in VCU Material or Manufacturing Process provided by VCU, if Contractor agrees that, or the independent laboratory finds that, any delivery of Product does not conform to the Warranty, and such deviation is determined to arise from Contractor's failure to comply with the Manufacturing responsibilities of Contractor, Contractor shall, at its option, either (a) Rework or Reprocess

the Product, at Contractor's cost and expense, so that the Batch can be deemed to have been Manufactured in compliance with applicable laws and the Quality Agreement, and to conform to Specifications; or (b) supply to VCU a replacement for such non-conforming Product within a time period that is acceptable to VCU. If such Rework or Reprocess is not possible or is reasonably disapproved by VCU and Contractor is not able to supply replacement Product within an agreed period of time, then Contractor will, reimburse VCU the payment received by Contractor in respect of the non-conforming Product and any reasonable and reasonably documented out-of-pocket costs associated with disposing or returning such non-conforming Product paid by VCU. Notwithstanding the foregoing, (i) unless the non-conformance is solely caused by gross negligence or willful misconduct of Contractor, the cost covered by Contractor under this Section 4.4 shall not include the cost of any Materials; and (ii) with regards to any Services that involve using a VCU Material, the cost covered by Contractor under this Section 4.4 shall not include the cost of such VCU Material under any circumstances.