UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): March 12, 2020

GALECTIN THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-31791**	**04-3562325**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4960 PEACHTREE INDUSTRIAL BOULEVARD, STE 240
NORCROSS, GA 30071
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (678) 620-3186

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	**GALT**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On March 12, 2020, Galectin Therapeutics Inc. ("Galectin") entered into a Master Services Agreement (the "MSA") with Covance Inc., pursuant to which Covance will serve as the contract research organization for Galectin for its upcoming clinical trials. Also on March 12, 2020 Galectin and an affiliate of Covance Inc. entered into a related Work Order (the "Work Order") for the first clinical trial, a hepatic impairment study that will run in parallel with the Company's phase 2b/3 trial as part of the Phase 3 development program. The cost of the hepatic impairment study is $2.039 million. The MSA also provides for additional contract research organization services to be provided to Galectin by Covance pursuant to additional work orders that may be entered into between Galectin and Covance during the term of the MSA, on the terms and conditions set forth in the MSA.

The term of the MSA is five years from the March 12, 2020 effective date, with automatic one year renewals unless notice of termination is provided sixty days in advance of the expiring term, unless earlier terminated pursuant to the terms of the MSA. The Work Order's term expires upon completion of the services contemplated under the Work Order, unless earlier terminated pursuant to the terms of the MSA.

The foregoing description of the MSA and Work Order is a summary only and is qualified by reference to the full text of the MSA and Work Order. The MSA and Work Order are attached hereto as Exhibits 10.1 and 10.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	
10.1	Master Services Agreement, effective as of March 12, 2020, by and between Galectin Therapeutics, Inc. and Covance Inc.*
10.2	Work Order, dated as of March 12, 2020, by and between Galectin Therapeutics, Inc. and Covance Clinical Research Unit Inc.*

* Certain portions of the exhibit have been omitted pursuant to Regulation S-K Item 601(b) because it is both (i) not material to investors and (ii) likely to cause competitive harm to the Company if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Galectin Therapeutics Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Galectin Therapeutics Inc.

Date: March 17, 2020

By: /s/ Jack W. Callicutt
Jack W. Callicutt
Chief Financial Officer

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (1) NOT MATERIAL AND (2) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

COVANCE MASTER SERVICES AGREEMENT

This Master Services Agreement is effective as of March 12, 2020 ("**Effective Date**") by and between

(1) **Covance Inc.** whose registered office is at 206 Carnegie Center, Princeton, NJ 08540 USA (the **Company**); and

(2) **Galectin Therapeutics Inc.** whose registered office is at Suite 240, 4960 Peachtree Industrial Boulevard, Norcross, Georgia 30071 USA (the **Sponsor).**

(each a **Party** and collectively the **Parties**).

RECITALS

(A) WHEREAS, the Sponsor develops drugs.

(B) WHEREAS, Company, through itself and its Affiliates (as defined below), provides a wide range of product development and testing services on a worldwide basis to the biotechnology, pharmaceutical and medical device industries, including, without limitation, preclinical efficacy and safety laboratory services, Phase I, II, III and IV clinical services, periapproval services, central laboratory services, health economics services, market access and commercialization and biotechnology services.

(C) WHEREAS, the Sponsor desires to contract with Company and/or its Affiliates for the purpose of providing services to assist the Sponsor in the execution of various projects.

(D) WHEREAS, when the Sponsor requests the services of the Company or any of its Affiliates, and the Company or its Affiliate is able to provide such services, the relevant parties shall enter into a separate service contract in accordance with this Agreement (as defined below).

(E) WHEREAS, each such separate contract shall be a Work Order (as defined below) each of which shall incorporate the terms and conditions set out in this Agreement.

IT IS AGREED

1 DEFINITIONS

1.1 In this Agreement, unless the context otherwise requires, the following words and expressions shall have the following meanings:

"**Affiliate**" means any entity controlling, controlled by, or in common control with a Party. For the purposes of this definition, "**Control**" shall mean ownership or control, directly or indirectly of more than fifty per cent (50%) of the common voting stock or ordinary shares in the entity or the right to appoint fifty per cent (50%) or more of the directors of that entity. With respect to the Company, the term Affiliate shall include Laboratory Corporation of America Holdings and any business entity that is controlled by or under common control with Laboratory Corporation of America Holdings.

"**Agreement**" means this MSA and any applicable Exhibit A.

"**Anti-Corruption Laws**" means any anti-bribery and anti-corruption laws, rules, regulations applicable to either Party (each as amended from time to time) including the Prevention of Corruption Act (Cap. 241) of Singapore, the US Anti-Kickback Law, the US Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions, together with any applicable implementing legislation, including any applicable local law addressing bribery or corruption.

"**Assumptions**" means any General Assumptions and any Study/Services Specific Assumptions.

"**Background IP**" means all pre-existing intellectual property belonging to or licensed to a Party or other intellectual property created outside the scope of the Services.

"**Budget**" means the fees and estimated pass through costs charged and/or incurred by Covance in the performance of the Services or Study as set out in a Work Order.

"**CFR**" mean the US Code of Federal Regulations.

"**Change Order**" has the meaning given in Section 10.

"**Claim**" means any third party claims, demands, assessments, actions, suits, proceedings, settlements or investigations.

"**Confidential Information**" means any and all commercial or technical information or materials and all derivatives thereof, in any and all forms, howsoever disclosed or obtained including business plans, financial information, client lists and requirements, techniques, designs, methods, processes and procedures which: (i) is identified by a suitable legend or other marking as being confidential (or similar designation) in a suitable prominent position; (ii) is described as confidential at the time of disclosure; or (iii) the Receiving Party regards or should reasonably be expected to regard as proprietary and confidential given the nature of the information and the reasonable efforts under the circumstances used to maintain its confidentiality; and any improvements, enhancement or modification made, conceived or developed thereto.

"**Covance**" means the Company and each Company Affiliate that signs an Exhibit A and thereby becomes a Party to this Agreement.

"**Covance Property**" means inventions, proprietary processes, software (including codes) data, technology, know-how and other intellectual property that have been independently developed, discovered or licensed by Covance, including those that relate to the proprietary innovative testing procedures, laboratory testing, data collection or data management, procedural manuals, delta flags, nucleic acid based vectors, analytical procedures and approaches (even if such are developed in the course of providing the Services or are captured in documents pertaining to the Services i.e. laboratory notebooks), techniques, skills, models, multimedia source codes, non-product specific components of questionnaires, management tools and any other materials, employed, developed or obtained by Covance, which are developed independently and not developed as a result of the Services or a Work Order, or based on the Sponsor's Confidential Information.

"**Data Protection Laws**" mean all applicable privacy, data protection or similar laws and regulations anywhere in the World, as the same may be amended from time to time, including to the extent applicable to the respective Services, the Data Protection Directive (95/46/EC), the Personal Data Protection Act 2012 of Singapore and any applicable implementing legislation or any amendment thereto and especially from 25 May 2018, the EU Personal Data Regulation (2016/679/EU) (which repeals Directive 95/46/EC) and the EU Personal Data Directive (2016/680/EU).

"**Delay**" means a delay, suspension or postponement of the Services and "**Delayed**" shall be construed accordingly.

"**Deliverables**" means as applicable to the Services, Results, Study Records or any other deliverable specified in the Work Order (including physical products).

"**Disclosing Party**" means a Party that discloses Confidential Information.

"**Exhibit A**" means the additional terms and conditions of a Company Affiliate which is executed by the Sponsor and a Company Affiliate and attached to this MSA. If more than one Company Affiliate is a party to this MSA, Exhibit A shall be numbered sequentially beginning with Exhibit A-1 and continuing as necessary.

"**FDA**" means the US Food and Drug Administration.

"**Financial Interest Claims**" means any claims related to the financial interest of a third party with whom the Sponsor has entered into an agreement for the development, licensing, and/or commercialization of the Test Materials and who has a financial interest in the outcome of the development of such Test Materials.

"**Force Majeure Event**" means any force majeure event as recognized by applicable law, but for the purposes of this Agreement, shall include all circumstances or causes beyond the reasonable control of a Party, including war, threat of war or warlike conditions, blockade, embargo, fire, explosion, lightning, storm, drought, flood, earthquake or other natural disaster, pandemic or epidemic, power failure, shortage of labor or supplies, supply chain issues, strikes, lock outs, acts of terrorism, riot, civil unrest, insurrection, acts of government or other international bodies, political subdivision and any other events which by nature could not have been foreseen by the Parties or, if it could have been foreseen, were unavoidable by a reasonable prudent business.

"**General Assumptions**" means (i) the scope of the Services remains constant; (ii) the Sponsor timely performs all of its obligations under this Agreement and any applicable Work Order; (iii) the full cooperation of the Sponsor and any third party not under Covance's reasonable control in the timely performance of Covance's obligations under this Agreement and any applicable Work Order; (iv) the Sponsor refrains from any actions, inactions or omissions that would prevent Covance from performing its obligations in a timely manner; (v) the proper and timely performance of all appropriate tasks relevant to the Services by third parties outside of Covance's reasonable control; and (vi) no other event or occurrence outside of Covance's reasonable control including Force Majeure Events or a change in Regulatory Requirements which affects the Study.

"**HBS Donor**" means an individual, living or deceased, from whom the HBS was obtained.

"**Human Biological Samples**" or "**HBS**" means any human biological material, including human bodily parts and organs in whole or sub-samples, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes or sub-cellular structures, such as DNA, or any derivative or product of such human biological materials including stem cells, cell lines, bodily fluids, blood derivatives and urine.

"**IEC/IRB**" means an independent ethics committee or institutional review board.

"**Informed Consent**" means an IEC/IRB approved informed consent form signed by the HBS Donor, their next of kin or legal representative authorizing the Use of their HBS.

"**Invention**" means any patentable invention or other registerable intellectual property rights discovered, conceived or made by Covance specifically as a result of performing the Services for the Sponsor and directly relating to the Test Materials and/or the Sponsor Information. For the avoidance of doubt, any commercially available methods, processes or assays provided by or on behalf of Sponsor shall not be deemed to be Inventions or Sponsor Information for the purpose of this Agreement.

"**Investigator**" means third party principal investigators and/or investigative sites.

"**Loss**" means any loss, cost, damage or expense (including reasonable legal expenses).

"**MSA**" means this master services agreement document.

"**Personal Data**" shall have the meaning set forth in any applicable Data Protection Legislation.

"**Protocol/Scientific Plan**" means a protocol or an equivalent document, which includes a scientific plan, laboratory testing procedure or sample analysis outline, whether provided by the Sponsor or prepared by Covance under the Sponsor's direction in relation to the Services, the Study and/or relevant Work Order.

"**Receiving Party**" means a Party that receives Confidential Information.

"**Regulatory Authority**" means any national or state (in the case of the US), or local agency, authority, of any government of any country having jurisdiction over the respective activities contemplated by this Agreement or Work Order, or over the respective Parties.

"**Regulatory Requirements**" means all laws, statutes, acts, rules, regulations, codes, orders, directives or other legally binding requirements of any Regulatory Authority and industry standards or codes of conduct applicable to the Services.

"**Results**" mean: (i) all materials, data, documents and information produced or developed by Covance specifically as a result of the Services and related to the Test Materials and/or the Sponsor Information; and (ii) the Study Records (if applicable).

"**Samples**" means biological samples associated with the Services.

"**Serious Breach**" means a reportable non-compliance issue that significantly and negatively: impacts: (i) the safety or rights of an individual in a Study or (ii) the reliability and robustness of the data generated in a Study.

"**Services**" means the services and/or applicable products provided by Covance to the Sponsor as more particularly described in the Work Order.

"**Sponsor Information**" means Test Materials, data, specification or other materials or information supplied by the Sponsor to Covance in connection with the Services.

"**Study**" means a clinical trial or scientific evaluation of the Test Materials to which the Services relate as further defined in the applicable Work Order and Protocol/Scientific Plan.

"**Study/Services Specific Assumptions**" means Study or project specific assumptions set forth in the applicable Work Order.

"**Study Records**" means in relation to contracted activities, all records, notes, reports (including case report forms; monitoring logs; data correction forms; case histories; medical images; drug safety records; records of receipt, use, processing and disposition of Test Materials and trial master file) and other observations, notations or data of activities or procedures (in each case whether in a written or electronic format) which Covance obtains from each Investigator or which Covance specifically generates or produces for the relevant Study under the Regulatory Requirements, excluding the Study subject's personal medical records.

"**Subcontractor**" means a third party service provider approved, qualified, reviewed and contracted by Covance for services that are generally provided directly by Covance and which are part of the Services within the scope of this Agreement or a Work Order.

"**System Data**" means control data from laboratory tests or transactional, volume and performance data related to the Services, which does not contain any: (i) data following treatment with any Test Materials; (ii) personally identifiable information; or (iii) Sponsor Confidential Information.

"**Taxes**" means VAT/GST, local, state (in the case of the US), federal sales or use taxes, excise taxes, import tax, country specific business or professional services tax or similar tax on international services or foreign entities providing services or consumption taxes.

"**Test Materials**" means compounds, materials, other substances, devices, products or other specific items as described in the Work Order and/or Protocol/Scientific Plan to be tested or used in the performance of the Services as provided to Covance by the Sponsor or that are the subject of the Services.

"**Use**" (in the context of Section 25) means collection, storage (including retention period) transfer (including import and export), use and return or disposal of HBS including by commercial organizations.

"**VAT/GST**" means value added tax or goods and services tax.

"**Vendor**" means third-party service providers other than a Subcontractor: (i) that the Sponsor requires Covance to use; or (ii) used by Covance that are ancillary to or outside Covance's business activities. Vendors include, third party service providers of electronic data capture/bedside data capture services, specialist referral laboratories, electrocardiogram services, interactive response technology/voice response services, drug depot and drug supply services, patient recruitment services, transcription services and translation services, providers of equipment or medical devices, adjudication services, medical imaging services, 24 hour medical coverage telephone line rental, external meeting planners, third party site networks and organisations, regulatory support services and courier services.

"**Work Order**" means an individual project agreement in the form of Exhibit B or such other mutually agreed upon form between the Sponsor and Covance containing details of the Services to be provided by Covance, the Budget, any Study/Services Specific Assumptions and any additional terms, conditions or other particulars applicable to the Services.

1.2 In this Agreement, unless the context otherwise requires, references to: (a) Exhibit and Section headings are inserted for convenience only and do not affect the construction or interpretation of this Agreement; (b) defined terms used in this Agreement, and any Work Order shall have the meanings in this Agreement or the relevant Work Order; (c) a particular law or statutory provision is a reference to it as it is in force for the time being taking account of any amendment,

extension, or re-enactment and includes any subordinate legislation for the time being in force made under it; (d) **writing** or **written** includes faxes and e-mail; (e) a person includes a corporate or unincorporated body; (f) one gender includes all genders; (g) **including**, **include**, **in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms; and (h) words in the singular include the plural and vice versa.

1.3 If this Agreement is translated, the English language text and version shall prevail.

2 FORM OF CONTRACT

2.1 The additional terms and conditions that apply to the services provided by Company or a Company Affiliate (and any Work Orders thereunder) are detailed in Exhibit A. Upon execution of the relevant Exhibit A, the respective Company Affiliate shall become an additional party to this Agreement and shall be subject to the terms and conditions herein.

2.2 Each Company Affiliate that enters into a Work Order shall be bound by all applicable terms and conditions of this Agreement and of the respective Work Order to provide the relevant Services. For the avoidance of doubt and as defined above “Covance” means the Company and any Company Affiliate. Each Company Affiliate who is a Party to this Agreement shall have the respective rights and obligations of the Company under this Agreement.

2.3 The terms and conditions of this Agreement shall apply to the Work Order to the exclusion of any other terms that the Parties may seek to impose or incorporate or which are implied by trade, custom, practice or course of dealing.

2.4 Each Work Order shall: (a) be entered into by Covance and the Sponsor; (b) constitute a separate and independent contract that binds the relevant Parties; (c) incorporate the terms and conditions of this Agreement, except to the extent as otherwise agreed by the Parties; (d) incorporate by reference the Protocol/Scientific Plan which shall be deemed part of the Work Order; (e) specify the Services to be provided; (f) specify any conditions and any information required for the Services; (g) be governed by the governing law of this MSA; and (h) specify the Budget for the Services and any Study/Services Specific Assumptions relating to the Budget together with a payment schedule or payment terms.

2.5 The Sponsor acknowledges and agrees that: (a) all issues and correspondence regarding the performance of such Services should be directed to the relevant person as set out in the applicable Work Order or otherwise identified by Covance; and (b) the relevant Company Affiliate shall be solely responsible and liable to the Sponsor for any breach of the relevant Work Order.

2.6 Each relevant Protocol/Scientific Plan forms part of (and is incorporated into) this Agreement. In the event of a conflict between the Protocol/Scientific Plan and this Agreement or Work Order, the terms of the Protocol/Scientific Plan shall prevail with respect to the scientific, medical, technical and regulatory guidelines used in the conduct of the Services. This Agreement and the Work Order shall govern in all other instances.

2.7 If there is a conflict between the provisions of this MSA, Exhibit A and the provisions of a Work Order and its attachments and except to the extent that a provision with a lower priority expressly states otherwise, whereby such provision shall have a higher priority, the conflict shall be resolved by interpreting the provisions in the following order of priority: this MSA, Exhibit A, the provisions of the Work Order and any other attachments.

3 PERFORMANCE AND PROVISION OF SERVICES AND/OR PRODUCTS

3.1 Covance:

(a) Shall perform the Services with due skill and care in accordance with industry standards and the Protocol/Scientific Plan;

(b) Shall supply the Services, including any applicable products, in accordance with this Agreement and any express terms set out in the Work Order and the Protocol/Scientific Plan;

(c) Represents that Covance's databases to be used by it for the tracking, handling, recording, reporting and transmitting of data generated during the performance of the Protocol/Scientific Plan have been fully verified and validated according to applicable industry standards;

(d) Represents that it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement.

(e) Represents that it has the experience, capability and resources, including but not limited to sufficient personnel to perform the Services under any Work Order in a competent manner and that it shall at all times devote the necessary personnel to perform the Services in a competent manner.

3.2 Represents that it will provide Services and conduct all activities pursuant to this Agreement in accordance with all applicable laws, regulations and applicable guidance documents, including without limitation, 21 C.F.R. Section 312 and the International Conference on Harmonization Good Clinical Practice Guidelines and including all requirements on clinical research organizations, including as designees of trial sponsors that relate to Services provided thereunder.

3.3 Covance shall use its commercially reasonable efforts to perform the Services within the timeframe estimated in the Protocol/Scientific Plan or applicable Work Order and within the Budget established under the applicable Work Order. Sponsor agrees and acknowledges that time estimate assumes the full cooperation of the Sponsor, Regulatory Authorities, IECs/IRBs and Investigators (if applicable) and other third parties not under Covance's reasonable control. Covance shall notify Sponsor promptly whenever it becomes aware that timeframes and Budgets may not be met, and Covance shall regularly communicate with Sponsor about steps that can be taken to achieve the applicable timeframes and Budgets and to mitigate any deviations from such timeframes and Budgets.

3.4 Covance reserves the right to refuse to perform any Services including in relation to the Test Materials deemed by Covance, in its sole discretion, as hazardous in nature.

3.5 Covance does not warrant or represent that the results of the Study will be acceptable to any regulatory authority or governmental agency to which they are presented or that the results of the Study will enable Sponsor to further develop, market or otherwise exploit the Test Materials or any other product or service.

3.6 Each Party is authorized to enter into this Agreement and that its execution, delivery and performance of this Agreement will not conflict with or constitute a default under any other agreement to which it is a party or by which its assets are bound.

4 TERM

4.1 This Agreement shall come into force on the Effective Date and shall remain in force for f**ive (5) years**. Thereafter, this Agreement shall renew automatically for successive one (1) year periods unless a Party provides the other Party with written notice of its intention not to renew and extend this Agreement, such notice shall be served at least sixty (60) days prior to the commencement of any such renewal term.

4.2 Each Work Order shall come into force on the last date of execution by the Parties or such date as specified in the Work Order and shall continue until the earlier of:

(a) expiry of the period specified in the Work Order (or such extended period as the Parties may agree in writing); or

(b) completion of Covance's provision of the Services (excluding archival obligations and similar ongoing obligations which would survive in accordance with this Agreement and the respective Work Order) and the Sponsor's payment of the relevant fees, pass through costs and other applicable costs and expenses incurred by Covance in the performance of the Services; or

(c) termination of this Agreement or the Work Order pursuant to Section 21.

5 REGULATORY COMPLIANCE

5.1 Each Party shall comply in all material respects with all applicable Regulatory Requirements relevant to the Services and applicable to the location of the Services to be provided and as may be specified in the respective Work Order or Protocol/Scientific Plan. In the absence of an agreed Protocol/Scientific Plan that is applicable to the Services, the Sponsor shall notify Covance of the intended regulatory use (if any) of the Services and the applicable Regulatory Requirements to be followed by Covance in performing the Services.

5.2 In the event of a conflict in any applicable Regulatory Requirements, the Sponsor shall designate which regulations shall be followed by Covance in its performance of the Services and the Sponsor shall be fully responsible and shall indemnify Covance for the outcome of such a decision. In the event that Covance cannot perform the Services in a Work Order as directed by the Sponsor under the Regulatory Requirements or which would place the Parties at risk of a potential Serious Breach, the Parties shall work together to agree what actions should be taken to resolve the conflict. If the Parties cannot resolve the conflict, Covance reserves the right to Delay or terminate any Services potentially at risk.

5.3 If any Regulatory Requirements are changed, upon notification by the Sponsor of such change, Covance shall use its reasonable commercial efforts to satisfy such new requirements. In the event that compliance with such new requirements necessitates a change in this Agreement or a Work Order, the Parties shall agree in writing on a Change Order prior to performing any new or revised Services.

6 PROTOCOL/SCIENTIFIC PLAN

6.1 Covance shall, if required and at the Sponsor's request and expense, consult with the Sponsor and assist the Sponsor in developing the Protocol/Scientific Plan and the design of the Services consistent with current Regulatory Requirements. Notwithstanding such assistance, Covance does not warrant that the Protocol/Scientific Plan, Study design or Results shall satisfy the requirements of any Regulatory Authority at the time of submission.

6.2 The Protocol/Scientific Plan shall, to the extent applicable to the Services, specify the Study design, estimated duration, any Regulatory Authority and the country or countries to which the Sponsor intends to submit the Results and other matters pertinent to the completion of the Study or Services. Covance shall perform the Services for the Sponsor in accordance with such Protocol/Scientific Plan and the respective Work Order.

7 TEST MATERIALS

7.1 If applicable to the Services, the Sponsor shall provide Covance with sufficient amounts of any Test Materials which shall be properly packaged and (except to the extent that labelling is included within the Services under a Work Order) labelled in compliance with any Regulatory Requirements. The Sponsor shall also provide Covance with all applicable, relevant, accurate and duly authorized Sponsor Information as may be required by Covance to perform the Services, which relates to the Test Materials, including the purity, stability, batch number, storage, transportation and safety requirements or other relevant information known by the Sponsor.

7.2 Sponsor must provide Covance with all available information regarding known or potential hazards associated with the use of any substances supplied to Covance by Sponsor prior to execution of a Work Order. As an ongoing obligation, Sponsor will promptly notify Covance of the emergence of information impacting the safety of Study subjects or which otherwise impacts the toxicity assessment or risk profile of the Study product.

7.3 Sponsor represents and warrants that all necessary approvals required under Regulatory Requirements will be obtained prior to the shipment of Test Materials.

7.4 Where the nature of the Test Materials requires additional services (including risk assessment and documentation of genetically modified organisms, radiolabelled material or material requiring import or export permits), Covance reserves the right to levy a mutually agreed charge to the Sponsor for such additional services.

7.5 Upon completion of the Services, and unless otherwise agreed in the Protocol/Scientific Plan, any remaining Test Materials shall, at the Sponsor's expense, be destroyed or, upon the Sponsor's request and expense, returned to the Sponsor for retention in compliance with applicable Regulatory Requirements.

7.6 The Sponsor represents and warrants that the use of any Sponsor Information or Test Materials by Covance in performing the Services shall not knowingly infringe the intellectual property rights or breach a party's confidentiality obligations to a third party.

7.7 Covance expressly disclaims: (a) any responsibility and liability for the accuracy of the Sponsor Information; and (b) any error or defect in the Services as a consequence of any inaccuracies in the Sponsor Information, and in each case Covance disclaims any responsibility and liability for any consequences of such errors or defects.

7.8 Covance makes no representation, warranty or guarantee regarding the value, prospects, performance, clinical or commercial success of any Test Material which is the subject of any Services performed by Covance, including the likelihood of such Test Material reaching any particular phase of development, obtaining any regulatory approval, or obtaining any level of sales or market acceptance.

8 FEES AND INVOICES

8.1 The Budget and the payment schedule or payment terms for the Services or a Study shall be detailed in a Work Order. The Budget shall be based on the scope of work, the fees, estimated pass through costs and the Assumptions which apply to the Services.

8.2 In consideration for the Services provided by Covance under the applicable Work Order, the Sponsor hereby agrees to pay Covance the fees and actual pass through costs incurred as specified in the applicable Work Order. Invoices shall be issued in accordance with the payment schedule or payment terms, in the Work Order.

8.3 The Sponsor shall pay Covance's invoices within thirty (30) days of the invoice date. Documentation for out of pocket expenses shall be provided via a summary report or detailed on the applicable invoice. Detailed expense reports or back-up documentation including actual expense receipts shall not be provided. If requested by Sponsor on an exceptional basis with reasonable advance written notice or as otherwise agreed under an applicable Work Order [*] for up to [*] per year per project shall be provided by Covance, requests for [*] in excess of [*] per project per year will be subject to an administrative fee of [*].

8.4 If the Sponsor disagrees with the accuracy of an invoice, the Sponsor shall notify Covance of such inaccuracy within twenty-five (25) days of receipt of the invoice. Moreover, the Sponsor agrees to pay the amounts for any items not in dispute and agrees not to unreasonably withhold payment. Payments received after [*] of receipt of invoice may be subject to interest computed at the rate of [*].

8.5 If the Sponsor requires a purchase order for the payment of Covance invoices, the Sponsor shall provide the purchase order at the time of returning the signed Work Order. Failure to provide a purchase order shall not preclude Covance from issuing an invoice in accordance with the payment schedule or payment terms, defined in the Work Order for milestones met or work performed and the Sponsor shall be responsible for payment of all invoices.

9 TAXES

9.1 The Budget for the Services under this Agreement shall not be construed to include any Taxes. Such Taxes now known or which may come to be known at a later time will be assumed by Sponsor without deduction to amounts owed to Covance.

9.2 Payments made by the Sponsor to Covance under this Agreement shall be inclusive of any VAT/GST, where applicable. Where VAT/GST is properly chargeable on the Services provided under this Agreement and Work Order, the Sponsor shall pay such amounts of VAT/GST to Covance on receipt of a valid tax invoice issued in accordance with the laws and regulations of the country in which the VAT/GST is chargeable.

9.3 Where any Test Materials relevant to the Services are imported for the purposes of the Services under the terms of this Agreement or a Work Order, import duty, import VAT or other excise duties may be incurred. Where an irrevocable duty is incurred, Covance shall charge the duty onto the Sponsor as a pass through cost. Covance and the Sponsor shall work together such that irrevocable costs are minimized.

10 CHANGE ORDER

10.1 If any of the Assumptions: (i) are not complied with by the Sponsor; or (ii) are invalid or incorrect; or (iii) if the Sponsor requests a change or an extension to the Services; or (iv) if any changes to the Protocol/Scientific Plan arise either at the request of the Sponsor or as a result of scientific obstacles identified during the provision of the Services (each a **Deviation**) then the Services, Budget and timelines as specified in the corresponding Work Order shall be modified in accordance with the terms of this Section 10.

10.2 In addition, a Deviation may arise if the Services are Delayed for (i) a Force Majeure Event; (ii) circumstances not attributable to Covance; or (iii) events outside Covance's reasonable control, including the following:

(a) failure of the Sponsor to deliver the Sponsor Information in due time; or

(b) amendments to previously agreed upon Protocol/Scientific Plans, procedures or documents required for the Services at the request of the Sponsor; or

(c) significant delays in pre-study meetings or in other tasks to be performed by Covance caused by the Sponsor; or

(d) Delays in obtaining or subsequent withdrawal of regulatory or ethical review approvals concerning the Services; or

(e) death, incapacity or disability of any third party Investigator or other research specialist to continue their services in connection with the Services; or

(f) unforeseen changes in the relevant medical practice or Regulatory Requirements; or

(g) if applicable, either a higher ratio of drop-outs among Study subjects or a lower enrollment rate than expected and agreed by Covance and the Sponsor under the applicable Work Order.

10.3 The Parties shall negotiate, in good faith, to agree, in writing, to a change order setting forth the revised terms for the respective Work Order (a **Change Order**) as described below.

10.4 Covance shall provide the Sponsor with a written estimate of the consequences arising from a Deviation. The estimate shall be provided to the Sponsor on a Change Order form in the form of Exhibit C or other such mutually agreed upon form by the Parties documenting a Deviation. The Sponsor shall forward to Covance an executed and approved Change Order or other such mutually agreed upon form and, upon receipt thereof, Covance shall implement the Deviation.

10.5 To the extent reasonably practicable, Covance shall continue to provide the Services pending approval of the Change Order by the Sponsor. Covance shall not be obligated to implement all or any part of the changes without an agreement in writing signed by both Parties. In the event that the Parties cannot agree on such changes, Covance shall not be obliged to provide non-contracted Services to the Sponsor under the relevant Work Order. In the event the Parties agree on such changes and Covance continues to provide services before the execution of the Change Order, Covance shall invoice the Sponsor for Services rendered.

11 SPONSOR VISITS

11.1 Sponsor or its representative (which shall not be a competitor of Covance and which shall be required to be bound by confidentiality and non-use obligations substantially similar to those contained herein) may visit Covance's premises where Services are being performed at reasonable times, on reasonable notice and with reasonable frequency during normal business hours to observe the progress of Services. Covance and Sponsor shall cooperate in scheduling such visits.

11.2 Sponsor acknowledges that Sponsor's representatives granted access to Covance facilities during any such visits may have access to confidential and proprietary information of Covance and its clients. Sponsor agrees that all such confidential and proprietary information of Covance obtained or observed by the Sponsor or its representatives during such visits shall remain the sole property of Covance, other third parties or the Sponsor (as applicable). Sponsor agrees that it and its representatives shall treat such information as Confidential Information in accordance with Section 14.

12 REGULATORY INSPECTIONS AND AUDITS

12.1 Except as otherwise provided in the additional terms and conditions of each Company Affiliate that apply to the services provided by a Company Affiliate (and any Work Orders thereunder) under Exhibit A, the terms of this section shall apply to Services provided under this Agreement and any applicable Work Order.

12.2 Covance shall during and up to two (2) years after the term of the Agreement, permit the Sponsor or its representatives (which shall not be a competitor of Covance) at reasonable times and on reasonable notice to: (a) audit and examine Covance's principal facilities, operations and quality systems and documentation that are used or that are intended to be used in the performance of the Services or a Study; and (b) audit and copy the Results, regardless of location. The provisions of this Section shall also apply to Study sites managed by Covance.

12.3 In the event that a Party receives a notice from a Regulatory Authority which directly relates to the Services or a Study, and where possible and permitted by the Regulatory Authority, the Party receiving such notice shall promptly forward to the other Party a copy of such notice (or extract thereof). Each Party shall cooperate with the other in responding to such notice especially before referring to the other Party in any regulatory correspondence or disclosing any Confidential Information to a Regulatory Authority. However, each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Regulatory Authorities.

12.4 Covance shall cooperate with any inspection or audit by a Regulatory Authority and shall, except where prohibited by the Regulatory Authority, notify the Sponsor promptly of any request by a Regulatory Authority to conduct such audit or inspection relating to the Services that Covance is providing under this Agreement.

12.5 Where possible and permitted by the Regulatory Authority and except where the Sponsor would be exposed to Confidential Information regarding other sponsor's development activities, Covance shall use its reasonable efforts to allow the Sponsor or its representatives to be present during any such inspection. Where possible and if acceptable to the inspecting Regulatory Authority, the Sponsor may attend the inspection and the daily summaries/close-out meetings to discuss topics related to any Studies where the Sponsor is the sponsor.

12.6 Any request by the Sponsor for Covance to provide assistance with an audit beyond those required to confirm that Covance is in compliance with its obligations under this Agreement and any relevant Work Orders shall be considered a separate service for which additional fees shall apply. Covance shall seek the Sponsor's written approval to pay any related fees before performing any additional audit services.

13 POTENTIAL FRAUD, MISCONDUCT AND SERIOUS BREACH

13.1 Potential Serious Breaches shall be initially assessed through Covance's issue escalation process. When a significant and potential regulatory reporting requirement applicable to the issue is confirmed by Covance, Covance shall promptly notify the Sponsor in writing.

13.2 Upon notification from Covance of a potential Serious Breach, the Sponsor shall review the issue and the Parties shall try to agree which Party shall have the responsibility for informing the relevant Regulatory Authority. Notwithstanding the foregoing, Covance reserves the right to act in accordance with its ethical responsibilities and legal obligations. Covance shall provide a copy of any such correspondence to the Sponsor.

14 CONFIDENTIAL INFORMATION

14.1 Each Party agrees that all Confidential Information of the Disclosing Party is and shall be the sole property of the Disclosing Party. Without prejudice to any Covance Property, all test information, Results, data and records developed by Covance specifically as a result of performing the Services and related to the Test Materials or Sponsor Information shall be the Confidential Information of the Sponsor.

14.2 The Receiving Party shall:

(a) hold the Confidential Information of the Disclosing Party in confidence and in a manner consistent with the way in which it maintains the confidentiality of its own proprietary information, being at least a reasonable standard of care; and

(b) disclose the Confidential Information of the Disclosing Party only on a 'need to know' basis, to its employees, officers, directors, representatives and third party Investigators.

14.3 The Receiving Party agrees that, except with the Disclosing Party's written approval or as necessary to fulfil its obligations under this Agreement or a Work Order and agreed by the Disclosing Party, it shall not use or disclose to any other third party any of the Confidential Information of the Disclosing Party.

14.4 The obligations of non-use and non-disclosure shall not apply to Confidential Information of the Disclosing Party that the Receiving Party can show:

(a) was, or becomes, publicly known through no fault of the Receiving Party;

(b) was lawfully obtained from a third party without restriction as to its use or disclosure;

(c) was already in the possession of the Receiving Party prior to disclosure; or

(d) was independently developed by the Receiving Party without the benefit of the Confidential Information of the Disclosing Party.

14.5 The Receiving Party shall be entitled to disclose Confidential Information of the Disclosing Party to the extent required by any law, rule, regulation, order, decree or subpoena, including the public filing of this Agreement, the Exhibits and the Work Orders with the Securities Exchange Commission, except that the Receiving Party shall, unless restricted by law or where not practicable, promptly notify the Disclosing Party of such requirement prior to the disclosure and shall cooperate with the Disclosing Party to seek to oppose, minimize or obtain the confidential treatment of the required disclosure.

14.6 The obligations in this Section 14 shall remain in full force and effect for a period of **seven (7) years** following disclosure of the relevant Confidential Information except with respect to Confidential Information which is considered a trade secret under applicable laws, which shall remain confidential as long as such Confidential Information retains its status as a trade secret.

15 INTELLECTUAL PROPERTY RIGHTS

15.1 All Background IP is and shall remain the exclusive property of the Party owning it and except as expressly provided in this Agreement, no Party shall acquire any rights in or to the Background IP of the other Party.

15.2 The Sponsor acknowledges that Covance owns or is licensed to use Covance Property. The Parties agree that any improvement, enhancement or modification made, conceived or developed by or for Covance to any Covance Property in the performance of the Services which is not developed as a result of the Services or a Work Order, or based on the Sponsor's Confidential Information for the performance of the Services shall be deemed Covance Property and shall vest absolutely and exclusively in Covance. In addition, Covance shall be entitled to use and exploit any skills, techniques or know-how acquired, developed or used in the course of the Services and a Work Order and not related to the Test Materials or Sponsor Information.

15.3 Strategic insight and proposed project design and scope provided in any quotation by Covance is and shall remain the property of Covance and may be used by the Sponsor only to assess whether it wishes to pursue such work with Covance.

15.4 Without prejudice to Sections 15.1 and 15.2, and as to any Deliverable upon receipt by Covance of payment in full of all amounts due and payable under a Work Order for such Deliverables, the Sponsor shall have title to the Deliverables and all intellectual property rights therein. Covance agrees to assign such rights to the Sponsor except that one (1) copy of any final report may be retained by Covance for regulatory or legal compliance purposes. Notwithstanding the foregoing, the Sponsor hereby grants Covance a non-exclusive, perpetual, irrevocable, royalty-free licence to aggregate and use, for internal quality, standards and performance measurement, instrument calibration and method validation purposes, any System Data produced by or for Covance as part of the Services with other System Data owned or licenced by Covance, provided that Covance shall not identify such data as belonging to the Sponsor.

15.5 Covance shall disclose to the Sponsor (or its nominee) all Inventions and, except in relation to Covance Property and at the Sponsor's request (provided such request is made within one (1) year of disclosure), Covance shall assign to the Sponsor or its nominee (as appropriate) the rights to such an Invention. At the Sponsor's request and expense, Covance shall do all reasonably necessary acts to vest the Invention in the name of the Sponsor or its nominee.

15.6 Except for any Covance Property owned by a third party, if any Covance Property is incorporated or included in any Deliverable (**Incorporated Covance IP**), Covance grants the Sponsor a royalty-free, perpetual, non-exclusive, non-transferable, non-sublicensable, world-wide license to use any Incorporated Covance IP for the sole purposes of and to the extent reasonably necessary to incorporate or explain any Deliverables (without modification) and for obtaining regulatory approvals in connection with such Deliverables.

16 RECORD RETENTION

Except as otherwise directed by the Sponsor, Covance shall retain all Results relating to a Study or the Services during the term of the applicable Work Order. Upon completion or earlier termination of a Study or the Services or earlier if requested by the Sponsor, the Results for the applicable Study or the Services shall be delivered to the Sponsor. Covance shall not be required to return ancillary documents related to the Study Records (including invoices and other similar records). Notwithstanding the foregoing, Covance shall be permitted to retain archival copies of such records if and to the extent that such Results are required to be stored or maintained by Covance pursuant to Regulatory Requirements or other requirements.

17 LICENSED TECHNOLOGY

17.1 If any software including third party software (**Software**) is made available by Covance and is used or disclosed to the Sponsor in connection with the Services, save as permitted by law, the Sponsor agrees not to: (a) modify, copy or create derivative works based on the Software; (b) reverse engineer, disassemble or decompile the Software in any manner; (c) resell, sublicense, lease, or time-share the Software; (d) publish the results of any benchmark tests run on the Software; and (e) use the Software to build a competitive product or service or for the purpose of copying its features or user interface.

17.2 To the extent that any Confidential Information includes Software that is licensed to Covance from third parties (such as, for example, licensors of electronic data capture software), such third parties shall be third-party beneficiaries of this Section 17 with the right to enforce the limitations herein, but shall not otherwise have any rights under this Agreement.

18 REMEDIES AND LIMIT OF LIABILITY

18.1 Except as otherwise provided in the additional terms and conditions of each Company Affiliate that apply to the services provided by a Company Affiliate (and any Work Orders thereunder) under Exhibit A, the terms of this section shall apply to Services provided under this Agreement and any applicable Work Order.

18.2 Covance's total liability to the Sponsor as to any Work Order or under this Agreement with respect to such Work Order, whether in contract, tort (including negligence) or otherwise shall in no circumstances exceed [*].

18.3 Nothing in this Agreement excludes or limits the liability of either Party where liability cannot be excluded or restricted as a matter of law.

18.4 In no event shall Covance be liable to the Sponsor for any Loss arising under or in connection with this Agreement and the Work Order in respect of any: (a) loss of profit, opportunity, business, saving or goodwill (in each case whether direct or indirect); or (b) any indirect, consequential punitive, exemplary or special damages or losses.

18.5 Covance shall not be liable for any failure, error or Delay in performing the Services if such failure, error or Delay is caused by the Sponsor or is a result of an express instruction from the Sponsor or a change in Sponsor Information.

18.6 Except for the representations, warranties, covenants and other obligations set out in this Agreement and Work Order, all warranties, conditions, terms and *undertakings*, express or implied, whether by statute, common law, custom, trade usage, course of dealings or otherwise (including as to quality, merchantability, performance or fitness or suitability for purpose) in respect of any services to be provided by Covance are excluded to the fullest extent permitted by law.

19 INDEMNITIES

19.1 Except as otherwise provided in the additional terms and conditions of each Company Affiliate that apply to the services provided by a Company Affiliate (and any Work Orders thereunder) under Exhibit A, the terms of this section shall apply to Services provided under this Agreement and any applicable Work Order.

19.2 Covance shall indemnify, defend and hold harmless the Sponsor and its respective officers, directors, employees and agents (the **Sponsor Group**) from any Loss resulting from and against any Claim arising from or related to:

(a) a violation of any applicable law, rule or regulation;

(b) a breach of this Agreement or Work Order by Covance; or

(c) the personal injury to a Study participant or personal injury to any employee within the Sponsor Group or property damage arising or occurring during the conduct of the Services

19.3 that arises as a result of Covance's negligence or intentional misconduct of Covance in performing the Services **provided that** if such Losses or Claims arise in whole, or in part, from the Sponsor's Group's negligence or intentional misconduct, then the amount of such Losses that Covance shall be responsible for pursuant to this Section 19.2 shall be reduced by an amount in proportion to the percentage of the Sponsor's Group's responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties. The Sponsor shall indemnify, defend and hold harmless Covance and its Affiliates and their respective officers, directors, employees and agents from any Loss resulting from and against any Claim arising from or related to:

(a) personal injury to a participant in a Study during the conduct of or in connection with the Services;

(b) the harmful or otherwise unsafe effect of the Test Materials including a Claim based upon the Sponsor's or any other person's use, consumption, sale, distribution or marketing of such Test Materials;

(c) a violation of any applicable law, rule, regulation or this Agreement or Work Order by the Sponsor;

(d) the Sponsor's use of the Results or Deliverables or its use or marketing of any Test Materials tested by Covance;

(e) the negligence or intentional misconduct of the Sponsor in connection with the Test Materials, this Agreement, a Work Order or a Protocol/Scientific Plan related to the Services; or

(f) the infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret, or other intellectual property of a third party by reason of Covance's use of the Sponsor Information or Test Materials in accordance with the terms of this Agreement,

provided that if such Losses or Claims arise in whole, or in part, from Covance's negligence or intentional misconduct, then the amount of such Losses that the Sponsor shall be responsible for pursuant to this Section 19.3 shall be reduced by an amount in proportion to the percentage of Covance's responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

19.4 Sponsor shall indemnify, defend, and hold harmless any third-party electronic data capture, electrocardiogram, drug supply/depot and interactive voice-response/interactive response technology Vendors approved by the Sponsor and under contract with Covance to provide any Services (**Ancillary Service Provider**) from any Claims to the extent the Claims arise from or relate to:

(a) the harmful or otherwise unsafe effect of the Test Materials, including a Claim based upon the Sponsor's or any other person's use, consumption, sale, distribution or marketing of such Test Material, or

(b) the negligence or intentional misconduct of the Sponsor in connection with the Test Materials, this Agreement, a Work Order or a Protocol/Scientific Plan related to the Services,

provided that if such Claims arise in whole or in part from such Ancillary Service Provider's: (i) negligence or intentional misconduct; (ii) violation of applicable law, rule or regulation; (iii) breach of its contractual obligations to the Sponsor or Covance; or (iv) any alleged or actual intellectual property infringement in the performance of the Services, then the amount of such Claims that the Sponsor shall be responsible for pursuance to this Section 19.4 shall be reduced in proportion to the percentage of such Ancillary Service Provider's responsibilities for such Claims as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the parties. An Ancillary Service Provider shall be an intended third-party beneficiary of the indemnification provided in this Section 19.4, but shall not otherwise have any rights under this Agreement.

19.5 The Party entitled to indemnification under this Section 19 (the **Indemnified Party**) shall promptly give written notice to the other Party (**Indemnifying Party**) of a Claim or other circumstances likely to give rise to a request for indemnification after the Indemnified Party becomes aware of the same. The Indemnifying Party shall be afforded the opportunity to undertake the defense of, and to settle by compromise, or otherwise, any Claim for which indemnification is available under this Section 19.

19.6 If the Indemnifying Party assumes the defense of any Claim, the Indemnified Party may participate in such defense with legal counsel of its selection and at its expense. If the Indemnifying Party, prior to the expiration of thirty (30) days after receipt of written notice of the Claim by the Indemnified Party under this Section 19.5, has not assumed the defense thereof, the Indemnified Party may thereupon undertake the defense on behalf of, at the risk and expense of, the Indemnifying Party with all reasonable costs and expenses of such defense to be paid by the Indemnifying Party.

19.7 In the event that the Indemnified Party assumes the defense of any Claim, no compromise or settlement of any such claim shall be made without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed.

19.8 To the extent that Covance has to indemnify the Sponsor Group for Financial Interest Claims, Covance's indemnification obligations for such claims shall not exceed and shall be subject to the limitation of liability terms in Section 18.

19.9 Nothing in this Section 19 shall restrict or limit an Indemnified Party's general obligation at law to mitigate a loss it may suffer or incur as a result of an event that may give rise to a Claim under this Section.

20 CARRIER LIABILITY

20.1 In the event that either: (i) the Sponsor delivers, ships or mails (**Transports**) substances, samples, material or documents (**Packages**) to Covance; (ii) the Sponsor requests that Covance Transports Packages; or (iii) Covance Transports Packages as part of the Services to the Sponsor, a Sponsor Affiliate, another Covance entity or a third party, then the expense and risk of damage (insurance) and loss of the Packages for such Transport together with any expenses

required under applicable Regulatory Requirements shall be borne by the Sponsor; provided however if such damage or loss of the Packages arises as a direct result of Covance's negligence or intentional misconduct in the manner in which the Package was prepared for shipment, or the manner and time in which it was consigned for shipment, or the way in which the Package was transported by Covance, then Covance shall bear such damage or loss in proportion to the percentage of Covance's responsibility for such damage or loss.

20.2 Subject to the foregoing, Covance shall have no liability whatsoever for any loss or damage to the Packages or delay, non-delivery or non-collection of the Packages caused by the acts or omissions of any third party delivery services or carrier (**Carrier**). Notwithstanding the foregoing, to the extent permitted by law, Covance shall have the benefit of any right or remedy permitted under international or domestic law and any sums recovered by Covance from a Carrier as a consequence of a loss incurred by the Sponsor due to the Carrier's involvement with the Services shall be paid to the Sponsor. For the avoidance of doubt, a Carrier is not considered a Subcontractor for the purposes of this Agreement.

20.3 Unless otherwise agreed in writing between the Parties, any physical Deliverables to be shipped to the Sponsor shall be to the delivery address specified in the Work Order. Upon delivery of any physical Deliverables, the Sponsor shall be responsible for carefully examining such Deliverables. The Sponsor shall be deemed to have accepted such Deliverables if Covance has not been notified by the Sponsor within thirty (30) business days of delivery of any defect in such Deliverables.

21 TERMINATION

21.1 On termination of this Agreement, howsoever arising, each Work Order then in force at the date of such termination shall nevertheless continue in full force and effect for the remainder of the term of such Work Order, unless expressly terminated in accordance with this Section 21. Termination of any Work Order shall not affect any other Work Order or this Agreement.

21.2 A Party may terminate a Work Order prior to completion of the applicable Services at any time for any reason upon ninety (90) days written notice to the other Party, except when the reason for termination is the safety of Study participants, whereupon it may be terminated immediately. Covance shall use reasonable efforts to conclude or transfer the Study as expeditiously as practicable and in accordance with all applicable Regulatory Requirements. Covance and the Sponsor shall cooperate with each other during such termination to safeguard patient safety, continuity of patient treatment and to comply with all applicable Regulatory Requirements.

21.3 To the extent permitted by law, either Party may terminate this Agreement and all relevant Work Orders with immediate effect by notice in writing to the other Party if:

(a) the other Party commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of forty-five (45) days after being notified in writing to do so; or

(b) the other Party repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or

(c) the other Party suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or is deemed unable to pay its debts; or the other Party suspends, or threatens to suspend, or ceases or threatens to cease to carry on, all or substantially the whole of its business; or

(d) the other Party presents a petition or has a petition presented for its winding-up or has a receiver or an administrative receiver appointed of all or any part of its assets or undertaking or if a notice of intention to appoint an administrator is served in respect of it or calls a meeting of, or enters into any composition or arrangement with, its creditors; or

(e) the financial position of either Party deteriorates to such an extent that in the other Party's reasonable opinion a Party's capability to adequately fulfil its obligations under the Agreement has been placed in jeopardy; or

(f) any event occurs, or proceeding is taken, in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned above.

21.4 Termination of this Agreement, or Work Order, shall not relieve either Party of their obligations to the other in respect of:

(a) maintaining the confidentiality of the Confidential Information;

(b) assignment of Inventions and assistance with respect thereto;

(c) obtaining consents for the use of names;

(d) indemnification;

(e) limitation of liability;

(f) compensation for the Services performed;

(g) retention of records;

(h) reimbursement and payment for legal proceedings;

(i) non-solicitation of employees.

The provisions of this Section together with and any other section which is necessary for the interpretation or enforcement of this Agreement shall survive the expiry or termination of this Agreement howsoever arising.

22 CONSEQUENCES OF DELAY, CANCELLATION OR TERMINATION

22.1 Except as otherwise provided in the additional terms and conditions of each Company Affiliate that apply to the services provided by a Company Affiliate (and any Work Orders thereunder) under Exhibit A, the terms of this section shall apply to Services provided under this Agreement and any applicable Work Order.

22.2 If the scheduled start up of the Services are Delayed due to: (i) delay by the Sponsor (e.g. due to non-delivery of Test Materials or any Sponsor Information required to begin or perform the Services); (ii) delay in any approval by a Regulatory Authority or IEC/IRB; (iii) at the request of the Sponsor; or (iv) any other reason outside the reasonable control of Covance, Covance shall be entitled to full payment for:

(a) all work properly performed by Covance for the Services up to the notification of Delay;

(b) all pass through costs related directly to the Services and incurred up to the notification of Delay;

(c) all other non-cancellable actual, non-refundable or irrevocably incurred expenses and financial obligations that Covance has incurred or undertaken in support of the Delayed Services or as a consequence of the Delay (e.g. the cost of staff members allocated to a Study which is Delayed who are not re-assigned to other work during the period of the Delay and regulatory expenses); and

(d) any additional fees listed in the relevant Exhibit A or Work Order as a consequence of the Delay.

22.3 In the event that the Services are cancelled or terminated in accordance with Sections 21.2 or 21.3, Covance shall be entitled to full payment for:

(a) all work properly performed by Covance for the Services up to the effective date of cancellation or termination regardless of the achievement of any milestones used as payment triggers (including any agreed wind down costs);

(b) all pass through costs related directly to the Services and incurred up to the effective date of cancellation or termination;

(c) all other non-cancellable actual, non-refundable or irrevocably incurred expenses and financial obligations that Covance has incurred or undertaken on the Sponsor's behalf up to the effective date of cancellation or termination; and

(d) any additional termination for convenience fees listed in the relevant Exhibit A or Work Order.

23 INSURANCE

Each Party shall secure and maintain in full force and effect through the performance of the Services the necessary insurance coverage in amounts appropriate to the conduct of its business. Certificates evidencing such insurance shall be made available for examination upon written request by the Sponsor or Covance. The additional insurance requirements that may apply to any specific Services are detailed in the relevant Exhibit A.

24 SAMPLE RETENTION

24.1 Subject to Section 24.2 and any provisions in Exhibit A, all Samples associated with the Services shall be retained, returned to the Sponsor or disposed of (including destruction) in accordance with the Work Order, Protocol/Scientific Plan or the Sponsor's reasonable written instructions and applicable Regulatory Requirements. Where no provision is made in the Work Order or Protocol/Scientific Plan, the Sponsor shall be contacted to determine whether the Samples should be destroyed, returned to the Sponsor or retained by Covance subject to agreement of the Parties on the time period and fees payable for retention.

24.2 Regulatory samples obtained from drug substance or drug product shall be retained and disposed of in accordance with the Protocol/Scientific Plan. Samples obtained from clinical trials and HBS shall be retained and disposed of in accordance with the provisions of Section 25 of this Agreement.

25 HUMAN BIOLOGICAL SAMPLES

25.1 Where Covance is performing Services that includes monitoring activities of a Study on behalf of the Sponsor at investigative sites, Covance shall:

(a) verify that the HBS Donor has given Informed Consent;

(b) confirm that any HBS and associated data are managed in full compliance with any and all applicable national laws, regulations, or codes of practice (including any submissions, approvals and registrations to any applicable Regulatory Authority) relating to the Use of HBS providing protection for human subjects in the country of origin;

(c) use its reasonable efforts to ensure that any HBS shall be de-identified or 'coded' according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor; and

(d) in the event of a withdrawal of or a material variation to the Informed Consent, promptly notify all relevant parties of such withdrawal or variation.

25.2 In all other circumstances, where the Sponsor or third parties for which the Sponsor is responsible supply HBS to Covance in connection with the Services, the Sponsor represents and warrants that:

(a) all HBS supplied in connection with the Services under this Agreement and any relevant Work Order are or have been procured and supplied to Covance ethically in full compliance with any and all applicable national laws, regulations, or codes of practice (including any submissions, approvals and registrations to any applicable Regulatory Authority) relating to the Use of HBS providing protection for human subjects in the country of origin;

(b) the HBS Donor has given Informed Consent;

(c) all HBS shall be de-identified or 'coded' according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor and shall be supplied to Covance without any information or data that could allow Covance to personally identify the HBS Donor under applicable Data Protection Laws and other applicable Regulatory Requirements;

(d) all HBS supplied to Covance (i) may be Used for the Services; (ii) may be used to provide data in support of commercial product development by Sponsor; and (iii) were procured without inappropriate financial benefit to the HBS Donor; and

(e) in the event of a withdrawal of, or a material variation to the Informed Consent (including any material changes that may affect the Services), it shall promptly notify Covance and any other relevant parties of such changes or withdrawal.

25.3 The Sponsor shall: (a) upon request, provide a copy of the relevant Informed Consent template; and (b) upon request, provide a copy of the relevant documents certifying that the HBS provided to Covance has completed the necessary submissions, approvals and registrations required to be made to any applicable Regulatory Authority. The Sponsor agrees that full date of birth shall only be collected if medically relevant to the Services (unless legally restricted in the country of operation).

25.4 Covance agrees to use the HBS in accordance with all applicable laws, regulations and codes of practice. Covance shall not use the HBS, even on a de-identified or coded basis for any purpose other than in accordance with the signed Informed Consent form.

25.5 Upon the Sponsor's request, Covance shall retain, return or dispose of all HBS in accordance with the Informed Consent, the Sponsor's reasonable instructions or any other specific requirements under applicable national law.

25.6 The Sponsor acknowledges that where Covance enters into a material transfer agreement (**MTA**) with the provider of any HBS, Covance shall act in accordance with the terms of the MTA and the disposition of the relevant HBS shall be as prescribed in the MTA. In the event of a conflict between the terms of the MTA, this Agreement, any Work Order and any instructions provided by the Sponsor, the terms of the MTA shall prevail.

26 DATA PROTECTION

26.1 Where Covance processes any Personal Data on behalf of the Sponsor, Covance shall process such Personal Data in accordance with all applicable Data Protection Laws in the territories in which the Services are performed (**Protected Data**).

26.2 If Covance processes any Protected Data on behalf of the Sponsor, Covance and the Sponsor each agree and acknowledge that the Sponsor shall be the data controller and Covance shall be the data processor with respect to the processing of such Protected Data. Covance shall only process such Protected Data on behalf and upon the reasonable instructions of the Sponsor for purposes notified to it by the Sponsor for which consent from the relevant data subjects has been obtained in accordance with all applicable Regulatory Requirements. Covance shall follow such procedures, policies and reasonable instructions as may be agreed by the Parties from time to time.

26.3 Covance shall take reasonable technical and organizational measures that are necessary to protect against the unauthorized or unlawful processing of or the unauthorized or unlawful disclosure of such personal data. Covance shall promptly notify the Sponsor in the event of a security breach involving any personal data which Covance is processing on behalf of the Sponsor.

26.4 The Sponsor warrants that it has complied with any and all notification and information requirements under the applicable Data Protection Laws.

27 SUBCONTRACTORS AND VENDORS

27.1 Notwithstanding Section 33.2, certain tasks other than data processing tasks specified in the Work Order or Protocol/Scientific Plan may be subcontracted by Covance to its Affiliates or Subcontractors. Covance shall be responsible for the performance of Subcontractors contracted by Covance for services within the scope of this Agreement.

27.2 Covance shall diligently identify, vet, engage, manage and monitor the performance of Vendors, but shall not otherwise be responsible for performance by Vendors that are not Subcontractors. The liability of Covance to the Sponsor with respect to Vendors shall be limited to the extent Covance defaults in the performance of its obligations under this Agreement or a Work Order. At the reasonable request of Sponsor Covance shall pursue on Sponsor’s behalf and at Sponsor’s expense any claims that Sponsor or Covance may have against Vendors as a consequence of a loss incurred by Sponsor as a result of any error or service failure on the part of such Vendors in connection with this Agreement or any Services under a Work Order, and Covance shall pay over to Sponsor any amounts that Covance may recover from such Vendors on account thereof.

27.3 For the avoidance of doubt, the Parties acknowledge and agree that third party Investigators shall not be considered Subcontractors of Covance. All third party Investigators shall exercise their own independent medical judgement and shall be considered independent contractors and shall not be deemed employees, subcontractors or agents of Covance. Covance’s responsibilities with respect to third party Investigators shall be limited to those responsibilities specifically set forth in the Agreement and the applicable Work Order.

28 FORCE MAJEURE

28.1 No Party shall be in breach of this Agreement or Work Order nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement or Work Order as appropriate, if such delay or failure results from a Force Majeure Event. In such circumstances, any time specified for completion of performance in the Work Order or Protocol/Scientific Plan falling due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to such event. The Party whose performance is delayed by Force Majeure shall use commercially reasonable efforts to mitigate any delays cause by the Force Majeure Event. Covance shall promptly notify the Sponsor if, by reason of a Force Majeure Event, Covance is unable to meet any critical timelines or critical deliverables specified in any Work Order.

28.2 Should any part of the Services be rendered invalid as a result of a Force Majeure Event, Covance shall, upon written request from the Sponsor, and at the Sponsor's sole cost and expense, repeat the affected part of the Services.

29 NOTICES

29.1 Except for the purposes of any legal notice or proceedings, which shall not include email or fax, all communications and notices required under this Agreement shall be in writing and deemed to be given if delivered personally, or mailed by overnight delivery or first class mail, postage prepaid, to the addresses set forth below, or via electronic mail or fax with hard copy confirmation, or to such other addresses as the Parties from time to time specify in writing.

29.2 Notices shall be treated as having been given upon delivery if delivered by hand or by commercial courier at the time of signature of receipt; if sent by prepaid first class mail or recorded delivery three (3) days from the date of posting; and if by airmail seven (7) days from the date of posting.

29.3 Notice shall be given to the parties at the addresses listed below or at such other place as a Party shall nominate:

(a) If to Sponsor to:

Galectin Therapeutics, Inc.
4960 Peachtree Industrial Boulevard, Suite 240
Norcross, Georgia 30071, Unites States
Attention: Chief Executive Officer

(b) If to Covance, the address set forth in the Notice Section of any relevant Exhibit A, with a copy to Covance Inc. at the following address:

Covance Inc.
3147 S. 17th Street, Suite 300 Wilmington, NC 28412
United States
Attention: General Counsel

30 PUBLICITY AND PUBLICATION

Neither Party shall (a) use the name, trademark or the name of any representative of the other, or the existence of this Agreement for any promotional or advertising purposes, or any other publication, without the prior written consent of the other Party; or (b) state or imply that the other Party endorses or approves any service, material, product or compound of the other Party without the prior written consent of the other Party. Such restrictions shall not apply to internal communications and publications to a Party's Affiliates or to communications or publications that are required for Sponsor to comply with US Securities laws.

31 PERSONNEL

31.1 Except as provided in Section 31.2, neither Party shall solicit or otherwise encourage any personnel or employees of the other Party with whom it has contact pursuant to this Agreement to seek employment with a Party throughout the course of the Agreement and for a period of twelve (12) months thereafter.

31.2 Section 31.1 shall not apply in the event: (i) the potential recruiting Party has consulted with the other Party and obtained permission to solicit such employee; (ii) an employee of a Party seeks employment with the other Party in response to an unsolicited response to a general advertisement or recruiting effort not directed at such employee or Party; or (iii) an employee of either Party who is terminated or otherwise released from employment by Party or its Affiliates.

31.3 The Services with respect to each Work Order shall be performed by Covance under the direction of the person identified as the operational lead in the applicable Work Order or other Services relevant documentation. Where reasonably practicable, Covance shall retain the operational lead for a Study in place during the term of the applicable Work Order unless Sponsor requests a change in writing. In the event that a change in the operational lead occurs, then Covance will discuss and make available to Sponsor qualified candidates to fill the role of the operational lead and will consult with the Sponsor about such replacement. After such consultation and review, Sponsor's acceptance and approval of the replacement operational lead shall not be unreasonably withheld or delayed.

32 COMPLIANCE

32.1 **Debarment**. Covance represents and warrants that to its knowledge it does not use and shall not use in any capacity the services of any person debarred under subsections §306(A) or §306(B) of the U.S. Generic Drug Enforcement Act 1992, disqualified as a testing facility under 21 CFR Part 58 Subpart K. or disqualified, restricted or having made assurances as a clinical investigator under 21 CFR §312.70 or otherwise debarred, restricted or disqualified under the corresponding laws of an applicable jurisdiction in connection with any of the Services performed under this Agreement. Covance shall promptly disclose in writing to the Sponsor if it becomes aware that any: (a) person who is performing the Services is debarred, disqualified or restricted; or (b) action, suit, claim, investigation or legal or administrative proceeding is pending relating to the debarment, disqualification, restriction of Covance or any person performing Services under this Agreement.

32.2 **Anti-Bribery**. Each Party agrees that it has not and shall not, either directly or indirectly, engage in the following conduct: bribery or offer, promise, authorize to pay, or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party agrees that it shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws.

32.3 **Trade Control**. Notwithstanding any other provision of this Agreement to the contrary, each Party shall comply with, and retain responsibility for its compliance with, all applicable export control laws (e.g., the U.S. Export Administration Regulations) and economic sanctions programs (e.g., economic sanctions maintained by the U.S. Treasury Department, as well as Specially Designated Nationals and Blocked Persons (**SDNs**)) relating to its respective business, facilities, and the provision of services to third parties (collectively, **Trade Control Laws**). It shall be in the sole discretion of Covance to refrain from being directly or indirectly involved in the provision of goods, software, services and/or technical data that may be prohibited by applicable Trade Control Laws, including sanctions currently in place against Cuba, Iran, North Korea, Sudan, Syria and SDNs.

33 GENERAL

33.1 **Independent Contractor**. It is understood and agreed that Covance shall perform its duties as an independent contractor and not as an agent, employee, partner or joint venture of the Sponsor. Neither Party shall have the authority to bind or commit the other Party in any manner whatsoever and shall not, at any time, hold itself out to third parties as having authority to enter into or incur any commitments, expenses, liabilities or obligations of any nature on behalf of the other party except as permitted in this Agreement, a Work Order, or other document expressly providing such authority.

33.2 **Assignment**. Each Party may transfer or subcontract any or all of its rights and obligations under this Agreement or a Work Order to its Affiliates. The assigning Party shall continue to remain liable for any accrued obligations under this Agreement or a Work Order prior to such assignment. Notwithstanding the foregoing and except in connection with an internal reorganization of a Party's corporate structure or in connection with a merger or sale of substantially all of the assets of a Party, this Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

33.3 **Waiver**. A waiver of any term, provision or condition of this Agreement or Work Order shall be effective only if it is in writing and no waiver, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver or estoppel of any such term, provision or condition or any other term of this Agreement or a Work Order. No failure or delay by either Party in exercising any right or remedy under this Agreement shall constitute a waiver of such right, nor shall it prevent or restrict its further exercise. The Parties acknowledge and agree that they have not relied upon any representations made before contract in deciding to enter into this Agreement and the Parties waive all and any right to pursue any claim for misrepresentation except for fraudulent misrepresentation.

33.4 **Variation**. No provision of this Agreement or Work Order may be amended, modified, varied, discharged or terminated except by the express written agreement signed by an authorized representative of each of the Parties.

33.5 **Severability.** If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. If any invalid, unenforceable or illegal provision of this Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

33.6 **Entire Agreement**. This MSA together with the Exhibits and Work Order sets forth the entire agreement between the Parties with respect to the performance of the Services and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto and shall take precedence over all terms, conditions, and provisions on any purchase order or other form of other acknowledgment or order release purporting to address the same subject matter; **except that** any agreement entered into prior to the Effective Date with respect to any Services that are being performed before the Effective Date shall remain effective and shall continue to govern such existing Services.

33.7 **Legal Testimony**. If Covance is obliged to provide testimony or records regarding the Services for the Sponsor in any legal or administrative proceeding other than testimony or records related to any alleged improper performance by Covance of its obligations under this Agreement or a Work Order, then the Sponsor shall reimburse Covance for its out of pocket costs plus a reasonable hourly fee for the involvement of its employees or representatives in such proceedings equal to the internal fully burdened cost of such employees or representatives.

33.8 **Third Party Rights**. Except as expressly set forth in this Agreement in respect of Covance Affiliates and Sections 17 and 19.3, nothing in this Agreement is intended to confer any rights, benefits or remedies of any kind whatsoever, and a person who is not a Party to this Agreement shall have no right to enforce any of its terms.

33.9 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original to this Agreement but all of which together shall constitute the same Agreement.

33.10 **Dispute Resolution**. It is the intention of the Parties that in the event disputes should arise over the interpretation and application of this Agreement, the Parties shall first attempt to settle such disputes by negotiation and consultation between the senior executives of the Sponsor and Covance and other parties familiar with this Agreement, any Work Order or Protocol/Scientific Plan. To the extent permitted by law, and except for any indemnity claim under Section 19, no claim or action arising out of or relating to this Agreement or any Work Order may be brought by a Party more than three (3) years after the termination of this Agreement, or an applicable Work Order, whichever is longer.

33.11 **Law**. All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of Delaware, without regard or giving effect to its principles of conflicts of law and, if applicable, with the express exclusion of the United Nations Convention on the International Sale of Goods.

33.12 **Jurisdiction**. The Parties irrevocably agree that any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims) shall be governed by the exclusive jurisdiction of the courts of State of Delaware.

Signed by the Parties or their duly authorized officers on the dates set forth below, to be effective on the date set forth on the first page of this Agreement.

Galectin Therapeutics Inc.		**Covance Inc.**	
Signature	/s/ Harold Shlevin	Signature	/s/ Pam Saker
Name:	Harold Shlevin	Name:	Pam Saker
Title:	CEO	Title:	Director, Contract Management
Date:	March 12, 2020	Date:	March 12, 2020

EXHIBIT A-1 – ADDITIONAL TERMS & CONDITIONS FOR THE PROVISION OF EARLY DEVELOPMENT SERVICES

WHEREAS

(A) **GALECTIN THERAPEUTICS INC.** (the **Sponsor**) and **COVANCE INC.** (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) **COVANCE LABORATORIES INC**. with its principal address of 3301 Kinsman Blvd, Madison, Wisconsin 53704, USA, together with its Named Affiliates (as defined below), (collectively "**CL-ED**") shall be considered parties to the MSA for the Services provided under this Exhibit A-1.

(C) This Exhibit A-1 to the MSA is for the provision of early development services to the Sponsor by CL-ED.

NOW THEREFORE the Parties agree as follows:

1. Definitions

1.1 Each capitalized term used in this Exhibit A-1, but not defined, has the meaning specified in the MSA unless a clear contrary interpretation otherwise applies.

1.2 For the purposes of this Exhibit A-1, the following definitions shall apply:

"Inspection Cycle" means the time period between inspections by Regulatory Authorities (if applicable) which shall be at least annually but will vary between Covance sites and according to applicable Regulatory Requirements.

"**Named Affiliates"** mean **Covance Bioanalytical Services LLC**, with its address of 8211 SciCor Drive, Suite B, Indianapolis, Indiana, 46214, USA; **Covance Laboratories Limited** with its registered office at Otley Road, Harrogate, North Yorkshire, HG3 1PY UK, and Covance **Preclinical Services GmbH**, with its registered office at Kesselfeld 29, DE48163, Muenster, Germany.

2. Protocol/Scientific Plan

2.1 In the absence of a Protocol/Scientific Plan agreed to by the Parties, the Sponsor shall notify CL-ED of the intended regulatory use (if any) of the Study and the applicable Regulatory Requirements to be followed by CL-ED. Notwithstanding any assistance provided by CL-ED in the development of the Protocol/Scientific Plan, CL-ED does not warrant that such Protocol/Scientific Plan sill satisfy the requirements of any Regulatory Authority at the time of submission.

2.2 Where applicable to the Services, the Sponsor and CL-ED shall agree to a quality agreement detailing the technical and regulatory matters associated with the provision of a Study (Quality Agreement). If there is any inconsistency between the MSA, this Exhibit A-1 and the Quality Agreement, the Quality Agreement shall prevail for quality and relevant regulatory matters.

3. Form of Contract

Upon receipt of the Sponsor's request for Services, Covance shall provide a written quotation pursuant to and referencing this Agreement. Upon signature by both Parties, a binding contract shall be formed and the document shall become the Work Order for the purposes of this Agreement, and for the purposes of Services provided by CL-ED, Exhibit B of this Agreement shall not apply.

4. Study Performance, Materials and Resources

The Sponsor shall provide CL-ED with any relevant occupational safety information known by the Sponsor, including a safety data sheet (SDS) and, if applicable, a certificate of analysis for the Test Materials. The SDS must conform to globally accepted standards for the applicable Test Materials of the Global Harmonization Standard.

5. Deliverables

5.1 All reports shall be prepared in a CL-ED standard format unless otherwise agreed upon by the Parties.

5.2 In the event that six (6) months from the date of the audited draft report (the Draft Report), CL-ED has received neither requested revisions nor instructions to finalise the Draft Report, CL-ED reserves the right to consider the Draft Report as “final” and issue it as the complete, approved output of the Study (the Final Report). The Final Report shall be signed by CL-ED and submitted to the Sponsor. Any modification or changes to the Final Report shall be performed at additional cost to the Sponsor. Where required by law or regulation, the Sponsor shall provide a copy of each Draft Report to CL-ED submitted to a regulatory authority within thirty (30) days of the submission.

5.3 The nature of the Services is experimental, and any timelines or quantities shown in the Work Order or Protocol/Scientific Plan are estimates only.

6. Raw Data and Sample Retention

6.1 All experimental data arising from the specific performance of the Services including tissues, blocks, slides, records, original laboratory accounts of the work performed and authorised documents, but excluding Samples and Test Materials (Raw Data) shall, unless otherwise agreed in the Work Order or Protocol/Scientific Plan be retained by CL-ED for one (1) Inspection Cycle from the date of the Final Report.

6.2 In the event that Raw Data is returned to the Sponsor within the Inspection Cycle, the Sponsor agrees that should the Raw Data be required by a Regulatory Authority conducting an inspection of CL-ED facilities, the Raw Data shall be immediately returned to CL-ED at the Sponsor’s cost.

6.3 Subject to Section 24 of the MSA, all Samples associated with the Services shall be retained, returned or destroyed in accordance with the Sponsor’s instructions. Where no instructions are received, after ninety (90) days following submission of the first Draft Report the Samples shall be retained by Covance and invoiced to the Sponsor. In the event that invoices are unpaid and no instructions are received, Covance reserves the right to dispose of the Samples

6.4 If the Sponsor instructs CL-ED to retain any Samples or Raw Data beyond the agreed retention period, CL-ED shall levy a charge on the Sponsor based on the amount and type of materials to be retained. Any Raw Data or samples not required to be retained shall, at the Sponsor’s cost and expense, either be returned to the Sponsor or destroyed. The Sponsor shall be responsible for any regulatory implications of the fate of the Samples or Raw Data.

6.5 CL-ED reserves the right to levy a charge for the handling, tracking, and storage of any Samples received which are ultimately not required by the Sponsor to be analysed as part of the Services.

7. Fees and Invoices

7.1 Any amount shown in the Work Order in respect of a Final Report shall become due and payable if CL-ED has not received any comments from the Sponsor forty-five (45) days after delivery of the Draft Report.

7.2 For a Study with a stated duration of more than twelve (12) months, CL-ED reserves the right to adjust prices annually based on the CPI rates published by the Organisation for Economic Co-operation (OECD) upon thirty (30) days prior written notice to the Sponsor. CL-ED reserves the right to adjust prices for Services if the initiation of the work is delayed by more than six (6) months beyond the original estimated start date as at the date of the Work Order.

8. Additional Fees for Delay or Termination for Convenience

8.1 In the event that the Study is Delayed for any reason as set out in Section 22.1 of the MSA, the fees listed in the table below shall be levied to the Sponsor in addition to the amounts due under [*].

Notice Period	Study Type	Charge Incurred
[*]	[*]	[*]
	[*]	[*]
[*]	[*]	[*]
	[*]	[*]
[*]	[*]	[*]
	[*]	[*]
	[*]	[*]
	[*]	[*]

* Values shown are in USD. Where the fees are in any other currency, the appropriate delay fee shall be applied based on the average New York or London spot rate for the year.

8.2 The Sponsor may terminate a Work Order by giving written notice of such termination to CL-ED in accordance with Section 21.2 of the MSA. In the event the Sponsor terminates a Work Order prior to completion of the Study, the fees listed in the table below shall be levied to the Sponsor in addition to the amounts due under Section 22.2 of the MSA:

Notice Period	Charges Incurred	Administrative Fee
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

8.3 Following a Delay of a Study, if the Sponsor agrees to a revised start date at the convenience of CL-ED, the number of weeks used to calculate the additional fees payable by the Sponsor pursuant to this Paragraph 7 shall be reduced by one (1) week for every two (2) weeks of flexibility that the Sponsor is willing to move the revised start date.

9. Payment Terms

The following payment schedule shall be followed for all Work Orders between the Sponsor [*].

	Study Type	Payment Schedule
[*]	[*]	[*]
	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
	[*]	[*]
	[*]	[*]
	[*]	[*]

10. Notices

All notices to CL-ED shall be sent to: Covance Laboratories Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK; Attention: Contracts Lead, Early Development.

SIGNED by an authorised signatory for and on behalf of:

Galectin Therapeutics Inc.

By: _____

Date: _____

Covance Laboratories Inc.

By: _____

Date: _____

Covance Inc.

By: _____

Date: _____

EXHIBIT A-2 – ADDITIONAL TERMS AND CONDITIONS FOR THE PROVISION OF CLINICAL RESEARCH SERVICES IN CLINICAL TRIAL SUBJECTS

WHEREAS

(A) **GALECTIN THERAPEUTICS INC.** (the **Sponsor**) and **Covance Inc.** (the **Company or Covance Clinical**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) This Exhibit A-2 to the MSA is for the provision of clinical research services in patients to the Sponsor by Covance Clinical.

NOW THEREFORE the Parties agree as follows:

1. Definitions

1.1. Each capitalized term used in this Exhibit A-2, but not defined, has the meaning specified in the MSA unless a clear contrary interpretation otherwise applies.

2. Transfer of Obligations

2.1. Covance Clinical acknowledges and agrees that the responsibility for Services performed as set forth under the applicable Work Order are being transferred to Covance Clinical in accordance with 21 CFR §312.52, EU Clinical Trial Directive (2001/20/EC), International Conference on Harmonization of GCP E6 (R2) (ICH GCP) or any other applicable regulations. The Sponsor shall at all times be considered the “Sponsor” of the Study pursuant to the terms of the Federal Food, Drug, and Cosmetic Act (as amended), the regulations of the US FDA (as promulgated in 21 CFR), and the regulations of the US FDA (as promulgated in 21 CFR) or any other applicable national regulations and ICH GCP. The obligations transferred should be included in Form FDA 1571, Section #14, the EudraCT form or an equivalent in the country in which the Services are being performed (Transfer of Obligations Form).

2.2. The Parties acknowledge and agree that although Covance Clinical may recommend investigative sites be closed (for example due to site non-performance), the Sponsor shall retain responsibility for formally approving the closing of such investigative sites.

2.3. For any Change Order that affects the scope of the regulatory obligations that have been transferred to Covance Clinical, the Sponsor and Covance Clinical shall execute a corresponding amendment to any Transfer of Obligations Form. The Sponsor shall file such amendment where appropriate or as required by any applicable Regulatory Requirements.

3. Insurance

3.1. The Sponsor hereby represents and warrants that it maintains adequate clinical trial and product liability insurance coverage consistent with industry standards through a reputable insurance carrier and in compliance with all applicable Regulatory Requirements with minimum coverage of ten million US dollars (US $10,000,000) per occurrence. The Sponsor further represents and warrants that such insurance policies shall not contains any additional exclusions clauses not normally found in insurance of such type that might limit and would not extend to the clinical trial for which the Services are being provided. Covance Clinical hereby represents and warrants that it maintains adequate general liability and errors and omissions / professional liability insurance coverage consistent with industry standards through a reputable insurance carrier and in compliance with all applicable Regulatory Requirements with minimum coverage of ten million US dollars (US $10,000,000) per occurrence.

3.2. Covance Clinical shall be listed as an additional insured on the Sponsor's clinical trial policy. The insurance of Sponsor shall insure Sponsor and Covance Clinical against third party claims asserted by all subjects screened or treated as part of the relevant clinical trial for personal injury suffered as a result of the participation in the Study and/or the Study screening process. Upon request Sponsor shall be listed as an additional insured on Covance's general liability insurance coverage.

3.3. The Sponsor and Covance Clinical shall each provide the other with a copy of its certificate of insurance to confirm that it has such insurance coverage. The insurance of each of Sponsor and Covance Clinical shall be with a company having a minimum of an A-rating by Best's rating service. The Sponsor shall maintain such insurance through the entire duration of Study and for three (3) years thereafter and shall immediately notify Covance Clinical in writing of any changes in coverage that impact the coverage requirements set forth above. In the event coverage is not maintained, a minimum three (3) year extended reporting period shall be purchased by the Sponsor.

3.4. In the event that either the Sponsor or Clinical Covance is unable to provide an appropriate: (i) certificate of insurance; or (ii) level of insurance cover as specified in this Paragraph 3, then the other party shall be entitled to terminate the relevant Work Order in which case the relevant Services thereunder will cease.

4. Delays or Cancellation

4.1. In the event that a Study is Delayed or placed on-hold for more than thirty (30) calendar days the Sponsor shall have the right to retain at their expense all core team members as defined in the applicable Work Order on a full time equivalent basis for the duration of the delay or on-hold period. If the Sponsor does not wish to retain any core team members for the duration of the on-hold or Delay period, Covance Clinical shall have the right to reallocate any and all such staff after a thirty (30) calendar day period. If the Delay or on-hold period continues for ninety (90) days either Party may, by provision of written notice, terminate the applicable Work Order.

4.2. If the scheduled start-up of any Study under a Work Order to this Exhibit A-[2] is Delayed or cancelled by the Sponsor, pursuant to Section 22 of the MSA, Covance Clinical shall be entitled to payment in full on a time and materials basis for all work properly performed by Covance Clinical for the Services (inclusive of wind-down costs) up through the effective day or Delay or termination regardless of: (i) the achievement of any milestones used as payment triggers for Fixed Price Work Orders or (ii) the achievement of any units or partial units as outlined in the Budget for Fixed Unit Price Work Orders.

5. Data Management Services

5.1. According to Covance Clinical's licensing agreements, Covance Clinical is prohibited from sharing dictionary terminology or data with any non-subscribing client. In offering Covance Clinical's coding services for a particular Study, the Sponsor undertakes that it has or shall obtain a current subscription for using such coding with the applicable licensor (including, Northrop Grumman/MSSO for MedDRA and Uppsala Monitoring Center for WHODRUG). Covance shall assist Sponsor in obtaining such subscription(s)

5.2. Covance Clinical is required to verify the Sponsor's subscription to such dictionary and data services before the start of a particular Study. If it is determined that the Sponsor does not have an appropriate subscription, Covance Clinical shall have the right to: (a) inform the applicable licensor; (b) cease provision of any of the terminology or data; and (c) be reimbursed all costs, expenses and damages associated with Sponsor's failure to be properly licensed to use such dictionary and data services.

6. Notices

All notices to Covance Clinical shall be sent to Covance Inc., 210 Carnegie Center, Princeton, NJ 08540-6233, USA, Attention: Global Director Contract Management.

SIGNED by an authorised signatory for and on behalf of:

Galectin Therapeutics Inc.	**Covance Inc.**
By: _____	**By:** _____
Date: _____	**Date:** _____

EXHIBIT A-3 – ADDITIONAL TERMS AND CONDITIONS FOR THE PROVISION OF CENTRAL LABORATORY TESTING SERVICES

WHEREAS

(A) **GALECTIN THERAPEUTICS INC.** (the **Sponsor**) and **Covance Inc.** (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) **COVANCE CENTRAL LABORATORY SERVICES LP** an Indiana limited partnership, with its principal place of business at 8211 SciCor Drive, Indianapolis, Indiana 46214, USA; and **COVANCE CENTRAL LABORATORY SERVICES SÀRL**, with its principal place of business at Rue Moise-Marchines 7, 1217 Meyrin, Geneva Switzerland (collectively **CCLS**) shall be considered to be a parties to the MSA for the Services provided under this Exhibit A-3.

(C) This Exhibit A-3 to the MSA is for the provision of central laboratory testing services to the Sponsor by CCLS.

NOW THEREFORE the Parties agree as follows:

1. Definitions

1.1. Each capitalized term used in this Exhibit A-3, but not defined, has the meaning specified in the MSA unless a clear contrary interpretation otherwise applies.

2. Advance Payments

2.1. Upon execution of a Work Order, CCLS shall assess a fee equal to [*] of the value of the Budget (Deposit).

2.2. Each month, CCLS shall invoice the Sponsor for all fees due and pass through costs incurred while providing Services during the previous month. The Deposit shall be retained by Covance until the Study reaches final account reconciliation. CCLS will issue repayment of the balance of the Deposit by first applying it to outstanding unpaid invoices.

2.3. If the Study is terminated before the Deposit is exhausted, and assuming all prior invoices have been paid by the Sponsor, CCLS shall apply the Deposit funds to the final invoice, then refund any remaining Deposit funds to the Sponsor within sixty (60) days.

3. Payment Dispute

In the event Sponsor disputes any charge in an invoice Sponsor may elect to withhold payment for the portion of the invoice that is in dispute, but shall pay any undisputed amounts in accordance with the payment terms provided in Section 8.3. The Parties hereby agree to use good faith efforts to reconcile the disputed amount as soon as practically possible. If the resolution of such dispute results in a credit to Sponsor, such credit will be reflected on the next monthly invoice of the applicable Work Order.

4. Additional Services

4.1. If the Sponsor requests additional Services that require modifications to an existing Protocol/Scientific Plan, CCLS will provide the Sponsor with the revised Protocol/Scientific Plan for review and approval.

4.2. Notwithstanding Section 10 of the MSA, upon CCLS' receipt of the Sponsor's written approval of the revised Protocol/Scientific Plan (as evidenced by Sponsor's signature on the revised Protocol/Scientific Plan), CCLS shall provide such services to the Sponsor and the Sponsor shall pay for costs associated with such services at its current standard rates.

4.3. During performance of Services, CCLS may be required to provide certain items including but not limited to ancillary supplies, logistics and minor modifications to database design (the **Items**). [*]

5. Billing and Invoicing

5.1. For budgeting purposes, CCLS creates a Budget using local unit pricing which is then converted to the billing currency, as agreed between the Parties using the Reuters exchange rate at the time the Budget is first created. Unless specified otherwise, this exchange rate remains unchanged during the course of the Study to simplify Budget comparisons and enable the Sponsor to track changes to the Study unrelated to changes in currency exchange rates.

5.2. For invoicing purposes, Services are billed based on the contracted local unit prices. Each month, at the time of invoice creation, the local unit prices are converted to the billing currency using the Reuters exchange rate for the month in which the Services were performed.

5.3. [*]

6. Auditing

Where an audit of CCLS concerns or relates to referral laboratory testing or shipping methods of CCLS, the Sponsor or its representative (which shall not be a competitor of Covance) may only confirm whether or not CCLS is properly billing such costs. The Sponsor expressly agrees that Sponsor's representatives may not directly or indirectly provide any details of the charges to the Sponsor, such as the actual amount of the referral laboratory testing or shipping costs incurred by CCLS.

7. Transportation Charges

Shipping costs are included in the Budget of the applicable Work Order as estimated pass-through costs. For the avoidance of doubt, shipping costs charged to the Sponsor within an applicable Work Order shall be inclusive of a logistical support fee with respect to the management and tracking of specimens.

8. Provision of Kits

8.1. In accordance with the Work Order, CCLS shall provide each Investigator site with Study and visit specific specimen collection supplies needed to collect and ship specimens back to CCLS for analysis (Specimen Kit). Each Specimen Kit may include test tubes, pipettes, collection needles and other required materials together with instructions for collection and shipment. Specimen Kits shall also have a test requisition form or other instructions to allow for the electronic capture of such data designated for the particular Study. Each Specimen Kit shall be barcoded to ensure tracking and testing audit trails upon its return to CCLS.

8.2. In the event that a Specimen Kit is lost, expired or otherwise rendered unusable for reasons outside the CCLS' reasonable control or should a Specimen Kit expire at an Investigator site, CCLS shall replace such Specimen Kits at a cost equal to the amount listed in the Budget of the applicable Work Order for each Specimen Kit that is replaced.

9. Storage of Samples

CCLS shall not destroy any Samples without giving prior written notice to Sponsor and giving Sponsor a reasonable opportunity to provide directions for the Samples to be sent to a different location for storage. If Sponsor does not respond to CCLS's request for Sample disposition within thirty (30) days, CCLS may return such Samples to Sponsor at Sponsor's cost. CCLS's liability for any breach or default for the storage of Samples shall not exceed the fees it has been paid for storage of such Samples for the previous twelve (12) months.

10. Samples During Force Majeure

10.1. In the event of Force Majeure Event, CCLS shall take all reasonable commercial steps to re-route Samples to another CCLS facility or to another qualified laboratory for testing**.**

10.2. If the Samples are routed to a non-CCLS laboratory for testing, the Sponsor agrees to pay all fees and charges related to those samples and testing.

11. Notices

All notices to CCLS shall be sent to Covance Central Laboratory Services LP, 8211 SciCor Drive, Indianapolis, Indiana 46214, USA, Attention: VP Finance.

SIGNED by an authorised signatory for and on behalf of:

Galectin Therapeutics Inc.

By: _____

Date: _____

Covance Central Laboratory Services LP

By: _____

Date: _____

Covance Central Laboratory Services Sàrl

By: _____

Date: _____

Covance Inc.

By: _____

Date: _____

EXHIBIT A-4 - ADDITIONAL TERMS & CONDITIONS FOR THE PROVISION OF PHASE I HEALTHY VOLUNTEER CLINICAL RESEARCH SERVICES

WHEREAS

(A) **GALECTIN THERAPEUTICS INC. (**the **Sponsor**) and **Covance Inc.** (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) **COVANCE CLINICAL RESEARCH UNIT INC.** with its principal address of 3402 Kinsman Blvd, Madison, Wisconsin 53704, USA; and **COVANCE CLINICAL RESEARCH UNIT LIMITED** with its registered office at Springfield House, Hyde Street, Leeds, LS2 9LH, UK (collectively **CRU**) shall be considered to be parties to the MSA for the Services provided under this Exhibit A-4.

(C) This Exhibit A-4 to the MSA is for the provision of Phase 1 healthy volunteer clinical research services to the Sponsor by the CRU.

NOW THEREFORE the Parties agree as follows:

1. Definitions

1.1. Each capitalized term used in this Exhibit A-4, but not defined, has the meaning specified in the MSA unless a clear contrary interpretation otherwise applies.

1.2. For the purposes of this Exhibit A-4, the following definitions shall apply:

"**Completion**" means the final visit by the last subject for the relevant Study.

"**Forgone Revenue**" means the revenue that would have been earned by CRU under a Work Order if the Sponsor had not cancelled or Delayed the Study (or part thereof) (such as lost bed space that had been reserved for Sponsor); and

"**Scheduled Start Date**" means the first subject first visit for a particular Study under a Work Order.

2. Transfer of Obligations

2.1. The CRU acknowledges and agrees that the responsibility for Services performed as set forth under the applicable Work Order are being transferred to the CRU in accordance with 21 CFR §312.52, EU Clinical Trial Directive (2001/20/EC), International Conference on Harmonization of GCP E6 (R2) (**ICH GCP**) or any other applicable regulations. The Sponsor shall at all times be considered the "Sponsor" of the Study pursuant to the terms of the Federal Food, Drug, and Cosmetic Act (as amended) and the regulations of the US FDA (as promulgated in 21 CFR) or any other applicable national regulations and ICH GCP. The obligations transferred should be included in Form FDA 1571, Section #14, the EudraCT form or an equivalent in the country in which the Services are being performed (**Transfer of Obligations Form**).

2.2. For any Change Order that affects the scope of the regulatory obligations that have been transferred to the CRU, the Sponsor and CRU, shall execute a corresponding amendment to any Transfer of Obligations Form. The Sponsor shall file such amendment where appropriate or as required by applicable Regulatory Requirements.

3. Safety Data and Clinical Holds

The Sponsor shall promptly inform the CRU in writing in accordance with all applicable Regulatory Requirements if: (i) the Sponsor is aware of any safety data from any source which is applicable to the Study and which may indicate a negative impact on subject safety or well-being; or (ii) if there is a clinical hold on the Study by the applicable Regulatory Authority.

4. Volunteer Compensation for UK Phase I Trials

Where applicable, the Sponsor agrees to abide by the current Association of the British Pharmaceutical Industry "Guidelines for Phase 1 Clinical Trials" (the **Guidelines**) and agrees that it understands the section entitled "Risk Management". The Guidelines may be found at the following link: http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx.

5. Informed Consent Forms

The Sponsor hereby directs and authorizes the CRU to act as the Sponsor's agent with actual authority to enter into and execute for and on behalf of the Sponsor and in the Sponsor's name a subject informed consent form for each volunteer study performed under the Agreement and a Work Order in accordance with all applicable Regulatory Requirements. The current informed consent form template is available upon request.

6. CRU Data Management Services

6.1. According to the CRU's licensing agreements, the CRU is prohibited from sharing dictionary terminology or data with any non-subscribing client. In offering the CRU's coding services for a particular Study, the Sponsor undertakes that it has or shall obtain a current subscription for using such coding with the applicable licensor (including, Northrop Grumman/MSSO for MedDRA and Uppsala Monitoring Center for WHODRUG).

6.2. The CRU is required to verify the Sponsor's subscription to such dictionary and data services before the start of a particular Study. If it is determined that the Sponsor does not have an appropriate subscription, the CRU shall have the right to: (a) inform the applicable licensor; (b) cease provision of any of the terminology or data; and (c) be reimbursed all costs, expenses and damages associated with Sponsor's failure to be properly licensed to use such dictionary and data services.

7. Record Storage and Retention

7.1. All reports shall be prepared in the CRU's standard format unless otherwise specified in the Work Order.

7.2. All primary investigator-related data generated by the CRU, or copies thereof (for example, laboratory records, CRFs, data sheets, correspondence, photographs and computer records etc.) that are a result of the original observations and activities of the Study and are necessary for the reconstruction and evaluation of the Study (**Investigator Records**) shall, unless specifically stated otherwise in the Work Order or Protocol/Scientific Plan, be collated by the CRU after issuing the final report. The Investigator Records shall be retained as required under current regulatory requirements after Completion of the Study.

7.3. Frozen Samples shall be shipped to the appropriate analytical laboratory according to the Sponsor's instructions or other requirements in the Work Order or Protocol/Scientific Plan. All other frozen Samples (e.g. secondary/backup or unanalysed samples) shall be retained by the CRU for a period of six (6) months after Completion unless otherwise specified in the Work Order or Protocol/Scientific Plan. Refrigerated Samples shall be retained for one (1) week after their analysis and then destroyed unless otherwise agreed upon by the Parties (each a **Retention Period**).

7.4. The Budget shall include the costs for archiving frozen Samples for the relevant Retention Period. At the end of the relevant Retention Period, the CRU shall contact the Sponsor to determine if a longer Retention Period for each of the Samples is required. If a longer retention period is not required, CRU shall ship the samples to the archive facility of the Sponsor's choice at Sponsor's expense

7.5. Where the Sponsor wishes the CRU to retain the Samples beyond the relevant Retention Period and/or Investigator Records beyond the current Regulatory Requirements, the CRU shall levy a periodic charge on the Sponsor based on the amount and type of materials retained. All records, raw data, Samples and materials not required for retention shall, at the Sponsor's expense, either be returned to the Sponsor or destroyed. The Sponsor shall be responsible for any regulatory implications of either option.

8. Insurance

8.1. The Sponsor hereby represents and warrants that it maintains adequate separate clinical trial and product liability insurance coverage consistent with industry standards through a reputable insurance carrier and in compliance with all applicable Regulatory Requirements. The sum insured shall be in compliance with all applicable Regulatory Requirements, but shall not be less than five million pounds sterling (£5,000,000) per occurrence for trials in the UK or five million US dollars ($5,000,000) per occurrence for trials in the US, except where the Study is a first-in-human study, where the minimum coverage of such insurance shall ten million US Dollars (US $10,000,000) per occurrence. The Sponsor further represents and warrants that such insurance policies shall not contain any additional exclusion clauses not normally found in insurance of this type that might limit such cover for the Study. CRU hereby represents and warrants that it maintains adequate general liability and errors and omissions / professional liability insurance coverage consistent with industry standards through a reputable insurance carrier and in compliance with all applicable Regulatory Requirements with minimum coverage of ten million US dollars (US $10,000,000) per occurrence.

8.2. The insurance of Sponsor shall identify the CRU as an additional insured and shall cover all subjects screened or treated as part of the Study for personal injury suffered as a result of the participation in the Study and/or the Study screening process. Upon request Sponsor shall be listed as an additional insured on CRU's general liability insurance coverage.

8.3. The Sponsor and CRU shall each provide the other with a copy of its certificate of insurance or such other documented evidence to confirm that it has such insurance coverage. For the avoidance of doubt, a statement of self-insurance is not acceptable. The insurance of each of Sponsor and Covance shall be with a company having a minimum of an A-rating by Best's rating. The Sponsor and CRU shall maintain such insurance through the entire duration of Study and for the duration according to applicable Regulatory Requirements, which shall be at least three (3) years thereafter. The Sponsor shall immediately notify the CRU in writing of any changes in coverage that affects the requirements above. In the event coverage is not maintained, a minimum three (3) year extended reporting period must be purchased by the Sponsor

8.4. In the event that the Sponsor or CRU is unable to provide an appropriate: (i) certificate of insurance; or (ii) level of insurance cover as specified in this Paragraph 8, then the CRU shall be entitled to cease the relevant Services whereupon the relevant Work Order may be terminated.

9. Additional Fees for Delay or Termination for Convenience

9.1. Except to the extent that any Services under a Work Order are Delayed or cancelled as a result of the CRU's breach of the Work Order, if the Scheduled Start Date to this Exhibit A-4 is Delayed or cancelled by the Sponsor within the following time periods, the Sponsor shall pay the CRU the following fees in addition to the amounts due under Section 22 of the MSA:

9.1.1. if the Services are cancelled or Delayed: (i) [*] before the Scheduled Start Date; or (ii) at any time where more than [*] of the Budget payable under a particular Work Order have been incurred and invoiced to the Sponsor[*];

9.1.2. if the Services are cancelled [*], the Sponsor shall pay the CRU [*];

9.1.3. if the Services: (i) are cancelled [*] before the Scheduled Start Date; or (ii) are cancelled after [*], the Sponsor shall pay the CRU a fee of [*];

9.1.4. if the Study or part of the Study is Delayed by [*], the Sponsor shall pay the CRU [*]. If the CRU is unable to reschedule the Study or part of the Study on the date requested by the Sponsor and the Sponsor elects to cancel the Study (or part thereof), [*].

9.2. Pursuant to Paragraphs 9.1.2 and 9.1.3, the additional fee shall be calculated on the standard rates of the CRU personnel assigned to the affected Work Order, provided that such personnel's time is not already being billed to the Sponsor for close out activities. The CRU shall act in good faith and use its reasonable commercial endeavours to promptly re-assign such personnel.

10. Third Party Investigator Sites

10.1. If the Sponsor requests that the CRU contracts with an Investigator for conduct of a Study, the Sponsor shall provide the authority for the CRU to contract with the Investigator on behalf of the Sponsor. Any indemnification rights granted to the Investigator shall be provided exclusively by the Sponsor and in the event that the Investigator invokes such rights, the Investigator shall deal directly with the Sponsor.

10.2. The Parties agree that Investigators shall be deemed to be independent contractors exercising independent judgment and shall not be considered either Subcontractors or Vendors of the CRU. The CRU's responsibility in connection with the contract with the Investigator shall be for the CRU to make payments that are payable to Investigator in connection with its services in accordance with the respective budget for the Investigator, (such budget shall be subject to review and approval by the Sponsor). The CRU shall cooperate with the Sponsor in accordance with the Sponsor's instructions in enforcing the contract with the Investigator sites.

11. Notices

11.1. For Phase 1 CRU services in the US, all notices shall be sent to Covance Clinical Research Unit Inc. 3402 Kinsman Boulevard, Madison, Wisconsin 53704, USA; Attention: Manager Contract Management.

11.2. For Phase 1 CRU services in the UK, all notices shall be sent to Covance Clinical Research Unit Ltd., Springfield House, Hyde Street, Leeds West Yorkshire, LS2 9LH, UK; Attention: Managing Director.

SIGNED by an authorised signatory for and on behalf of:

Galectin Therapeutics Inc.	**Covance Clinical Research Unit Inc.**
By: _____	**By:** _____
Date: _____	**Date:** _____

Covance Clinical Research Unit Limited

By: _____

Date: _____

Covance Inc.

By: _____

Date: _____

EXHIBIT B1 - PRO-FORMA WORK ORDER: LEGAL REPRESENTATIVE SERVICES

This **WORK ORDER** is made the date the last party signs below between:

(1) **Galectin Therapeutics Inc**. whose registered office is at Suite 240, 4960 Peachtree Industrial Boulevard, Norcross, Georgia 30071 (the **Sponsor**); and

(2) **COVANCE [ ]** whose registered office is at [insert address] (**Covance**),

(each a **Party** and collectively the **Parties**).

RECITALS

(A) WHEREAS Sponsor and Covance are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) WHEREAS subject to the terms and conditions of the MSA [and the additional terms and conditions set forth in [insert any relevant Exhibits]], the Sponsor and Covance hereby agree to execute a Work Order relating to the Services for Sponsor's Protocol/Scientific Plan [insert reference].

NOW THEREFORE the Parties agree as follows:

1. Definitions and Interpretation

1.1. Each word and term used in this Work Order, but not defined, has the meaning specified in the MSA unless a clear contrary interpretation otherwise applies.

1.2. In this Work Order, unless the context otherwise requires, the following words and expressions shall have the following meanings:

"**Legal Representative**" shall mean Covance's role in providing the Legal Representation Services to the Sponsor.

"**Legal Representation Services**" shall mean Covance's agreement to act as the agent of the Sponsor as legal representative in [insert relevant country/region] and to provide the Services described at Annex 1 to this Work Order under the heading "*Legal Representation Services*".

1.3. In the event of conflict between the terms and conditions of this Work Order and those of the MSA, the terms of the MSA shall prevail except to the extent that this Work Order expressly and specifically states an intent to supersede the MSA on a specific matter.

2. Term and Termination

The term of this Work Order [shall commence on …] [shall be deemed to have commenced on ...] and shall continue until completion of the Services or earlier termination of the MSA in accordance with the termination provisions set out in the MSA (the **Term**).

3. Services

3.1. The Parties acknowledge that the Services (as defined in the MSA) include the Legal Representation Services. For the avoidance of doubt, Legal Representation Services shall not include any services relating to compliance with any Data Protection Laws in [country], which shall remain the responsibility of the Sponsor.

3.2. Covance agrees to perform the following Services for the Sponsor as set forth in the attached description of Services at Annex 1, which shall also detail the Study/Services Specific Assumptions that apply to the Services.

4. Budget

4.1. The Budget for the Services is set out in the detailed Budget in this Work Order attached at Annex 2.

4.2. In consideration for its performance of the Services under this Work Order, the Sponsor shall pay Covance in accordance with the payment schedule or payment terms set out in this Work Order attached as Annex 3.

4.3. Invoices are due within thirty (30) days of receipt by the Sponsor.

5. Payment and Invoice Details

5.1. All invoices to the Sponsor should be sent to the following address:

[insert]

5.2. All payments to Covance should be sent to the following address:

Covance Inc.

210 Carnegie Center

Princeton, New Jersey 08540-6233

United States

Attention: [**insert**]

6. Change Control

In the event that any of the Assumptions used to calculate the Budget or in the provision the Services change, in accordance with Section [**insert – NB: usually section 10**] of the MSA, the Parties shall negotiate an amendment to this Work Order if appropriate. No amendment to this Work Order shall be binding unless agreed in writing.

7. Power of Attorney

The Power of Attorney appended to this Work Order at Annex 4 shall be completed by the Parties and executed appropriately prior to the commencement of the Legal Representation Services. The Parties acknowledge that the Power of Attorney shall give Covance the authority to act as Legal Representative for the Sponsor when providing the Legal Representation Services.

8. Insurance

This paragraph shall replace Section 23 of the MSA. The Sponsor hereby represents and warrants that it maintains adequate separate clinical trial insurance and product liability coverage consistent with industry standards and in compliance with all Regulatory Requirements through a reputable insurance carrier having a minimum of an A-rating by Best's rating service or higher which shall have a minimum discovery period of three (3) years inclusive of the period covering clinical trials insurance. For the avoidance of doubt, if the certificate of liability covers a period of twelve (12) months, the insurance coverage must include an extended reporting period of an

additional two (2) years. Sponsor shall be required to maintain such insurance through the life of the study and shall notify Covance in writing of any changes in coverage which impact requirements set forth above. The sum insured shall not be less than ten million US dollars (US $10,000,000) per occurrence. The Sponsor further represents and warrants that such insurance policies shall not contains any additional exclusions clauses not normally found in insurance of such type that might limit and would not extend to the study for which the Services are being provided. Covance shall be an additional insured under Sponsor's policy of insurance. The insurance of Sponsor shall insure against third party claims asserted by all subjects screened or treated as part of the Study for personal injury suffered as a result of the participation in the Study and/or the Study screening process.

9. Termination

9.1. Should the Sponsor: (a) reduce the level of Services (including the Legal Representation Services) to be provided by Covance to the extent that it is no longer commercially viable for Covance to perform the Legal Representation Services for the Sponsor; (b) become eligible to assume responsibilities of legal representative itself; (c) unable to provide the level and form of insurance required as specified above at Section 8; or (d) any regulatory or statutory requirement prevents the provision of Legal Representation Services by Covance, it shall notify Covance promptly in writing. Covance shall, upon written notice from the Sponsor have the right to: (a) terminate any Legal Representation Services; and/or (b) refuse any additional or revised Legal Representation Services which are not already ongoing under the relevant Work Order.

9.2. In the event that Covance terminates the Legal Representation Services under this Work Order, it shall cease to be the Legal Representative of the Sponsor in respect of the Services provided hereunder.

10. Entire Agreement

This Work Order (including any annexes hereto) and the terms of the MSA represent the entire and integrated agreement between the Sponsor and Covance and supersede all prior negotiations, representations or agreements, either written or oral, regarding the Services.

11. Choice of Law and Jurisdiction

Any contractual dispute or claim arising between the Parties to this Work Order arising out of or in connection with the MSA or the Services defined herein shall be construed, governed, interpreted, and applied in accordance with the provisions of Section **33.11** of the MSA.

Galectin Therapeutics Inc.		**Covance [ ]:**	
Name:	_____	Name:	_____
Signature:	_____	Signature:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

ANNEX 1 – DESCRIPTION OF SERVICES

1. Legal Representation Services

1.1. The Parties have agreed that Covance shall provide the Legal Representation Services which shall form part of the Services to be provided under this Work Order. Covance shall perform the Legal Representation Services in compliance with [insert relevant clinical trial law], which shall include the following, in each case, only in relation to the Study:

a) provision of a contact address, fax number, telephone number and e-mail address along with any other necessary contact details to Regulatory Authorities for the purpose of communications with such Regulatory Authorities and third parties in connection with Covance's role as the Sponsor's Legal Representative;

b) provision of an individual employee of Covance who shall be familiar with the Study and shall act as a contact or liaison with Regulatory Authorities and third parties in connection with Covance's role as the Legal Representative of the Sponsor;

c) where reasonably necessary in accordance with Regulatory Requirements, assisting the Sponsor in notifying or obtaining approval from the relevant Regulatory Authorities in respect of its appointment and in consultation with the Sponsor, preparation of any other documents that are necessary to confirm or formalise such appointment or to inform third parties;

d) preparation and signing of applications, notifications and other documents in connection with the Study (including, as applicable, letters of authority, applications for clinical trial authorisations and ethical approvals, applications for amendments thereto and notifications of the termination or completion of the Study);

e) where Covance expressly takes responsibility for compiling the clinical trial application, supervision, preparation and submission of such clinical trial application to any relevant Regulatory Authorities within [**specify relevant Country or region**];

f) performance of all other tasks and activities, including communication, where necessary, with the relevant Regulatory Authorities and as required in connection with the appointment and fulfilment of the regulatory obligations of Covance as the Sponsor's Legal Representative;

g) seeking and obtaining the Sponsor's instructions and approval before communicating with Regulatory Authorities and other third parties or performing any other task or activity in connection with Covance's role as Legal Representative, provided that where urgent action is required (e.g. an urgent request is received from a Regulatory Authority) and Covance does not have and is not able to obtain instructions or approval from the Sponsor in the time available, then Covance shall take such action as it reasonably believes to be in the best interests of the Sponsor;

h) promptly supply to the Sponsor copies of all relevant communications made or received by Covance in connection with Covance's role as Legal representative;

i) promptly notify the Sponsor of and attend and report on any meetings or hearings involving Covance in connection with Covance's role as Legal Representative, provided that, where requested by the Sponsor, Covance shall use all reasonable efforts to ensure that representatives of Sponsor are also permitted to attend such meetings and hearings; and

j) in the event that legal proceedings are instigated in the [Territory **specify relevant Country or region**], accept the service of legal documents, but not including payment of legal, consultancy, medical, specialist or expert fees associated with any claim made against either Covance or the Sponsor.

1.2. Subject to Covance acting as the Legal Representative of the Sponsor under the Agreement, the Sponsor represents and warrants that:

a) it shall review all information and material contained or referenced in all clinical trial notifications (**CTNs**) and all clinical trial applications or similar required documents (**CTAs**) for the investigational medicinal product to be tested or used in the performance of the Study as provided to Covance by the Sponsor or that are subject of the Services provided by Covance hereunder (**Test Materials**) to ensure that all such information and material is accurate, complete and not false or misleading;

b) it will provide sufficient amounts of the Test Materials as required by law or as reasonably requested by Covance;

c) the Test Materials shall be manufactured, packaged and (except to the extent that labelling, coding and distribution is to be provided as Services under the Agreement pursuant to a Work Order) labelled, coded and distributed in compliance with all applicable laws, rules, regulations and procedures, including Good Manufacturing Practice;

d) at the close of the Study, the Sponsor shall retain any and all records relating to the Study, including records received from Covance and shall maintain those records for twenty-five years or such other longer period of time as required by law. In addition, the Sponsor shall make such records available for inspection by any applicable Regulatory Authority; and

e) the Sponsor shall provide to Covance all such information as Covance may reasonably request from time to time and/or as may be necessary to enable Covance to perform all responsibilities as the Legal Representative for the Sponsor. The Sponsor shall provide all safety information pertinent to the Test Materials to Covance including, all Serious Adverse Event reports, consistent with applicable requirements as necessary to maintain in a legally compliant manner, all CTNs and CTAs.

1.3. The Sponsor shall indemnify, defend and hold harmless [*] from any Loss resulting from any means, any claim, demand, assessment, action, suit, proceeding, settlement or investigation arising from or related any liability imposed on the Covance Group as a result of its responsibilities as a Legal Representative, local sponsor or a similar role for the Sponsor under this Work Order; provided that Sponsor shall not be obliged to indemnify, defend or hold harmless Covance to the extent any Loss arises from (i) any act or omission of Covance, their Affiliates or Subcontractors or Vendors that is a breach of any provision of the Agreement, Work Order or this Annex; (ii) any negligence, recklessness or wilful misconduct of Covance, their Affiliates or Subcontractors or Vendors; or (iii) any losses arising from Covance, or their respective Affiliate's or Subcontractor's or Vendor's failure to mitigate any such claim, demand, assessment, action, suit, proceeding, settlement, investigation

2. Services

[insert any other general Services]

ANNEX 2 – BUDGET

The pricing for the Work Order shall be deemed to be a Fixed [Unit] Price Work Order, which means a fixed set of Services and delivered in accordance with the fixed [fees]/[unit budget] outlined in this Annex.

Additional paragraph for Fixed Unit Price: Fixed Unit Prices reflect the average unit price to perform the task and are not illustrative of the actual effort associated with the unit. If the scope of an individual unit changes or the projected number of units are not achieved, adjustments shall be made to the Fixed Unit Price or the development of a new unit (as the case may be) in accordance with Section 10 of the MSA to reflect the actual effort associated with the unit.]

ANNEX 3 – PAYMENT SCHEDULE OR PAYMENT TERMS

[insert]

ANNEX 4 – POWER OF ATTORNEY FOR LEGAL REPRESENTATION SERVICES

THIS POWER OF ATTORNEY is made on [insert date] by, a company with its [principal place of business] [registered office] at [insert address] and [registered number [insert if applicable]] (the "**Principal**").

1. APPOINTMENT AND POWERS

1.1 The Principal hereby appoints **COVANCE INC.** with its principal place of business at 210 Carnegie Center, Princeton, New Jersey, 08540 USA as its attorney in fact (the "**Attorney**") and gives authority for the Attorney to act in the Principal's name or otherwise and on its behalf to the extent necessary to perform the following activities relating to the conduct of the clinical trial under Protocol Number:[insert] and with study title: ["insert name of Study"] (the "**Clinical Trial**") and provided that any powers granted herein shall apply only to the conduct of the Clinical Trial in [insert relevant country/region]:

(a) prepare and sign documents required for the Clinical Trial by the local ethics committees and central ethics committees;

(b) correspond with ethics committees for purposes related to the Clinical Trial;

(c) handle, negotiate and sign site agreements and other agreements relating to the provision of clinical services for the Clinical Trial on its behalf and/or, subject to approval by the Principal in writing, in the Principal's name as its Attorney;

(d) monitor and manage the Clinical Trial;

(e) import any investigational medicinal product required for the Clinical Trial in accordance with the relevant customs procedures;

(f) store and distribute materials related to the Clinical Trial;

(g) obtain export licenses for the Clinical Trial if required;

(h) assist the Principal to report serious adverse events related to the Clinical Trial to ethics committees in accordance with local requirements; or

(i) collect any investigational medicinal product from sites at which the Clinical Trial is conducted and return to the Principal or arrange for destruction as required by the Principal,

in each case, in accordance with and subject to the Covance Master Services Agreement entered into between the Principal and the Attorney on [**insert**] relating to the conduct of the Clinical Trial.

1.2 Except for those agreements referred to in Paragraph 1.1(c) above, the Attorney shall have no authority to enter into any agreements in the name or on behalf of the Principal or otherwise act on behalf of or bind the Principal, and the Attorney shall not hold itself out as having authority to do the same.

1.3 This Power of Attorney cannot be transferred or delegated by the Attorney to any other persons or entity.

2. DURATION

2.1 Subject to Paragraphs 2.2 and 2.3, this Power of Attorney shall be valid until completion of the Clinical Trial in accordance with the protocol for the Clinical Trial.

2.2 The Principal may revoke the Power of Attorney in relation to the Attorney with immediate effect by written notice at any time to the relevant Attorney at the relevant address above.

2.3 The Attorney may revoke the Power of Attorney with immediate effect in accordance with paragraph 9 of the relevant work order forming part of the Agreement.

2.4 The Attorney must immediately cease to exercise any of the powers granted by this Power of Attorney if this Power of Attorney expires, terminates or is revoked by the Principal.

3. RATIFICATION

The Principal undertakes to ratify and confirm whatever the Attorney does or purports to do in good faith in the exercise of any power conferred by this Power of Attorney.

4. VALIDITY

The Principal declares that a person who deals with the Attorney in good faith may accept a written statement signed by the Attorney to the effect that this Power of Attorney has not been revoked as conclusive evidence of that fact.

5. LANGUAGE

The official text of this Power of Attorney and any notices given hereunder shall be in English. If any dispute occurs concerning the construction or interpretation of this Power of Attorney, reference shall be made only to the Power of Attorney as written in English and not to any translation into any other language.

6. JURISDICTION

This Power of Attorney (and any dispute, controversy, proceedings or claim of whatever nature arising out of or in any way relating to this Power of Attorney or its formation or any act performed or claimed to be performed under it) shall be governed by and construed in accordance with [insert relevant law].

[INSERT RELEVANT EXECUTION BLOCK]

EXHIBIT B2 - PRO-FORMA WORK ORDER: NO LEGAL REPRESENTATIVE SERVICES

This **WORK ORDER** is made the date the last party signs below between:

(1) **Galectin Therapeutics Inc.** whose registered office is at Suite 240, 4960 Peachtree Industrial Boulevard, Norcross, Georgia 30071 (the **Sponsor**); and.

(2) **COVANCE [ ]** whose registered office is at [insert address] **(Covance),**

(each a **Party** and collectively the **Parties**).

RECITALS

(A) WHEREAS Galectin Therapeutics Inc. (**Sponsor**) and Covance Inc. (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) WHEREAS Covance is a party to the MSA by virtue of Exhibit A-[ ] to the Agreement [intent/language needs to be clarified about which Covance entity will be a party. Language suggest that the entity to sign this is not the party to the Master Agreement]

(C) WHEREAS subject to the terms and conditions of the MSA and the additional terms and conditions set forth in the relevant Exhibit A, the Sponsor and Covance hereby agree to execute a Work Order relating to the Services for Sponsor's Protocol/Scientific Plan [insert reference].

NOW THEREFORE the Parties agree as follows:

1. Definitions and Interpretation

1.1 Each word and term used in this Work Order, but not defined, has the meaning specified in the Agreement unless a clear contrary interpretation otherwise applies.

1.2 In the event of conflict between the terms and conditions of this Work Order and those of the Agreement, the terms of the Agreement shall prevail except to the extent that this Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter.

2. Term and Termination

2.1 The term of this Work Order [shall commence on …] [shall be deemed to have commenced on ...] and shall continue until completion of the Services or earlier termination of the Agreement in accordance with the termination provisions set out in the Agreement (the Term).

3. Services

Covance agrees to perform the following Services for the Sponsor as set forth in the attached description of Services at Annex 1, which shall also detail the Study/Services Specific Assumptions that apply to the Services.

4. Budget

4.1 The Budget for the Services is set out in the detailed Budget in this Work Order attached at Annex 2.

4.2 In consideration for its performance of the Services under this Work Order, the Sponsor shall pay Covance in accordance with the payment schedule or payment terms set out in this Work Order attached as Annex 3.

4.3 Invoices are due within thirty (30) days of receipt by the Sponsor.

5. Payment and Invoice Details

All invoices to the Sponsor should be sent to the following address:

[insert]

All payments to Covance should be sent to the following address:

[insert]

6. Change Control

In the event that any of the Assumptions used to calculate the Budget or in the provision the Services change, in accordance with Section 10 of the MSA, the Parties shall negotiate an amendment to this Work Order if appropriate. No amendment to this Work Order shall be binding unless agreed in writing.

7. Insurance [FOR COVANCE CLINICAL, CRU]

[Sponsor hereby represents that insurance referred to in Paragraph 3 of Exhibit A-[ ] (Covance Clinical) of the Agreement is applicable to and valid for the duration of this Study.]

[Sponsor hereby represents that insurance referred to in Paragraph 8 of Exhibit A-[ ] (CRU) of the Agreement is applicable to and valid for the duration of this Study.]

8. Entire Agreement

This Work Order and the terms of the Agreement represent the entire and integrated agreement between the Sponsor and Covance and supersede all prior negotiations, representations or agreements, either written or oral, regarding the Services.

9. Choice of Law and Jurisdiction

Any contractual dispute or claim arising between the Parties to this Work Order arising out of or in connection with the Agreement or the Services defined herein shall be construed, governed, interpreted, and applied in accordance with the provisions of Section 33.11 of the Agreement.

Galectin Therapeutics Inc.		**Covance [ ].**	
Signature	_____	Signature	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

ANNEX 2 – BUDGET

[Wording for Covance Clinical: The pricing for the Work Order shall be deemed to be a Fixed [Unit] Price Work Order, which means a fixed set of Services and delivered in accordance with the fixed [fees]/[unit budget] outlined in this Annex.

Additional paragraph for Fixed Unit Price: Fixed Unit Prices reflect the average unit price to perform the task and are not illustrative of the actual effort associated with the unit. If the scope of an individual unit changes or the projected number of units are not achieved, adjustments shall be made to the Fixed Unit Price or the development of a new unit (as the case may be) in accordance with Section 10 of the MSA to reflect the actual effort associated with the unit.]

EXHIBIT C - PRO-FORMA CHANGE ORDER

This **CHANGE ORDER** is made the date the last party signs below between:

(1) **Galectin Therapeutics Inc.** whose registered office is at Suite 240, 4960 Peachtree Industrial Boulevard, Norcross, Georgia 30071 USA (the **Sponsor**); and.

(2) **COVANCE** [ ] whose registered office is at [insert address] (**Covance**),

(each a **Party** and collectively the **Parties**).

RECITALS

(A) WHEREAS Galectin Therapeutics Inc. (**Sponsor**) and Covance Inc. (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2020 (the **MSA**).

(B) WHEREAS Covance is a party to the MSA by virtue of Exhibit A-[ ] to the MSA.

(C) WHEREAS the Sponsor and Covance are Parties to a work order effective as of [date] under the Agreement relating to the Services (the **Work Order**).

(D) WHEREAS subject to the terms and conditions of the Agreement the Sponsor and Covance hereby agree to amend the Work Order.

NOW THEREFORE the Parties agree as follows:

1. Scope and Definitions

1.1. Each word and term used in this Change Order, but not defined, has the meaning specified in the Agreement unless a clear contrary interpretation otherwise applies.

1.2. Pursuant to Section 10 of the MSA, the Parties have agreed to vary the terms agreed in the Agreement or Work Oder by the terms set out in this Change Order No #.

1.3. In the event of conflict, the terms in this Change Order shall take precedence over the Agreement or the Work Order.

2. Term and Termination

The term of this Change Order [shall commence on …] [shall be deemed to have commenced on ...] and shall continue until completion of the Services or earlier termination of the Agreement in accordance with the termination provisions set out in the Agreement (the **Term**).

3. Amendments

3.1. It has been agreed between the Parties that the Work Order shall be extended for a further term of ... until .....

3.2. In consideration of agreeing to provide the Services as amended by this Change Order:

3.2.1. the description of Services (Annex 1) of the Work Order is hereby replaced in its entirety by revised description of Services attached at Annex 1 of this Change Order.

3.2.2. the Budget attached at Annex 2 of the Work Order is hereby replaced in its entirety by the revised Budget attached at Annex 2 of this Change Order. [The revised Budget reflects the revised description of Services and Study/Services Specific Assumptions contained in Annex 1 to this Change Order.]

3.2.3. the payment schedule (Annex 3) of the Work Order is hereby replaced in its entirety by the revised payment schedule attached at Annex 3 of this Change Order.

3.3. In all other respects the Agreement and the Work Order shall continue in full force and effect.

SIGNED in duplicate by an authorised signatory for and on behalf of:

Galectin Therapeutics Inc.		**Covance [ ]**	
Signature	_____	Signature	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (1) NOT MATERIAL AND (2) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

WORK ORDER

This **WORK ORDER** is made the date the last party signs below between:

(1) **GALECTIN THERAPEUTICS INC.** whose registered office is at Suite 240, 4960 Peachtree Industrial Boulevard, Norcross, Georgia 30071 **(**the **Sponsor); and.**

(2) **COVANCE CLINICAL RESEARCH UNIT INC.**, whose registered office is at 3402 Kinsman Boulevard, Madison, WI 53704 **(Covance),**

(each a **Party** and collectively the **Parties**).

RECITALS

(A) WHEREAS Sponsor and Covance Inc. (the **Company**) are parties to a Master Services Agreement effective as of March 12, 2010 (the **MSA**).

(B) WHEREAS Covance is a party to the MSA by virtue of Exhibit A-4 to the Agreement.

(C) WHEREAS subject to the terms and conditions of the MSA and the additional terms and conditions set forth in the relevant Exhibit A, the Sponsor and Covance hereby agree to execute a Work Order relating to the Services for Sponsor's Protocol entitled, *"A Single-dose, Open-label, Pharmacokinetic Study of GR-MD-02 in Subjects with Normal Hepatic Function and Subjects with Varying Degrees of Hepatic Impairment."*

NOW THEREFORE the Parties agree as follows:

1. Definitions and Interpretation

1.1 Each word and term used in this Work Order, but not defined, has the meaning specified in the Agreement unless a clear contrary interpretation otherwise applies.

1.2 In the event of conflict between the terms and conditions of this Work Order and those of the Agreement, the terms of the Agreement shall prevail except to the extent that this Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter.

2. Term and Termination

The term of this Work Order shall commence as of the date of the last signature below and shall continue until completion of the Services or earlier termination of the Agreement in accordance with the termination provisions set out in the Agreement (the **Term**).

3. Services

Covance agrees to perform the following Services for the Sponsor as set forth in the attached description of Services at Annex 1, which shall also detail the Study/Services Specific Assumptions that apply to the Services.

4. Budget

4.1 The Budget for the Services is set out in the detailed Budget in this Work Order attached at Annex 2.

4.2 In consideration for its performance of the Services under this Work Order, the Sponsor shall pay Covance in accordance with the payment schedule or payment terms set out in this Work Order attached as Annex 3.

4.3 Invoices are due within thirty (30) days of receipt by the Sponsor.

5. Payment and Invoice Details

All invoices to the Sponsor should be sent to the following address:

Galectin Therapeutics Inc.
4960 Peachtree Industrial Boulevard, Suite 240
Norcross, GA 30071

All payments to Covance should be sent to the following address:

If by check:

Covance Clinical Research Unit Inc.
PO Box 2454
Burlington, NC 27216

If by wire:

[*]

6. Change Control

In the event that any of the Assumptions used to calculate the Budget or in the provision the Services change, in accordance with Section 10 of the MSA, the Parties shall negotiate an amendment to this Work Order if appropriate. No amendment to this Work Order shall be binding unless agreed in writing.

7. Insurance

Sponsor hereby represents that insurance referred to in Paragraph 8 of Exhibit A-4 (CRU) of the Agreement is applicable to and valid for the duration of this Study.

8. Entire Agreement

This Work Order and the terms of the Agreement represent the entire and integrated agreement between the Sponsor and Covance and supersede all prior negotiations, representations or agreements, either written or oral, regarding the Services.

9. Choice of Law and Jurisdiction

Any contractual dispute or claim arising between the Parties to this Work Order arising out of or in connection with the Agreement or the Services defined herein shall be construed, governed, interpreted, and applied in accordance with the provisions of Section 33.11 of the Agreement.

Galectin Therapeutics Inc.		**Covance Clinical Research Unit Inc.**	
Signature	/s/ Harold Shlevin	Signature	/s/ Catherine Prescott
Name:	Harold Shlevin	Name:	Catherine Prescott
Title:	CEO	Title:	Senior Manager, Contract Management
Date:	March 12, 2020	Date:	March 12, 2020

ANNEX 1 – DESCRIPTION OF SERVICES

Division of Responsibilities

Activity	Responsibility	
Project Management	**Covance**	**Galectin**
Study project management	✓	
Maintain Galectin trial master file (TMF)	✓	
Covance will only be responsible for filing documents associated with the services for which Covance is contracted		
Coordinate project team meetings	✓	
Covance template status reporting	✓	
Coordinator support to audits (internal and Galectin)	✓	
Project financial oversight	✓	
Development of site survey	✓	
Outreach management for confidential disclosure agreements (CDAs) and surveys	✓	
Provide recommendations for site selection	✓	
Compilation and review of investigator list	✓	
Conduct pre-study surveys of sites	✓	
Review site specific informed consent form (ICF)	✓	
Negotiate central IRB	✓	
Negotiate site contract/budget	✓	
Collect regulatory documents and review	✓	
Administer investigator payments	✓	
Site management/maintenance	✓	
Clinical trial management system (CTMS) setup (for site payments)	✓	
CTMS maintenance and status reporting (for site payments)	✓	
Regulatory	**Covance**	**Galectin**
Investigational new drug (IND) application submission		✓
Investigators' brochure (IB) preparation		✓
Biometrics and Medical Writing	**Covance**	**Galectin**
Prepare clinical study protocol	✓	
Publishing of clinical study protocol	✓	
Design electronic case report form (eCRF)	✓	
Perform data coding	✓	
Perform data review, quality control (QC), validation and query management, including reconciliation of any external vendor data received	✓	
Conduct database lock	✓	

Prepare statistical analysis plan (SAP)	✓	
Study data tabulation model (SDTM) datasets and associated documentation (eCRF, Define.xml and reviewers guide)	✓	
Analysis dataset model (ADaM) datasets and associated documentation (Define.xml and reviewers guide)	✓	
Perform statistical analysis of safety data for clinical study report (CSR)	✓	
Perform pharmacokinetic (PK) parameter calculations	✓	
Perform statistical analysis of PK data for CSR	✓	
Perform statistical analysis of pharmacodynamics (PD)/efficacy data for CSR		NA
Provide tables, figures, and listings (TFLs)	✓	
Preparation of integrated CSR	✓	
Publishing of CSR	✓	
Independent Clinical Monitoring	**Covance**	**Galectin**
Conduct phone pre-study visit(s)	✓	
Conduct site initiation visit(s)	✓	
Conduct routine monitoring visits(s)	✓	
Conduct close out visit(s)	✓	
Medical Monitoring	**Covance**	**Galectin**
Prepare medical responsibility plan	✓	
Independent medical monitoring	✓	
Drug Device Safety Solutions and Adjudication	**Covance**	**Galectin**
Prepare safety management plan (SMP)	✓	
Receipt, review and distribution of serious adverse event (SAE) reports	✓	
Notify sites of suspected unexpected serious adverse reactions (SUSARs)	✓	
Project Scientist	**Covance**	**Galectin**
Scientific review of protocol, SAP, TFL shells, TFLs and CSR	✓	
Bioanalytical	**Covance**	**Galectin**
Method development	✓	
Method validation	✓	
Sample analysis	✓	

Project Management Assumptions

Project Management

Plans, Timeline, Budget, General Team Oversight Management

- General project management, day-to-day communication with Galectin and internal communication, project management reports, management of patient recruitment, corrective action steps, metrics management, budget management, and timeline management.

Manage Project-related Staff Training

- Time and costs have been included for initial and ongoing project-related training of the Covance study team. This includes but is not limited to: training for team members that join post initial study start and ongoing training as necessary for all team members individually or as a group.
- Covance will assemble an appropriately experienced project team to manage and deliver the study for Galectin. Resources will be available throughout the study to ensure deliverables are met.
- Covance is responsible for the management of all of the study meeting logistics and will provide teleconference numbers and minutes through the use of a project log. Covance and Galectin will agree on the timeline in which the project log will be distributed to the team post the meeting.

Investigator Site Master File and Galectin Trial Master File

- Covance assumes each external site will maintain their own investigator site master file (SMF) for the duration of the clinical conduct of the study.
- Covance, through delegation of responsibility, will also maintain the TMF on behalf of Galectin.
- Covance will leverage Veeva Vault as its electronic TMF (eTMF) clinical collaboration platform for managing the final clinical study documents.
- Covance will set up the eTMF in accordance with Covance file structures and maintain them for the duration of the clinical conduct and reporting phases of the study. The eTMF will include all essential documents as described in the Guidance for Industry International Council on Harmonization (ICH) GCP Consolidated Guidance.
- If Galectin requires Covance to utilize their eTMF system, additional costs may be incurred.

Biometrics and Medical Writing Budget Assumptions

General

- Covance will follow Covance SOPs and utilize Covance standard templates and style guides unless specifically stated
- Covance assumes that for all deliverables with review cycles, Galectin will provide all comments in a single consolidated document and that any differences in opinion among Galectin reviewers will have been resolved prior to sending the document to Covance. Covance can consolidate comments and conduct a consensus development meeting, if necessary, but this will also result in additional costs.

Data Management
Database Build

- Covance will utilize the Covance library to initially design the data entry screens based upon review of the protocol. If Galectin has any standards or templates for the database screens, these templates need to be received before the database development begins. Any modules not available in the library will be designed based on the information in the protocol and Galectin provided standards. The screens will be reviewed and approved internally by Covance. One Galectin review cycle is planned which would include a screen review meeting.
- The database build will not contain any data integrations into Rave. All external study data will be held outside the database in Statistical Analysis Software (SAS®).
- The edit check specifications will use the Covance edit check specifications template. One Galectin review cycle is planned. The edit check specifications must be finalized prior to programming of the edit checks into the database.
- Covance will perform all testing and validation required for releasing the database into production; internal reviews by our data management, quality review, and clinical staff will be performed where appropriate. Galectin involvement in the testing of the database is not currently planned per Galectin requirements.
- The eCRF completion guidelines will be prepared and reviewed by the data management and clinical staff. One review by Galectin is planned.

General

- Data collected to determine subject eligibility will not be entered in the database but will be recorded and held in source documents.

Data Management Activities

- Data review guidelines will be created, reviewed, and approved by Covance's data management team; one Galectin review cycle is planned.
- Galectin will review and sign the DMP; one review cycle is planned.
- All query management and data review will be performed by Covance.
- All ancillary data will need to be received electronically from Covance and/or Galectin's vendors.
- All medical term coding will be performed by Covance. Galectin will be provided one review cycle.
- Galectin will approve database lock.

Statistical Analysis Software Programming
Study Data Tabulation Model and Analysis Dataset Model Datasets

- Covance will follow CDISC requirements for dataset production.
- Covance will utilize the Covance SDTM library to design the SDTM datasets.
- ADaM datasets will be produced based on the required outputs from the SAP and TFL shells.
- SDTM and ADaM datasets will be reviewed, approved, and finalized by Covance; no Galectin review will be conducted.
- The SDTMs and ADaM datasets along with the Define.xml and reviewers' guide will be provided to Galectin after finalization of the CSR.
- Versions of SDTM to be used, as well as coding, will be included in the DMP. ADaM versions will be included in the SAP.

Tables, Figures and Listings

- TFLs will be produced based on the SAP and TFL shells.
- TFLs will be provided in a separate file(s) to Galectin for review at the same time as the provision of the first draft CSR for review.

Biostatistics
Sample Size Calculation

- Covance assumes that the study will not require sample size calculations to be performed.

Statistical Analysis Plan and Tables, Figures and Listings Shells

- A SAP and TFL shells will be produced before, or soon after, the end of the clinical phase. Covance's SAP and TFL shell template will be utilized unless the use of a Galectin template is defined early in the process. Galectin will have two review cycles (four days and two days) for the SAP and TFL shells.
- Galectin will approve the SAP and TFL shells. The SAP must be finalized before SAS Programming can begin.
- Estimated TFLs are included in the 'Study Specific Details' section of the proposal. After development of the final SAP the counts will be re-evaluated and the price may be adjusted to reflect the actual number.

Pharmacokinetic Analysis

- NCA PK analysis using validated Phoenix WinNonlin.
- Galectin may review the PK analysis results (Phoenix project) before finalization, but this may have an impact on the study timeline.
- One PK analysis will be performed on final data. Any additional PK analyses will incur additional costs.
- Covance will follow the SAP for PK analysis.
- Additional PK parameters not listed in the SAP or the study protocol can be calculated but may incur additional costs.

General

- Compartmental analysis and PK modelling are outside the scope.

Medical Writing

General

- Prior to the delivery of the first draft documents, they will undergo Covance internal review by subject matter experts, including but not limited to; clinical operations, medical, pharmacokinetics, and statistics.
- During Galectin document review cycles, the medical writer will address all Galectin comments and, if requested, will provide documentation as to how the comments were addressed. Galectin is responsible for returning the comments in a timely manner. Comments received late, will result in a change in the timelines which may result in additional costs.
- Changes to text that has been previously reviewed and approved by Galectin will result in a change in the timelines which may result in additional costs.
- Changes to CSR sections and in-text table formats previously reviewed and approved will result in a change in the timelines which may result in additional costs.
- Covance will provide an electronic copy of the final documents to Galectin as PDF files. The documents will be electronically published as submission-ready documents.
- Covance will perform a QC review of the final draft documents. QC review of the first draft documents can also be performed at additional cost, if requested by Galectin and their content is considered unlikely to undergo major changes. The extent and timing of the QC will be agreed with Galectin prior to initiation of writing. The QC checks will be performed using Covance QC checklists. Galectin may specify their own QC checklists or modify the Covance checklists if desired.

Protocol

- The protocol can be prepared using either Covance or Galectin templates or style guides. If the Galectin template is used, it is assumed that any standard template text will have been reviewed and approved by Galectin and will not be changed.
- Covance will develop the protocol synopsis with input from Galectin and the Covance project team. Once this synopsis is approved, a full protocol will be developed.
- Any information provided by Galectin for inclusion in the protocol will assumed to have been reviewed, verified and approved by Galectin prior to sending to Covance.
- Covance assumes that Galectin will require two rounds of review of the protocol prior to finalization. Additional rounds of review will result in additional costs.
- Amendments to the protocol will be prepared as necessary at a specified cost.

Clinical Study Report

- One complete ICH E3 compliant, integrated CSR will be prepared. The report can be prepared using either Covance’s ICH E3 compliant CSR template and the Covance style guide or the Galectin template and style guide. Covance assumes that if the Galectin template is used, it will be similar to an ICH E3 standard report template; if the template is not similar, costs will be re-evaluated.
- The report preparation estimates do not include costs for preparing an interim analysis report or for preparing a separate statistical report.
- Time has been included for one discussion with Galectin to cover the CSR preparation process (including provision of statistical input), report requirements (e.g., format and style), and projected timelines; additional meetings will be subject to a change order and charged at Covance’s standard hourly rates.
- Time has also been included for one discussion with Galectin to cover the background science, clinical concerns, operational issues, and regulatory strategy relevant to the CSR.
- As Covance is creating the SAP and protocol, they will be available electronically as Microsoft Word documents for use in CSR development. The blank eCRF will be developed from the EDC system and will be available in an electronic format suitable for use in the CSR development. Should any documents be needed from Galectin, Covance assumes they will be provided in a suitable format to allow usage for CSR development.

General

- Covance assumes that the statistical methodology section of the CSR can be prepared by minimal modification of the SAP.
- Covance medical writing staff will prepare the CSR in partnership with the Covance or Galectin biostatistician. Medical writing staff will prepare all sections of the CSR. Medical writing staff will prepare a draft of the statistical methodology section based on the SAP, but the final responsibility for these sections will remain with the biostatistician. The biostatistician will also provide the statistical documentation appendix.

Draft Clinical Study Report Preparation

- Covance will prepare the draft CSR once final Covance-generated TFLs are available. If there are any TFLs or data related items that will be provided by Galectin for the CSR, Covance assumes that Galectin will accept responsibility for the quality of those items and for any re-work needed because of errors.
- No more than 10 in-text tables will be prepared for the CSR; additional in-text tables will be subject to a change order. Data in the in-text tables of the report will be reported as presented in the final TFLs; no manual derivation or calculation of data will be performed by the medical writer.
- There will be one review cycle (i.e., Galectin will review the draft CSR only once before receiving the final CSR).
- Galectin will receive an electronic copy of the draft CSR, comprising CSR body text, TFLs and informational appendices.

Final Clinical Study Report Preparation

- There will be one review cycle (i.e., Galectin will review the final report only one time).

Clinical Study Report Appendices

- Covance medical writing staff will compile the appendix materials and review for completeness (i.e., all required pages are included) and copy quality (e.g., adequate margins, no black lines, etc.).
- If Covance has not conducted the study or the analyses, Galectin will need to provide the source materials for the informational appendices.

Narratives

- Subject narratives will be prepared for subjects with SAE(s), discontinuations due to AE(s), and AEs of special interest.
- The CSR preparation estimate includes costs for preparing the narratives, based on estimated numbers. This cost is based on the assumption that narratives for SAEs are prepared using the final TFLs and either CIOMS forms, or MedWatch forms. If other sources of documentation are to be used (e.g., hospital discharge letters), costs will be re-evaluated. Should the number of narratives exceed the estimated numbers, preparation of the additional narratives will be charged through the change order process once the final number of narratives to be prepared is known.

Publishing

- Galectin will receive a bookmarked and hyperlinked eCSR. The eCSR will be provided in eCTD granular format. The text of the CSR (synopsis and body) will also be supplied electronically as a Microsoft Word file.
- A 100 percent QC review of all bookmarks and hyperlinks will be performed on the final eCSR. All QC issues and comments will be addressed, and changes implemented before submitting the final CSR.

Independent Clinical Monitoring Budget Assumptions

Administrative Setup/Site Management

- Protocol/CRF review
- Monitoring plan
- Teleconferences

Site Visits

Phone Pre-Study Visit

Review the following items with the principal investigator (PI) and site staff, as applicable

- Protocol overview, enrollment target, and study timeline.
- Recruitment strategy and availability of subject population.
- Qualifications, experience, and interest of site staff and resource availability.
- The PI's/site's regulatory audit experience, if any, and the outcome of the audit(s).
- Process and documentation requirements for informed consent.
- Source document and study record requirements.
- Monitoring visit schedule and site staff availability.
- Turnaround time for data entry and data query resolution.
- Local/site-specific requirements.
- EDC requirements, including vendor-specific experience, internet connectivity, and computer availability, if applicable.

Confirm the following items, as applicable

- Adequate staff to conduct the study.
- Adequate facilities.
- Adequate storage area and conditions for IMP/other study supplies.
- Request/collect any required site documentation.

Site Initiation Visit

- Review procedures and conduct expectations of the study protocol.
- Review documentation of study procedures (source document worksheets and CRF completion).
- Review of IMP administration/handling, etc.
- Inventory of the IMP (if available at the site) and all related materials.
- Review procedures for reporting of AEs/SAEs.
- Review of PI responsibilities and delegation of responsibilities.
- Discussion of monitoring schedule and expectations.
- Ensure site maintenance of regulatory documents (e.g., study protocol and IB, IRB approval letter(s) for the study and ICF, 1572, current CVs for all listed on the 1572, current medical licenses, financial disclosure, laboratory documents, and audit requirements).

Routine Monitoring Visit

- Confirm informed consent for all subjects screened.
- Verify all enrolled subjects' eligibility (inclusion/exclusion).
- Verify 100 percent source documents to CRFs.
- Verify 100 percent AE reports.
- Verify completion of CRF monitor clarification/corrections and completion of data alerts (queries).
- Review SAE reporting and follow-up activities.
- Review study file for current regulatory/IRB documents.
- Confirm site adherence to the protocol.
- Verify IMP inventory and storage/drug accountability.

Close-Out Visit

- Ensure site and regulatory documentation are complete and accessible for future audits.
- Ensure that the investigator is aware of his/her responsibilities.

- Ensure that any remaining clinical trial material is shipped to the appropriate vendor or destroyed onsite, as directed by Galectin.
- The close-out visit will be scheduled based upon database lock to ensure that all outstanding queries have been resolved.

General

- Each visit will include time for preparation, travel, on-site activities, and report generation.
- Covance will provide a trip report to Galectin within 15 business days of the visit using the Covance standard trip report format.
- Travel expenses will be forwarded to Galectin, at cost, as pass-through costs.
- Covance monitoring SOPs and templates will be utilized.
- Covance uses standard trip report templates which are part of our CTMS. Our CTMS allows our monitors to start writing their trip reports on a laptop during the visit or while traveling. Covance strives for a 10-day turnaround time from date of visit to date of final approval and availability to Galectin. CTMS has electronic signature functionality so there is no need for paper copies to be generated for wet ink signature. The CTMS trip report module is Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (CFR) Part 11 compliant. Should Galectin wish to use your own trip reports, there is a cost to do so.

Clinical Pharmacology Safety Support Budget Assumptions

Prepare the Safety Management Plan

- Covance clinical pharmacology medical/scientific will generate a study specific safety plan (SP) describing agreed procedures and timelines.
- It is assumed that the final SP will be signed off by Galectin prior to the beginning of the AE reporting period.

Safety Database

- Not applicable. Covance services do not include a US FDA Title 21 CFR Part 11 compliant safety database.

Receive, Review and Distribute SAE Reports

- For the purposes of this costing, Covance clinical pharmacology medical/scientific has assumed one SAE is expected.
- Covance clinical pharmacology medical/scientific assumes there will be three reports per SAE – one initial and two follow-ups. Additional follow-ups will require a change order.
- Upon receipt by Covance clinical pharmacology medical/scientific, Covance clinical pharmacology medical/scientific will review the SAE report for legibility, completeness, accuracy and consistency, identify queries as necessary, and write the SAE narrative.
- The Covance clinical pharmacology medical/scientific physician will perform a medical review of the SAE information for sense, expectedness and causality, and provide comments and more queries if any, to Covance clinical pharmacology medical/scientific.
- Covance clinical pharmacology medical/scientific will incorporate changes, if any, collate queries, and forward the SAE report and identified queries to Galectin within agreed timeframes detailed within the SP.
- Galectin will be responsible for forwarding queries arising after their medical review to Covance clinical pharmacology medical/scientific within one business day including confirmation of the event assessment; Covance assumes to receive queries from only one Galectin source (contact person) versus multiple sources.
- Covance clinical pharmacology medical/scientific will follow up queries with sites and/or CRAs.
- Covance clinical pharmacology medical/scientific will manage applicable pregnancy and AEs of special interest reports and process and invoice these consistent with the SAE reports.

Transfer Safety Database

- Not applicable. Covance services do not include a safety database

Notify Sites of Suspected Unexpected Serious Adverse Reactions

- For the purposes of this costing, Covance has assumed one SUSAR is expected.
- In the event a SUSAR surfaces and requires distribution, the following will apply:
  - Covance clinical pharmacology medical/scientific will notify the site(s) of SUSARs.
  - Where Galectin is providing SUSARs for cross reporting purposes, if Galectin provides SUSARs to Covance clinical pharmacology medical/scientific outside the timelines agreed upon within the SP, Covance cannot guarantee SUSAR delivery within applicable regulatory timelines.

Notify Regulatory Authorities and Institutional Review Boards of SUSARs

- For the purposes of this costing, Covance has assumed one SUSAR is expected.
- In the event a SUSAR surfaces and requires distribution, the following will apply
  - Regulatory authorities—Covance assumes Galectin will notify the FDA of all applicable SUSARs.
  - Central IRB—Covance will notify the central IRB of all SUSARs, where applicable.
  - Local IRBs—local IRBs will receive safety reports via the investigators.

Prepare and Submit Periodic Safety Reports

- Not Applicable. Covance services do not include a safety database.

Additional Information

- Assumptions not explicitly stated are not to be implied as a Covance clinical pharmacology medical/scientific responsibility.

Medical Monitoring Budget Assumptions

Start-Up

- Protocol preparation/review
- IB review
- Preparation/review of the medical responsibility plan
- Preparation/review of the safety plan (if needed)
- Attendance and participation/presentation at the KOM
- Attendance (by phone unless travel is included) and participation/presentation at the SIVs

Subject Eligibility (Screening and Enrollment)

- Answering any inclusion/exclusion clarifications/queries
- Review subject eligibility during screening and prior to check-in (review limited to key inclusion/exclusion criteria such as medical history, con meds and laboratories)
- Approval of subject eligibility prior to dosing

Teleconferences

- Attendance of internal and Galectin teleconferences by the medical monitor and/or medical/scientific associate
- Follow-up required to complete any “action items” assigned during teleconference

Ongoing Study Monitoring

- Answering any IRB queries
- Answering any site/project manager (PM)/clinical research associate (CRA) queries
- Reviewing any protocol deviations with a potential impact on safety/data integrity
- Reviewing safety/PK data
- Documentation of significant medical decisions
- Inclusion of important medical monitoring-related documents in the TMF

Medical Coverage

- Medically qualified team member familiar with the protocol is available for emergency questions/support from the sites after normal business hours, on weekends and on holidays

Close-out

- Answering data queries
- Review of AE coding and TFLs
- Medical and Scientific review of CSR
- Preparation of patient narratives for AEs/subjects of interest

Additional Information

- Assumptions not explicitly stated are not to be implied as a Covance clinical pharmacology medical/scientific responsibility

Project Scientist

Start-Up

- Protocol preparation/review
- IB review
- Preparation/review of the unblinding plans, if applicable
- Participate in completion of risk assessment registry
- Attendance and participation/presentation at the kick-off meeting (KOM)
- Attendance (by phone unless travel is included) and participation/presentation at the SIVs
- Prepare ICF risk language and/or core ICF, as applicable

Teleconferences

- Attendance of all internal and Galectin teleconferences, if necessary

Scientific Review

- SAP review and comment
- TFL shells review and comment
- TFLs review and comment
- CSR review and comment

Additional Information

- Assumptions not explicitly stated are not to be implied as a Covance clinical pharmacology medical/scientific responsibility

Drug Device Safety Solutions and Adjudication Budget Assumptions

Prepare the Safety Management Plan

- Following agreement with Galectin requirements, generate one project specific SMP describing agreed procedures and timelines.
- Covance assumes two review cycles with Galectin providing only one set of consolidated comments. The final SMP will be provided to Galectin for signature.
- It is assumed that the final SMP will be signed off by Galectin prior to the beginning of the AE reporting period.
- Covance assumes no other parties are involved with the SAE process. If Galectin specifies the Galectin SMP template is to be used, additional time will be included for familiarization with the Galectin template. If Covance does not author the SMP, additional time will be put forward to create a Galectin specific work instruction outlining additional process details specific to Covance’s needs.

Prepare the Safety Management Plan

- Hours provided assume no annual review of the SMP.

Safety Database

- Covance will set up one SAE database using Argus Safety Web™ upon receipt of the first SAE. Setup may take up to six weeks, and manual processing will be performed until the database is available.
- Covance assumes Galectin has a current MedDRA license with Northrop Grumman/MSSO and/or current WHODRUG license with the Uppsala Monitoring Center (UMC). Covance is prohibited from sharing dictionary terminology or data with any non-subscribing company.

Receive, Review, and Distribute Serious Adverse Event Reports

- For the purposes of this costing, Covance has assumed one SAE is expected.
- Covance assumes there will be three reports per SAE – one initial and two follow up reports.
- Upon receipt by Covance DDSSA, Covance DDSSA will review the SAE report for legibility, completeness, accuracy, and consistency; identify queries as necessary; and write the SAE narrative.
- The Covance drug safety physician will perform a medical review of the SAE information for sense, expectedness, and causality; and provide comments and more queries (if any) to Covance DDSSA.
- Covance DDSSA will incorporate changes, if any, collate queries, and forward the SAE report, identified queries, and any Argus outputs to Galectin within agreed timeframes detailed within the SMP.
- Galectin will be responsible for forwarding queries arising after their medical review to Covance DDSSA within one business day including confirmation of the event assessment; Covance assumes to receive queries from only one Galectin source (contact person) versus multiple sources.
- Covance DDSSA will follow up queries with sites and/or CRAs.
- Covance DDSSA assumes that all translations of SAE or source documents requested by Galectin or required by local regulations will be handled as an out of pocket expense.
- For invoicing purposes, the number of SAEs (or event terms) are counted versus the number of SAE ‘cases’/manufacturer numbers, since each ‘case’/number could have more than one SAE term and subsequent information.
- Covance DDSSA will manage applicable pregnancy reports and process and invoice these consistent with the SAE reports

Transfer Safety Database

- Covance assumes standard database transfer in E2B format, if applicable.

Notify Sites of Suspected Unexpected Serious Adverse Reactions

- For the purposes of this costing, Covance has assumed one SUSAR is expected.
- In the event a SUSAR surfaces and requires distribution, the following will apply
    - Covance will notify the site(s) of SUSARs.
    - Covance assumes our responsibilities to distribute SUSARs to sites begin when the respective site has been activated by the monitor.
    - Covance assumes that SUSAR reports to sites will be made electronically.
    - Where Covance holds the safety database, Covance DDSSA will provide the necessary outputs (CIOMS, etc.).
    - Where Galectin holds the database, if Galectin provides SUSARs to Covance outside the timelines agreed upon within the SMP, Covance cannot guarantee SUSAR delivery within applicable regulatory timelines. If Galectin is providing 7 day and 15 day SUSARs to Covance, DDSSA expects to receive these no later than calendar day 5 and 12, respectively.

Notify Regulatory Authorities and Ethical Bodies of Suspected Unexpected Serious Adverse Reactions

- For the purposes of this costing, Covance has assumed one SUSAR is expected.
- In the event a SUSAR surfaces and requires distribution, the following will apply
    - Covance will notify the central IRB of all SUSARs.
    - Covance assumes Galectin will notify the FDA of all applicable SUSARs in the US.
    - Covance assumes our SUSAR distribution to IRBs begins at the time of approval.
    - Where Covance's Argus database is being assumed and utilized, Covance will supply the applicable forms for reporting SUSARs.
    - If Galectin is providing 7-day and 15-day SUSARs to Covance, DDSSA expects to receive these no later than calendar day 5 and 12, respectively.
    - Local IRBs will receive the notifications via the investigators.
    - Covance assumes that submissions to IRBs will be made in the preferred method of the recipient.
    - Covance assumes Galectin will be responsible for comparator safety reporting, if applicable, as well as any reporting related to concomitant medication usage, where applicable

Prepare and Submit Periodic Safety Reports/Development Safety Update Reports

- Unit/contingency costs have been put forth for these summary reports.
- Covance will provide line listings of all suspected adverse reactions (SARs) and SUSARs from the Covance Argus database, provide the safety analysis, prepare, and distribute.
- Covance assumes that the safety report will be based on the clinical study data held in the Covance Argus database.

Additional Information

- Covance recognizes that some countries worldwide may have special or evolving safety reporting requirements for SUSARs and periodic safety summary reports (development safety update report [DSUR], every six months, every three months, etc.) that have not been captured in this original budget. If these specifics surface during the study startup and/or maintenance periods and affect the number or frequency of submissions provided, it may require additional costs to be paid by Galectin. In this case, costs will be collated and presented as a change order.
- Assumptions not explicitly stated are not to be implied as a Covance responsibility.

Laboratory Services Budget Assumptions

Bioanalytical

360 Estimated Serum Samples
36 Estimated ISR Samples
72 Estimated Reassay Samples (20% of original #)
468 Total Estimated Serum Samples

Urine testing will be Galectin's responsibility through third party vendor.

<u>General</u>

- Galectin will provide documentation and relevant historical data regarding previous development, validation, and/or general performance of the applicable method(s).
- Galectin will provide critical reagents. Covance will provide commercially available reagents which are reasonable and customary. Other costs will be passed on to the Galectin.
- The cost of kits, plates, CDs, and/or matrix is not included. If included, it is only an estimate. If additional kits, plates, CDs, and/or matrix are required, the need to assign costs for these will be discussed with the Galectin prior to incurring the charges.
- Plate utilization efficiency may have a cost impact for all kit and non-kit assays.
- Labeling of study specific reagents can be performed [*].

- It is assumed that sample and reagent stability can be proven for the duration of the project or at least >1 year. Fees may apply if additional qualifications are required due to instability of samples or reagents.
- Any Galectin-requested work adding to, or deviating from, a protocol and/or sample analysis outline will be costed separately (e.g., unplanned development, additional troubleshooting, or decisions that alter the direction or scope of a study, including unexpected changes in sample number, receipt rate, or urgency of analysis may have a cost impact).
- Prices include archival of all raw data, documentation, protocol, and final report for the studies (except for the biological samples) for one (1) inspection cycle from the date of the final report. The archival period can be extended if required, at an additional charge. At the end of this time period, the Covance archives staff will contact the Galectin to determine disposition of those archived materials.

Method Development

- The number of days quoted is only an estimate, and we will only bill for the days used. If additional days are needed, we will request separate authorization before proceeding. Covance will make all efforts to design and execute method development activities to limit the cost for the Galectin when additional matrices and species are requested. The additional time quoted is to allow us to resolve potential issues so we can develop a compliant, robust method for the additional species/matrix. No guarantees or warranties are implied as to when or if the development will be successfully completed. Should the development not be progressing effectively in the reasonable opinion of either party, then either party may terminate the development without any further obligation occurring.
- QA will not be involved during Method Development phase.
- Results for these studies are provided by email. If a development/transfer report is required, this can be done at an additional fee.

Method Validation

- Method Validation will be conducted per regulatory requirements and QA audits will be performed per Covance procedures.
- Full validation will be in compliance with Covance SOPs and includes one long-term stability assessment between 2 and 4 weeks, at two temperatures. Any additional long-term stability evaluations will be charged per time point per temperature. A validation report addendum fee may apply.
- An assay specific protocol will be drafted in conjunction with the Galectin to meet your needs once work is awarded. If additional work is required beyond the scope included in the quote, then this will be charged per additional day.
- Additional specificity investigations may be required to assess the potential for co administered drugs to interfere with the assay. Additional fees will apply if this testing is required.
- Whole blood stability evaluation can be performed at an additional charge.
- Assays required to be validated to CLIA standards will incur additional charges.
- The price includes electronic and paper versions, if applicable, of the report (one draft and final), which will be written using a Covance report template. Galectin-specific report templates, provided by the Galectin, may also be used at an additional cost per report. Final bioanalytical reports will be provided as an electronic copy of the signed final report in fully text searchable Portable Document Format.

Sample Analysis

- Sample Analysis will be conducted per regulatory requirements and QA audits will be performed per Covance procedures.
- Samples are analyzed in duplicate at a single dilution (PK/TK/Biomarkers, ADA-Screen and Confirmatory only).
- The number of samples is approximate. We will charge for the actual number of samples assayed or a minimum batch fee, as applicable.

Bioanalytical

- It is assumed that assays will be maintained in active status, meaning that assays will be performed at least once each 6 months as part of normal sample testing or execution of long-term stability (LTS) time points. If methods will not be run as part of normal sample testing or LTS, it is our recommendation that Galectin authorizes a maintenance run (at an additional fee) in order to keep the method in active status. If Galectin declines to perform a maintenance run and the method moves to an inactive status, additional charges may be applied to resurrect the method back to active status, such as any qualifications of new reagents, lots of calibrators, or QCs.
- All reassays, due to the Test Article's concentration falling above the dynamic range of the standard curve or Galectin requested repeats, will be charged at the agreed per sample price or as a minimum batch fee shown above, whichever is greater. Unless otherwise requested, reassays will be batched with future shipments/analysis when possible to avoid inefficiencies; if requested to perform repeat analysis, fees stated above will apply.
- Assays required to bridge between different lots of Compound are not included and will incur additional charges.
- Incurred Sample Reproducibility (ISR): The Crystal City Whitepaper (Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays, BMV Whitepaper, May 2006 Crystal City Meeting) recommends an evaluation of incurred sample reproducibility for clinical studies and each species used for GLP toxicology studies. During the preparation of the study protocol or sample analysis outline, it will be necessary to discuss the most suitable approach to the repeat analysis of incurred samples.
- The number of ISR samples is an estimate for your budgetary purposes only. Our standard approach for ISR is [*] or at least [*] and [*] up to [*]. Any analysis of incurred samples for reproducibility experiments will be subject to the above per assay charge.
- Minimum Project Fee and Minimum Batch Fee:

  If the analysis study contains less than [*], a study setup fee [*], a study report fee [*] and an analysis fee of the number of samples at the per sample price or minimum batch fee, whichever is applicable (per method) will be applied for TK/PK/ADA screening sample analysis. In addition, a [*] minimum fee for confirmatory and titer samples will be included if the total number of samples from the study is [*] or the study is terminated with fewer than [*] samples being analyzed prior to completion.

  If we are requested to analyze and provide interim data for the sample size less than what is indicated below, a minimum batch fee could be applied:

Type of Assay	Minimum Batch Size	Minimum Batch Fee
[*]		

- Samples will be stored free of charge for [*] following submission of first draft report and/or final data delivery, whichever comes later. Covance reserves the right to charge for the handling, tracking, and storage of any samples received which are ultimately not required by the Galectin to be analyzed as part of the services or samples stored beyond the complimentary storage period. These samples will immediately incur monthly storage charges of [*] for standard samples or [*] for radioactive and tissue samples. All studies are subject to a minimum monthly storage charge of [*]. In the event the Galectin is unresponsive in providing final disposition instructions, Covance will charge the Galectin for additional storage of samples in [*]. If storage fees are unpaid for [*] from receipt of the first invoice, samples may be disposed of without Galectin approval. Samples may be shipped to you at an additional cost.
- The price includes electronic and paper versions, if applicable, of the report (one draft and final), which will be written using a Covance report template. Galectin-specific report templates, provided by the Galectin, may also be used at an additional cost per report. Final bioanalytical reports will be provided as an electronic copy of the signed final report in fully text searchable Portable Document Format.

Budget Exclusions

Budget Exclusions

- IB production.
- Annual updates to IB after completion of the study.
- Preparation of protocol amendments.
- Submission of protocol amendments to the IRB.
- Purchasing of all study drugs.
- Independent medical monitoring (external to Covance medical monitoring).

ANNEX 2 – BUDGET

Estimated Budget Summary [*]

Direct Fees	Cost (USD)
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Direct Fees Subtotal	**942,315**
Estimated Pass Through Fees	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Grand Total Value	
Total[*]	**2,039,057**

[*]

The pricing for the Work Order shall be deemed to be a [*] Work Order, which means a [*] set of Services as detailed in the Study-Specific Assumptions and delivered in accordance with the [*] outlined in this Annex.

ANNEX 3 – PAYMENT SCHEDULE

Milestone	Percentage	Payment Amount
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Grand Total		**$ 2,039,057.00**