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 6, 2015

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))

Item 1.01. Entry into a Material Definitive Agreement

On March 6, 2015, Galectin Therapeutics Inc. ("Galectin") entered into a Project Addendum to Master Services Agreement for clinical management services with PPD Development, L.P. ("PPD"). Pursuant to the Project Addendum, PPD will provide Galectin with clinical development services for its Phase II NASH-CX study. The specific services provided by PPD to Galectin are described in the Project Addendum. Galectin and PPD entered into the Master Services Agreement on January 8, 2015, however, until the parties entered into the Project Addendum, neither party had any material obligations under the Master Services Agreement. Galectin will make payments to PPD on a periodic basis as described in the Project Addendum.

Pursuant to the Project Addendum and in exchange for the services provided by PPD, Galectin will pay PPD a sum anticipated not to exceed approximately $14,941,804, consisting of direct fees of $8,866,490.71 and pass through costs estimated at $6,075,313.45. The term of the Project Addendum will commence on the effective date and end upon completion of all the services provided by PPD, unless terminated earlier in accordance with the provisions of the Master Services Agreement, which states that any Project Addenda is terminable by either party on 30 days' notice. In the event of early termination, Galectin will pay PPD all direct fees and pass through costs for all services performed through the termination date.

The foregoing description of the Project Addendum is a summary only and is qualified by reference to the full text of the Project Addendum. The Project Addendum, together with the Master Services Agreement, is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 8.01 Other Events

On March 12, 2015, Galectin issued a press release announcing, among other things, its relationship with PPD, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.:	
10.1	Project Addendum (with Master Services Agreement), dated March 6, 2015, by and between Galectin Therapeutics Inc. and PPD Development, L.P.*
99.1	Press Release

* *Galectin Therapeutics, Inc. has requested confidential treatment with respect to portions of this exhibit. Those portions have been omitted from the exhibit and filed separately with the U.S. Securities and Exchange Commission.*

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 12, 2015

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

Exhibit Index

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99.1	Press Release

* *Galectin Therapeutics, Inc. has requested confidential treatment with respect to portions of this exhibit. Those portions have been omitted from the exhibit and filed separately with the U.S. Securities and Exchange Commission.*

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT (INDICATED BY ††) HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT.

PROJECT ADDENDUM

THIS PROJECT ADDENDUM (the "***Project Addendum***") is made and entered into as of January 10, 2015 (the "***Effective Date***") by and between **PPD DEVELOPMENT, LP**, a Delaware limited partnership, with its principal executive offices located at 929 North Front Street, Wilmington, North Carolina 28401 (***"PPD"***) and **GALECTIN THERAPEUTICS, INC.**, a Nevada corporation with its principal executive offices located at 4960 Peachtree Industrial Boulevard, Suite 240, Norcross, Georgia 30071 (***"Sponsor"***).

WHEREAS, PPD and Sponsor entered into a certain Master Services Agreement ("***Agreement***") dated January 8, 2015; and

WHEREAS, pursuant to Section 1.2 of the Agreement, the parties now wish to enter into this Project Addendum for the purposes of setting forth the responsibilities and obligations of the parties in regards to PPD providing services for Sponsor's Phase II NASH-CX study, (the "Project").

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. Services.

PPD shall perform those certain services set forth in the proposal submitted to Sponsor by PPD, which proposal is attached hereto as Exhibit A and incorporated herein by reference ("***Services***").

2. Compensation and Payment.

2.1 - Compensation - For its performance of Services under this Project Addendum, PPD and Sponsor have established a budget of not to exceed $**14,941,804.16** of which $**8,866,490.71** shall be Direct Fees (as defined in the Agreement), and of which $**6,075,313.45** shall be Pass Through Costs (as defined in the Agreement), with each of the Direct Fees and Pass Through Costs to be as determined under and limited by the Study Budget attached hereto as Exhibit B. PPD shall only invoice and Sponsor shall only be responsible for paying those Direct Fees and Pass Through Costs that are actually and reasonably incurred by PPD in the performance of the Services, and further subject to the amount limitation set forth herein unless otherwise agreed by the parties in writing. Should a material change in any of the key Study parameters , e.g., countries included, number or country distribution of sites, number of patients, number of CRF pages, number of statistical tables or listings, study timeline or protocol design justify an increase or decrease in the Study budget, PPD and Sponsor will negotiate in good faith changes to the Study Budget, which will be effective when summarized in writing and approved by Sponsor. PPD will promptly notify Sponsor in writing when it learns of facts or events that could be a material change in key Study parameters.

The Direct Fees are determined and limited by the quantities and the unit prices set forth in the Study Budget (less the consulting services discount as provided on page 9 thereof), as may be adjusted above, with payments of the Direct Fees billed and paid as set forth in Section 2.2. Sponsor and PPD recognize that the Direct Fees from time to time earned hereunder may be greater than or less than the payments then made under Section 2.2, and that in the event of early termination of the Services to be provided under this Project Addendum the Sponsor and PPD will negotiate in good faith the final payment or refund based on worked performed as compared to the Study Budget. Pass Through Costs are estimated and may vary as circumstances require but will be prudently managed by PPD so that they are reasonable and necessary to the conduct of the Study. PPD will promptly notify Sponsor in writing when it learns of facts or events that could cause the Pass Through Costs to exceed the sum of $6,075,313.45.

2.2 - Payment - PPD shall submit to Sponsor monthly invoice describing the Services performed on the Study, the Direct Fees due for such Services, and all Pass Through Costs paid by PPD, each as compared to the Study Budget so that Sponsor can track the level of expenditures against the Study Budget. For cash flow purposes, payments will be billed and remitted in accordance with the Payment Schedule attached hereto as Exhibit C, and PPD will provide information to Sponsor with each billing so that Sponsor can confirm that the amount billed is then due. Sponsor shall pay each monthly invoice within thirty (30) days of receipt of said invoice.

2.3 – Payments to PPD shall be made to:

PPD Development, LP
26361 Network Place
Chicago, Illinois 60673-1263
Tax ID# ††

Or, if wired to: JPMorgan Chase
Acct #: ††
R/T Number: ††(ACH & Wire)
SWIFT/BIC: ††
Beneficiary: PPD Development, LP

Any changes to the payee information set forth above require a writing signed by PPD's treasurer or chief financial officer.

3. Standard Operating Procedure

PPD shall conduct the Study according to PPD's Standard Operating Procedures ("SOPs"), which have been provided to Sponsor for review. These SOPs are subject to reasonable revision by PPD in which case PPD shall notify Sponsor of revision. If any such SOP revision can be reasonably expected to affect the budget or timelines for the Study, PPD shall submit to Sponsor revised cost estimates or timelines for the relevant Services which will become a part of this Project Addendum upon written approval by Sponsor. The current SOPs for conducting and monitoring clinical trials are available for review upon request by Sponsor.

Upon mutual agreement in writing, the parties may conduct the Study under Sponsor's standard operating procedures. In such case, Sponsor shall provide prompt and reasonable training to any PPD personnel subject to such SOPs at Sponsor's expense.

4. Term and Termination.

The term of this Project Addendum shall commence on the Effective Date and end upon the completion of Services unless otherwise terminated in accordance with the Agreement.

5. Incorporation by Reference/Conflict of Terms.

The terms and conditions of this Project Addendum and Exhibits hereto are hereby incorporated into and made a part of the Agreement. To the extent any terms contained in an Exhibit hereto conflict with this Project Addendum, the terms of this Project Addendum shall govern and control. In the event of any inconsistency between the Agreement, the Project Addendum, and the Protocol, the terms of the Protocol shall govern first, followed by the Project Addendum, and then by the Agreement unless otherwise specified.

6. Modifications.

Any changes to this Project Addendum or its Exhibits shall be documented by written Amendments executed by both parties and shall be attached hereto.

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

7. Notices.

Each Party represents that its respective contact person set forth below shall have the authority to make all executive decisions regarding this Project Addendum. Any notice required or permitted to be given hereunder by either party hereunder shall be in writing and shall be deemed given on the date received if delivered personally or by fax or five (5) days after the date postmarked if sent by registered or certified U.S. mail, return receipt requested, postage prepaid to the following address:

If to PPD:
PPD Development, LP
929 North Front Street
Wilmington, North Carolina 28401
Attention: CEO & General Counsel
Tel: (910) 251-0081
Fax: (910) 762-5820

If to Sponsor:
Galectin Therapeutics, Inc.
4960 Peachtree Industrial Blvd.
Suite 240
Norcross, Georgia 30071
Attention: Chief Operating Officer
Tel: (678) 615-3213

8. Counterparts and Facsimiles.

This Project Addendum may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement by facsimile transmission or in Portable Document Format sent by electronic means. Signatures of authorized signatories of the parties transmitted by facsimile or sent by electronic means in Portable Document Format shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Project Addendum.

IN WITNESS WHEREOF, this Project Addendum has been executed and delivered on the 6th day of March, 2015, by their duly authorized officers as of the Effective Date.

PPD DEVELOPMENT, LP
By: PPD GP, LLC
Its General Partner

By: /s/ Paul Colvin
Name: Paul Colvin, RPh.
Title: Exec. VP Global Clinical Development

GALECTIN THERAPEUTICS, INC.

By: /s/ Peter G. Traber
Name: Peter G Traber
Title: CEO / President

Exhibit A

Proposal
(Specs/Assumptions and Statement of Services)

1 Specifications and Assumptions

1.1 General

	North America
Number of Screened Subjects	††
Number of Randomized Subjects	††
Number of Completed Subjects	††
Participating Countries (sites)	††
Estimated Enrollment Period (months)*	12.10
Estimated Enrollment Rate (patients/site/month)	††
PPD Assumption or Galectin Assumption	PPD/Galectin
Maximum Duration of Subject Participation in Months	12.10
Number of Face-to-face Client Meetings	††
Number of Conference Calls With Galectin	††
SAE (serious adverse event) Rate (%)	††

* PPD regards subject enrollment as fundamental to a successful study but also recognizes that factors outside its control can affect the rate of enrollment. On this basis, PPD commits to employing all reasonable efforts to meet or exceed enrollment expectations but cannot offer contractual guarantees on enrollment.

1.2 Clinical

	North America
Number of Protocol Summary Translations	0
Protocol Summary Translations Languages	N/A
Number of Informed Consent Form Translations	2
Informed Consent Form Translations Languages	††
Clinical Trial Agreement Template*	PPD
Number of Sites Using Local IRB/EC	††
Number of Sites Using Central IRB/EC	††
Number of Sites Identified by PPD	††
Number of Pre-study Evaluation Visits	††

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

	North America
Number of Pre-study Evaluation Visit Waivers	††
Number of Initiation Visits	††
Number of Active Sites	††
Number of Back Up Sites	††
Interim Monitoring Frequency in Weeks**	
During Enrollment	††
During Treatment	††
Total Number of Interim Monitoring Visits	††
Total Number of Un-Blinded Drug Accountability Visits	††
Average Time on Site per Monitoring Visit in Hours***	††
Number of Close-out Visits	††
% Source Data Verification	100%
Number of Protocol Amendments per Site	1
Frequency of Status Reports	Weekly
Frequency of Investigator Payments	Quarterly

* PPD's proposal is based on use of PPD's standard clinical trial agreement templates. Deviations from these templates can considerably extend the site startup process. If alterations are required involving negotiations with trusts/investigators, additional review cycles and/or translations/back translations, PPD will work with Galectin to identify the workload impact. Should this lead to extensions in the total study timelines or additional labor requirements, a revised study budget will be required.

** Adjustments to monitoring visit cycles and their budgetary impact will be discussed as needed with Galectin.

*** Time on site may vary according to site recruitment, site performance and monitoring frequency. This average time on site will allow PPD's monitors to spend more time at some sites and less at others.

1.3 Regulatory

PPD will appoint a global Regulatory Affairs Lead (RAL) to the study. This person will be Galectin's regulatory contact and will have overall responsibility for the following:

- Preparation of the †† Quality section from source documents provided by Galectin.
- Management of the regulatory aspects/timelines of the study and coordination of the regulatory submissions in the countries participating in the study.
- Attendance at a kick-off meeting to establish a communication plan, discuss responsibilities for document provision and establish deliverables and timelines.
- Preparation of a comprehensive list of documents required for the CTAs for the countries participating in the study, indicating the responsibilities for their provision.
- Arranging the master CTA to create the country-specific CTA submission packages for the countries participating in the study in compliance with the regulations in force at that time.

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- Submission of the CTA documents to the regulatory and local authorities (where applicable) in the countries participating in the study, following review and approval by Galectin.
- Provision of the necessary follow-up and act as local agent and regulatory affairs contact in the countries participating in the study and as instructed by Galectin.
- Provision of electronic copies of regulatory documents to the regulatory counterpart at Galectin at the frequency/interval agreed in the contract with Galectin.
- Preparation and submission of end of trial notifications.

PPD will also assign a local Country Approval Specialist (CAS) from each market involved in this study to support local submission activities and other regional assessments as required.

Local regulatory professionals will notify and frequently update the RAL regarding any regional issues such that the RAL can convey such information to Galectin without the need for Galectin to discuss with the local regulatory professionals directly.

PPD will review and provide regulatory intelligence input into study documents (e.g., protocol, investigator's brochure) and locally translated documents (e.g., customized ICF, study drug labels) in order to minimize potential for questions during authority review and maximize successful outcome.

Assumptions

PPD assumes the following:

- Galectin will provide all necessary documentation requested by PPD, in a timely fashion and in appropriate electronic format.
- No pre-CTA meetings with local agencies are included. PPD will separately inform Galectin if one is considered advantageous and will provide a separate quotation for the cost.
- The global RAL is the Galectin contact, and hours allocated to that interaction are included in this proposal.
- Provision for local professionals to participate on sponsor calls is not included; however, if a specific regional issue arises and Galectin requires the local regulatory professional to participate in such calls, an estimate of additional hours can be provided.
- Translations management is generally organized by Clinical Management.
- PPD will maintain an effective CTA on behalf of Galectin. CTA maintenance activities include but are not limited to:
    - Acting as the liaison between regulatory authority and Galectin.
    - Preparing and submitting notifications and/or amendments to the CTA/IND (see below).
    - Reporting SAEs to the regulatory authority when PPD is contracted to do so.
    - Registering the participating investigator to the CTA, as appropriate.
    - Maintaining a chronology of all submissions and correspondence with the regulatory authority.

CTA Amendments/Notifications

- Assuming any advice provided by PPD during CTA preparation is adhered to, PPD will not charge extra for responses to agencies during the initial CTA approval process prior to submission.
- Costs for amendments are not included as part of the CTA service as the timing and frequency of these amendments cannot be predicted. The following costs are identified as chargeable for any CTA amendments/notifications required during the course of the study.

††

Task	Estimated Cost*
Protocol Amendment	$ ††
Chemistry Amendment	$ ††

* Based on 2014 rates.

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

1.4 Investigational Product Services

Services Required	• Clinical supplies contact for study team (PPD and Galectin). • Investigational product (IP) forecasting. • Label text translation review. Including country regulatory compliance check assessment. • Packaging and labeling via PPD cGMP certified vendor in USA. • Assist in interactive voice response system (IVRS) specifications development upon request (when applicable). • Development of a global distribution and clinical site resupply strategy. • Global depot management. • Global inventory tracking. • Global expiry date tracking. • Global import/export permits tracking, management and consultancy. • Global shipments to site tracking. • Global product return, accountability, reconciliation and destruction coordination.
Products Forecast and Number of Forecast Reviews for Each Product	• Two: initial and mid-term.
Drugs to be Procured by PPD	• Not applicable.
Number of Label Translations (assumes one review cycle)	• Four texts (primary packaging, secondary packaging, outer cartoon and patient card). One regulatory compliance check/review per each text per each country-language. • One country-language.
Number of Packaging Runs	• Approximately two packaging and labeling campaigns.
Ancillary Supplies to be Procured by PPD	• To be determined on a trial-by-trial basis.
Length of Clinical supply management	• 31.2 months.

Depot specifications	• One Depot: USA. • Approximately 25 months of Depot distribution management. • Approximately fifteen resupplies per depot. • Approximately six resupplies per clinical site. • Approximately tree returns from clinical site to respective country/regional depot. • Approximately one consolidated destruction per country depot at the end of the trial.
Import/Export specifications	• One import/export permit per country.

Indirect Costs

- Domestic freight charges have been included in this proposal as initial/standard estimations only and can change subject to final weight and box size variations for each shipment.
- Estimated material costs associated with shipments (e.g., normal packaging material, temperature recording devices, normal filling material) have been included in this proposal and can be subject to change when assumptions such as enrollment or number of sites change.
- Estimated destruction costs have been included in this proposal. Final values will be driven by both actual weight and actual volume/size of materials that will be disposed. These costs will be invoiced as pass-through costs to Galectin at actual rates and defined at end of study.
- Costs associated with external translations of study drug labels have been included in this proposal. Final values will be driven by actual amount of text to translate and actual number of countries/languages considered for the trial.
- This proposal includes estimated costs for payment of duties and import taxes where applicable. Final costs will be dependent on material description, quantities and valuation price(s) declared by Galectin or supplier. Galectin will be billed actual costs as pass through. Galectin is responsible for the description and valuation of all material imported or exported to be used on all required import/export documents.
- Estimated costs associated with third-party depots have been included in this proposal. These costs include estimations for storage fees assuming two storage locations per depot per month during 25 months. Final values will be driven by actual quantities and actual volume/sizes of materials that will be handled. These costs will be invoiced as pass-through on a monthly basis. (Depot in United States).
- This proposal does not include a provisional cost estimate for acquisition of ancillary supplies (e.g., lab kits, thermometers, pregnancy kits, equipment, documentation).
- This proposal does include estimated costs for materials associated with packaging and labeling of study drugs. Final costs will be driven by actual quantities to pack and label and can be subject to change depending on changes in quantities to be produced.

1.5 Quality Assurance

	North
Information Governance & Compliance - Trial Master File (TMF) Set-Up, Maintenance, Archiving and Transfer	Yes
Information Governance & Compliance - Unblinded Investigator File Set-Up, Maintenance, Archiving and Transfer	Yes
% of Clinical Investigator Sites to be Audited	10
Current Clinical Investigator Site Audit Number	5
Clinical Quality Assurance (QA) Project Support	Yes
Clinical Supplies QA - Project Support	Yes

Assumptions

- PPD will provide clinical quality assurance (QA), clinical supplies QA and information governance & compliance (TMF management) services to Galectin.
- The TMF will be transferred to Galectin electronically at the end of the study. If Galectin requires a paper TMF then there will be additional costs that have not been included in the study budget.
- A final report including audit observations and auditee responses will be compiled for each audit and forwarded to Galectin.
- Clinical QA support for the project will average two (2) hours a month while the clinical investigator sites are active.
- Clinical Supplies QA will support PPD’s investigational product manufacturing, storage and distribution operations. Support will be provided by personnel based at PPD’s facility in Raleigh, NC.
    - A quality agreement will be set up between Galectin and PPD.
    - PPD can provide regulatory inspection support, if required. PPD will discuss costs for support with Galectin once the scope of the regulatory inspection is known.

1.6 Pharmacovigilance/Medical Monitoring

	NA
Serious Adverse Events (SAEs)	15
Protocol Inquiries	260

	NA
Physician Assessment Diagnostic Forms	19
Safety Listing Review	8 (quarterly)
Coding Listing Review	4 (every 6 months)
Lab Draws (per randomized subject)	3
Face-to-Face Data Monitoring Committee Organizational Meeting	1
Data Monitoring Committee Teleconferences	6
Clinical Trial Application (CTA) Review	1
CTA Amendment Review	1

Services Included*

* PVG contracted services include set up and management, as applicable.

- Kick-off meeting attendance.
- Investigator meeting attendance.
- 24-hour/7-day medical safety availability.
- Develop Safety and Medical Management Plan (SMMP)/Expedited and Periodic Safety Reporting Plan (ESRP), as applicable.
- Set up/maintain the safety database.
- Project team/sponsor meeting attendance, as applicable.
- Medical monitor consultation for protocol inquiries. (Note: PPD policy does not grant prospective exemptions to inclusion/exclusion criteria.)
- Protocol deviation review.
- Medical monitor review of panic/alert labs (excluding screening labs) via the central lab. Follow-up as needed via physician assessment diagnostic forms.
- Medical review of safety listings; includes adverse event [AE] listing with cross reference to medical history and concomitant medications).
- Medical review of coding listings; includes AE, medical history and concomitant medications.
- SAE/event processing: receipt and follow-up assessment, database entry, database auto-narrative generation and medical review.
- SAE reconciliation - (frequency will be specified in the SMMP).
- Expedited and periodic safety report preparations.
    - Analysis of Similar Events (AOSE), as required.
- Data monitoring committee (DMC).
    - Charter development.
    - Assistance with member selection.
    - Coordination of DMC meetings.

Assumptions*

* Galectin represents and warrants that it shall not name any PPD employee or other PPD representative on Line 16 of Form FDA 1571.

- PPD's PVG global standard operating procedures (SOPs)/working practice documents (WPDs) and standard processes will be utilized for applicable services.
- Pass-through charges will be incurred for postage/shipping/courier, third-party electronic distribution tool transaction fees, regulatory authority fees for review of aggregate reports, translations, travel and meeting costs (e.g., teleconferences, materials), as applicable.
- Costs associated with sponsor-requested audits have not been included, and if required, will be billed at time and materials expended.
- Changes to narrative template formats, procedures or edits of auto-generated narratives will incur additional costs.
- PPD utilizes ARISg as its validated safety database. ARISg is a well-established, industry leading safety system that provides comprehensive adverse event management and regulatory reporting capabilities for the biopharmaceutical industry.
- If the number of SAEs is greater than specified in the accompanying budget, then each additional SAE will be billed on a per event basis (refer to the budget grid for per event costs).
- If the number of protocol inquiries is greater than specified in the table above, then each additional protocol inquiry will be billed on a per inquiry basis (refer to the budget grid for per inquiry costs).
- The PPD medical monitor is a member of a cross-functional team that identifies and reviews protocol deviations throughout the study. The medical monitor will:
    - Assist the clinical operations team (as needed) in formulating site education strategies in an effort to decrease the frequency of protocol deviations.
    - Assist in determining if protocol deviations are considered significant or non-significant.
- If the number of physician assessment diagnostic forms is greater than specified in the table above, then each additional physician assessment diagnostic form will be billed on a per form basis. (Refer to the budget grid for per form costs.)
- SAEs reported to PPD, processed, reviewed by a PPD medical monitor and subsequently downgraded to "not serious" will be billed at the cost of an SAE.
- Pregnancy events will be processed in the same fashion as an SAE and will be billed as such. These events are not included in the SAEs estimated for this proposal.
- Translation vendor coordination includes the submission, tracking and follow-up on documents that have been submitted to the third-party vendor for translation. In addition, all translated documents will be reviewed to ensure that all patient identifiers have been removed once translation is completed.
- Costs associated with an end-of-study safety database transfer have not been included and will require additional discussions to determine the transfer method and estimated costs.
- All SAEs will be processed in PPD PVG's NA office for maximum cost benefit to the sponsor.
- DMC:
    - Assistance with member selection includes:
        - Identification of three members.
        - Obtaining documents such as CVs, W-9s and confidentiality agreements, as applicable.
        - Distributing protocol and pertinent study information to DMC members.

- Meeting materials and DMC master files are maintained electronically.
- Schedule and coordinate DMC meetings includes:
    - Coordinating meeting logistics (e.g., travel, hotel, catering) as needed or requested.
    - Receiving tables and listings in electronic format for inclusion in the DMC review packets.
    - Preparing electronic meeting packets for DMC review (blinded and unblinded).
    - Preparing meeting minutes (open and closed session versions).
    - Meeting minutes consist of a brief summary of actions taken and decisions made in the meeting.
    - Distributing meeting minutes and recommendations in accordance to charter requirements.
    - DMC face-to-face organizational meeting will be international.

Senior Medical Officer (SMO) Services

Services Required:

- PPD will identify an individual in †† to act as the Senior Medical Officer (SMO) for the clinical trial application (CTA) as required by ††. The guidance document is titled ††. The SMO will act as the liaison between †† and SPONSOR.
- After the SMO receives a fully executed Contract that includes the cost and services for SMO Services, the SMO will review the Clinical Trial Application (CTA) or Clinical Trial Application Amendment (CTA-A) and work with the SPONSOR on any concerns identified during CTA or CTA-A preparation prior to document submission to †† by PPD Regulatory Affairs.

Assumptions:

- As per †† regulations, the SMO assumes significant legal responsibilities above and beyond medical review of *serious adverse event (*SAE*)*/patient data review during the maintenance phase of the study. This legal responsibility is incurred directly by PPD and by PPD's SMO regardless of the number of SAEs that occur. The monthly maintenance fee reflects both medical review and legal responsibility aspects of PPD's SMO involvement and is independent of the number of patients actively on the study or the number of anticipated SAEs.
- There must be adequate indemnification provided by the sponsor (and assessed as adequate by PPD) for PPD SMO to provide this service.
- PPD PVG Global SOPs/WPDs and standard processes will be utilized for applicable services.
- Galectin elects not to have a pre-CTA meeting with †† prior to filing the CTA.
- Galectin will provide the following information electronically in Microsoft Word format:
    - Existing investigator brochure
    - Protocol

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- Required information necessary to complete the chemistry section of the CTA
- Informed consent form template

- Monthly maintenance includes SMO bi-annual periodic information reviews and ongoing review of pertinent documents such as SAEs, clinical trial site information forms (CTSIF), and notifications and letters provided by the designated Regulatory Affairs group to ††.
- Galectin will provide the SMO with all information relating to the safety of the investigational drug. As a part of confirming the SMO has access to all pertinent safety information, Galectin will prepare, sign and provide to the SMO, on a bi-annual basis, a Periodic Information Review Form (PIRF) that attests that Galectin has provided the relevant documents.
- The PIRF template will be provided as a part of, and included in, the contractual scope of services.
- Galectin will provide any additional documents requested by the SMO.
- If there is an extension to trial timelines such that the monthly maintenance exceeds the budgeted hours for the SMO services, then a contract modification will be required.
- When PPD Regulatory Affairs is also contracted:
  - PPD Regulatory Affairs will prepare all other documents that are required for submission in the CTA based on information provided by Galectin. This scope of work is detailed in the Regulatory Affairs section of the contract.
- Should †† request the sponsor /SMO to conduct a site audit/inspection, Galectin along with PPD will arrange for any such audits/inspections at the site within the stipulated time by †† and provide the findings and any corrective action plan for review and approval to the SMO before it is sent to ††.
- If the number of CTA-As are greater than specified in the table above, each additional amendment review will be billed as incurred (please refer to the budget estimate for amendment review costs). This will enable work to be carried out efficiently without recourse to completion of any additional contracts.
- Costs for †† audits have not been included, therefore, SMO preparation and meeting with †† representatives for audits will be billed at time and materials expended.
- Galectin represents and warrants that it shall not name any PPD employee or other PPD representative on Line 16 of Form FDA 1571.

Please note: The SMO can only begin the review of the CTA or CTA-A after he/she receives a copy of the fully executed Contract that includes SMO Services.

Development Safety Update Reports (DSUR)

PPD understands that Galectin has requested that PPD prepare their clinical trial annual safety reports in the Development Safety Update Report (DSUR) format. Galectin will, in a timely manner, provide PPD with all requested data pertaining to the relevant investigational product(s) in English, including, but not limited to, data lock dates, submission schedules and safety information, including from relevant development/marketing partners.

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Additional assumptions:

- Galectin will retain overall responsibility for the DSUR
- Should there be multiple companies involved with a product, Galectin will maintain responsibility for coordinating activities and data and provide information to PPD
- Galectin will appoint a contact person to liaise with PPD, provide requested information and liaise with internal Galectin /partner contacts
- Galectin will provide PPD with all requested data/input in agreed formats:
    - For items not dependent on data lock, no later than the date of data lock
    - For items dependent on data lock, no later than 15 calendar days post data lock

PPD will prepare DSURs in accordance with ICH-E2F and applicable EEA/US regulatory guidance, and the assumptions listed below:

- PPD will discuss the report strategy with Galectin during the report kick-off meeting
- PPD will determine which data will be included and discussed
- Where applicable, PPD will extract the necessary line listings from the PPD safety database following data lock
- Where Galectin has provided data from another safety database(s) in the requested format, PPD will integrate the data as required
- PPD will review the complete data set for consistency and readily identified data errors
- PPD will draft the DSUR “non-analysis” sections (up to and including section 3.17)
- PPD will draft the DSUR analysis sections 3.18.1 “Evaluation of the Risks” and 3.20 “Conclusions”
- A PPD PVG physician will provide a medical review
- PPD management will review the draft report prior to submission to Galectin
- Galectin will prepare sections 3.18.2 “Benefit-risk Considerations” and 3.19 “Summary of Important Risks”; PPD will only provide input where specifically requested
- Galectin will review the draft DSUR and provide feedback to PPD within the agreed upon timeframes
- PPD will work with Galectin on revisions and incorporation of sections prepared by Galectin
- Galectin will approve the final report version

PPD will provide drafts to Galectin, which may be in varying stages of completion based on the size of the report, for review. Galectin will return comments within five (5) working days. Due to the time-sensitive nature of each DSUR submission and in consideration of assigned resources, both PPD and CLIENT will endeavor to adhere to mutually agreed timelines. The final document should be approved by Galectin no later than four (4) business days prior to the earliest required submission date. PPD understands that Galectin will be responsible for submission of the aggregate report(s) to the appropriate regulatory agencies.

Pricing for DSURs depends upon several factors, including the volume of serious adverse reactions and size of the trials, as well as the format, volume and availability of the relevant data; therefore, these tasks are billed based on the actual time taken to complete the report. PPD has prepared a cost estimate based on our periodic safety update report (PSUR) experience; PPD has assumed 266 hours, on average, will be required including hours for preparation, analysis, writing and medical review of reports.

1.7 Pharmacovigilance Safety Reporting

Expedited Safety Report Submissions (assumes each expedited report requires 3 submissions)	Units ††

Services Included*

* PVG safety reporting contracted services include set up and management, as applicable.

Expedited and periodic safety report submissions.

- Receive routine expedited safety reports from Galectin/third party (global safety reports relating to the concerned investigational medicinal product and comparator, regardless of originating protocol).
- Coordinate submission of routine periodic safety reports to applicable regulatory authorities, ethics committees/institutional review boards/research ethics boards** and investigators, as indicated in the statement of services.

** Includes ethics committees, institutional review board and research ethics boards where Galectin has reporting responsibility.

Assumptions

- PPD has made standard general volume assumptions for budget purposes based on the North America region, not country-specific reporting requirements. Galectin will be invoiced based on actual submissions.
- Costing includes the production of necessary cover letters, submission and tracking.
- Pass-through charges will be incurred for postage/shipping/courier, third party electronic distribution tool transaction fees, translations, travel and meeting costs (e.g., teleconferences, materials), as applicable.
- Galectin will grant PPD all necessary Power of Attorney to accomplish contracted safety reporting responsibilities.
- PDF safety reports will be provided in Adobe format.
- Unless otherwise directed by Galectin, all SUSARs will be deemed IND safety reports for the purposes of reporting within the US.
- PPD utilizes a third-party, Web-based secure electronic distribution tool as the standard method for SUSAR reporting to investigator sites, providing enhanced security, traceability and efficiency over traditional distribution methods. The tool also has the flexibility to accommodate fax and e-mail distribution when required, for which additional pass-through charges may apply.
- For efficiency, PPD submits reports remotely from central locations except in countries where this is not practical due to local regulatory requirements. In this situation, the submission will be made via a local PPD office or third-party vendor, incurring additional charges.

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1.8 Data Management

	Units
Total Number of eCRF Pages Per Patient (inclusive of eCRF, diary, and other pages)	††
Number of Unique Pages (data collection modules) Per eCRF*	††
Number of Unique Pages (data collection modules) Copied from PPD Standards or Previous Galectin protocol Per eCRF	††
Total eCRF Pages Processed**	††
Maximum Number of Edit Checks	††
Maximum Number of Internal Data Cleaning Listings	††
Expected Terms Requiring Medical Coding per Enrolled Patient	††
Maximum Number of Manual Discrepancies/Queries***	††
Maximum Import File Formats	††
Maximum Number of Imports (one file format/one time)	††
Maximum Transfer Formats	††
Maximum Number of Interim Transfers (all included files /one time)****	††
Maximum Number of Clean Transfers (all included files /one time)*****	††

* Defined as one data collection module (DCM), which is equivalent to a discrete section of an eCRF (e.g., demographics, vitals, adverse events) or CDISC data domain. Unique pages, identical PPD standard DCMs or DCMs used with PPD for other Galectin studies significantly impact the budgeting assumptions for database set up and programming.

** All pages received that require data management handling, including multiple copies of a single page, are included in the total page count for the purposes of estimating the data management budget.

*** An issue raised and tracked in the discrepancy management system regardless of action taken. A query is any discrepancy that requires interaction with the investigator's site including those raised for confirmation of data values that do not result in database changes.

**** Includes one test transfer in addition to other interim transfers as expected. Interim data transfers are expected to represent the data at that point in time and may include data in various stages of the data validation process.

***** A clean database is defined as one that includes all first round queries that have been run, updated and coded except the final database transfer, which will include fully validated data.

Assumptions

- If Galectin-supplied dictionaries are required for coding of AEs and concomitant medications, they must be received in the same format as their standard counterpart (i.e., MedDRA, WHOART, COSTART, WHO Drug).
- PPD's proposal does not include costs for licensing and does not allow distribution of coded items for standard dictionaries (e.g., MedDRA, WHO Drug) unless the recipient holds a valid license.
- Costs for patient summaries or other custom data listings to be sent to Galectin have not been included in this bid.
- PPD will perform coding on adverse events and concomitant medications. It is assumed that anatomical therapeutic chemical (ATC) coding will be required for this study.

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- Data transformation and/or mapping will not be required.
- Data transfers will be in the form of SAS® transport files created directly from the clinical database.
- All data imports files will contain cumulative data from the external vendors.
- No interim data locks will be required.
- One representative from data management will attend all investigators meetings to present the CRF, general completion guidelines and the query guidelines and process.
- Costs include providing CDs to each site and to Galectin with final eCRF data. Note: these are directly out of the clinical database and are not submission ready eCRFs (including bookmarking, relational hyperlinks, embedding fonts, margins, etc). Medical Writing can provide costing for submission ready eCRFs.

1.9 Electronic Data Capture (EDC)

EDC System	• †† Data Management Platform • EDC system user access request management • 45 standard EDC reports • Integrated dictionary coding • Integrated IVRS data loads
Help Desk (provided by Medidata)	• 24/7 support coverage • Global toll free phone support • Multilingual staff covers ten core languages within the associated working time zones. Core languages supported by in-house helpdesk staff are English, German, French, Spanish, Italian, Russian, Bulgarian, Japanese, Mandarin and Korean. An additional 170 languages are accommodated by use of a third-party translation service. This on-demand translation service provides real-time support in a three-way call between the caller, Medidata and the translator. Medidata finds this approach to be highly effective in resolving calls to the help desk. Regardless of the language or site location, all calls are handled and processed using Medidata's standard support methodology.
Training Options	• Computer-based training • Training tools and materials

Assumptions

- PPD assumes all sites will have adequate Internet capabilities for EDC.
- PPD assumes that all sites will use EDC. The inclusion of any sites using paper CRFs will result in additional costs.

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1.10 Biostatistics

	Units
Number of Tables - Unique*	††
Number of Tables - Repeat*	††
Number of Listings - Unique*	††
Number of Listings - Repeat*	††
Number of Figures - Unique*	††
Number of Figures - Repeat*	††
Number of DMCs (15 Tables and 10 Listings)	††
Number of Elapsed Weeks for Production of TLFs, After Corresponding Data Transfer or Lock	4 weeks

* The unique and repeat TLF counts listed above are for the Final Analysis. All TLFs included in the DMCs are assumed to be repeat TLFs of the Final Analysis.

Assumptions

The proposed biostatistics work scope for the study includes the following statistical services and deliverables:

- Project initiation and CRF review.
- Monthly statistical project maintenance.
- Randomization plan and schedule generation.
- Statistical analysis plan development (one draft and one final).
- †† Data and Safety Monitoring Board (DSMB) safety data summaries.
- †† DSUR’s (5 safety tables)
- Production of statistical TLFs for final analysis.
- Up to †† productions of the TLFs for final analysis (data review meeting [DRM], after database lock, one additional if needed).
- Statistical collaboration on final report.
- Final analysis database transfer.

1.11 Medical Writing

Clinical Study Report (CSR)

- 1 Draft report
- 1 Final report

Number of Patient Narratives Up to †† patient narratives

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Clinical Study Report (CSR)	• 1 Draft report • 1 Final report
Appendices	• 1 Draft • 1 Final
Electronic Publishing	Full agency-compliant study report completed within five days of receipt of Galectin's executed CSR signature page

Assumptions

- Assumes use of PPD's template and the AMA Manual of Style or the Oxford Style Manual at no additional cost.
- Should Galectin wish to use a different template or style, Galectin will also provide the necessary template along with requisite training and/or any associated style guide.
- Galectin will supply consolidated comments.
- Assumes four weeks from receipt of final data to first draft of CSR.
- Includes 100% verification of the data in the CSR with the source documents.
- All patient narratives will be prepared from a locked clinical database.
- Does not include electronic publishing of CRFs.
- Does not include provision of paper copies of the CSR.
- Assumes only principal investigator information included in the appendices. If sub-investigator information is needed, additional hours will apply.

1.12 IVRS/IWRS

The table below outlines the general specifications PPD has assumed for this study.

IVRS/IWRS Study Specification	Details
Type of System	Web only (IWRS)
Number of System Users per Site	5
Language Options	• IWRS: †† • User Guides: ††
Number of Data Transfers	††

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IVRS/IWRS Study Specification	Details
Support Coverage	• 24x5 • If the call estimates are exceeded by more than 10% (based on the expected time to address/resolve issues for any subjects and active sites), a contract modification may be required to cover the extra support. • If a caller does not speak English (or another language spoken by IVRS Support), a professional interpreter will be conferenced into the call to assist. • Costs for calls requiring the service of an interpreter will be passed through on a monthly basis and have not been estimated in this proposal.

IVR/IWR System Functionality	Complexity	Details
Site Status Management	Simple (follows PPD standards)	Statuses applicable based on the study specific modules (activate access to certain functionality/deactivate access to certain functionality).
Screening	Simple	• Collect date of birth (or age) and gender. • Assign subject number.
Randomization	Complex	• Enter subject number. • Verify DOB (or age)/gender. • Verify visit being recorded. • Block stratified design. • Assign kit(s).
Subject Visit Tracking and Drug Re-supply	Moderate	• Enter subject number. • Verify DOB (or age)/gender. • Verify Visit being recorded. • Assign re-supply kit(s). • 26 post-randomization visits per subject.
Subject Status Change	Simple (follows PPD standards)	• Enter subject number. • Verify DOB (or age)/gender. • Select new subject status (e.g., screen failure, withdrawn, completed). • Select reason for status change (if needed). • Select date of status change (if needed).

IVR/IWR System Functionality	Complexity	Details
Emergency Code Break	Simple (follows PPD standards)	• Enter subject number. • Verify DOB (or age)/gender. • Receive treatment assignment.
Study Drug Ordering	Moderate	• Site level ordering. • Threshold based for accrual and visit predictive for subject re-supply at visits. • Confirmation of receipt of shipment module.
Confirmation Notifications	N/A	Generated real-time after completion of each module (excluding change PIN/password).
System Integration Service (internal)	Standard Interface	Transferring of subject enrollment and visit information into PPD's clinical trial management system (CTMS) and PPD's EDC system.

IVR/IWR System Reports	Standard/Configurable/Custom
Overall Study Summary Report	Fully Customizable
Site Status Report	Standard
Site Summary Report	Configurable
Site PIN Packet Report	Standard
Subject Screening Detail Report	Configurable
Subject Randomization Detail Report	Configurable
Subject Visit Detail Report	Configurable
Subject Status Change History Report	Configurable
Study Drug Inventory Report	Configurable
Study Drug Shipping Summary Report	Configurable
Warehouse Study Drug Inventory Report	Configurable

IVR/IWR Process (must be completed in order)	Duration
System Design	††
System Development/Programming	††
System Validation	††
System User Acceptance Testing	1 Week

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IVR/IWR Process (must be completed in order)	Duration
System Live	2 business days after UAT completion

1.13 Central Labs

	US + CAN Scenario Units
# of Subjects Screened	††
# of Subjects Enrolled	††
# of Subjects Completed	††
# of Sites	††
# of Countries	††
Study Start Date or First Patient In (FPI)	March 2015
Study End Date or Last Patient Out (LPO)	March 2017
Any Third-party Lab	• PK Serum • Plasma • ADA

Assumptions

General

- Computerized billing is generated monthly and is based upon the actual volume of specimens analyzed.
- As part of PPD's commitment to quality and patient safety confirmation testing will be performed on all positive screens for HIV, HCV, and HBV unless PPD receives a letter from Galectin declining such services in the study.

Analysis

- All analysis with the exception of the assays listed below will be performed at PPD's central labs facilities in Highland Heights, Kentucky and Brussels, Belgium.
    - PK samples

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- Serum samples
- Plasma samples
- ADA samples

- PK samples will be sent to PPD BioAnalytical for analysis at quarterly intervals.
- PPD will provide sample handling for the above samples. These specimens will be shipped with the safeties on the day of collection and forwarded to the designated referral lab at quarterly intervals. Upon further discussions with Galectin, central labs will support Galectin in the identification of a referral lab for the analysis of the above named assays.

Supply/Kits

- PPD central labs provides all the kits and materials needed for sampling and sample handling.
- All kits are visit specific and standardized across all the PPD central labs.
- Kits and materials provided by PPD central labs are in compliance with International Air Transport Association (IATA) regulations for the transport of diagnostic specimens.

Transportation

- Transportation estimates are based on first-tier cities. Prices are subject to fuel charges and import duties/taxes.
- No local dry ice supply is included, but may be provided with the charge passed through upon request. Pass-through charges will equal the actual courier charge, dry ice if supplied plus a logistics handling fee.
- For budgeting purposes, the number of inbound shipments represents one patient visit/shipment.
- Sample management specimens will be sent to PPD on day of collections and stored for two months, when they will be forwarded to a referral lab designated by sponsor (PK specimens to PPD BioAnalytical).

1.14 Regulatory Inspections

Should Galectin require assistance from PPD in responding to a sponsor or investigative site regulatory inspection, Galectin and PPD will mutually agree the scope of services to be provided in writing. For these services Galectin will compensate PPD based on the unit pricing table below, unless the inspection occurs as a result of PPD's inadequate service delivery or negligence. Each unit represents 8 hours of PPD effort to aid in Galectin response to the inspection(s).

	Unit Cost NA (USD)*	Unit Cost EMEA (EUR)*	Unit Cost APAC (USD)*	Unit Cost LA (USD)*
Regulatory Inspection of Sponsor - †† Hour Unit	$ ††	€ ††	$ ††	$ ††

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	Unit Cost NA (USD)*	Unit Cost EMEA (EUR)*	Unit Cost APAC (USD)*	Unit Cost LA (USD)*
Inspection of Site - †† Hour Unit	$ ††	€ ††	$ ††	$ ††

* Inspection costs will be converted to the contract currency at the time of invoicing.

1.15 Clinical Pharmacology (Pharmacokinetics)

Number of PK Analytes for Population PK Modeling	††
Number of PK Analytes and PD Markers or Clinical Endpoints for Population PK/PD Modeling	N/A

Assumptions for Population PK Modeling

- The pharmacokineticist will develop an analysis plan for the population PK analysis. The population PK analysis plan will be a separate document from the statistical analysis plan of the main studies.
- The clinical pharmacology department is evaluating bioanalytical data for one drug analyte in plasma.
- No interim PK analyses are included in this budget.
- QA-released bioanalytical data for the drug are being generated and delivered in electronic format acceptable for generation of NONMEM data file for population pharmacokinetic analysis.
- Population PK analyses will be performed using NONMEM by the clinical pharmacology department once QA approved bioanalytical data, sampling time deviations and clinical data after database lock are available.
- Model-building steps will be conducted on available data prior to the database lock. Any changes to the drug analyte will incur additional costs.
- The pharmacokineticist will provide a draft and a final written PK modeling report as laid out in the analysis plan.

Assumptions for PK TLFs in the CSR

- PK project team will review the statistical analysis plan (SAP), develop text for PK analysis, provide input to statistical analysis of PK parameters, and generate tables, listings and figures (TLFs) shells for the display of the PK data.
- SAS datasets of the PK parameters and concentration data will be generated based on CDISC Analysis Data Model (ADaM).
- The following TLFs count is included in Clinical Pharmacology/PK cost:

PK TLFs

Tables: 1 (1 Unique, 0 Repeat)
Listings: 1 (1 Unique, 0 Repeat)
Figures: 1 (1 Unique, 0 Repeat)

- PPD's Lead Pharmacokineticist will collaborate with the Lead Medical Writer to write the CSR for the study. The Pharmacokineticist will provide text for PK sections and input to PK data presentation in the CSR.

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

1.16 Estimated Timeline

Activity	Duration in Months
Region	NA
Pre-Study Activities	††
Enrollment Period	††
Treatment Period	††
Close-Down Period	††
Total PPD Commitment	~††

2 Statement of Services

2.1 Project Set-Up Activities

Task/Activity	Galectin	PPD
Design/Prepare Protocol	X	
Review Protocol		X
Produce Protocol Translations	N/A	N/A
Review Protocol Translations	N/A	N/A
Produce Investigator's Brochure	X	
Review Investigator's Brochure		X
Case Report Form (CRF) Design		X

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Task/Activity	Galectin	PPD
Review CRF		X
Prepare CRF Completion Guidelines		X
Set Up Master Action Plan		X
Translate Study Drug Labels		X
Database Design/Review/Build		X
Data Validation Manual Design/Review		X
Edit Check Design/Review/Build		X
Data Management Listing Design/Review/Build		X
Prepare Monitoring Plan		X
Project Familiarization and Initial Team Training		X
Kick-off Meeting Preparation and Attendance	X	X
Clinical Trial Management System (CASCADE) Set Up		X
Investigators Meeting Preparation, Presentation and Attendance	X	X

2.2 Project Management and Team Meetings

Task/Activity	Galectin	PPD
Project Management and Administration		X
Vendor Management		X
Face-to-face Client Meetings	X	X
Internal Team Meetings and Ongoing Training		X
Client Teleconferences	X	X

2.3 Site Set Up

Task/Activity	Galectin	PPD
Site Identification		X
Site Evaluation Visits		X
Design Master Informed Consent Form		X

Task/Activity	Galectin	PPD
Translate Master Informed Consent Form		X
Essential Document Collection		X
Essential Document Review		X
Regulatory Compliance Review of Essential Documents for Test Article Release		X
Develop and Negotiate Site Contract Language		X
Investigator Payment Negotiation		X
Site Initiation Visits		X

2.4 Ongoing Clinical Operations

Task/Activity	Galectin	PPD
Interim Monitoring Visits		X
Un-Blinded Drug Accountability Visits		X
Site Management		X
Drug Supply Management		X
Investigator Payment Administration		X
Investigator Files Set Up and Maintenance		X
Trial Master Files Set Up and Maintenance		X
Clinical Participation at Site Audits		X
Investigational New Drug Safety Report Distribution		X
Management of Non-drug Trial Supplies		X
Newsletters Development and Distribution		X
Query Resolution		X
Site Close-out Visits		X

2.5 Test Article Management

Task/Activity	Galectin	PPD
Clinical supply chain project set up		X
Clinical supply Vendor audit	N/A	N/A
Clinical supply forecasting		X
Manufacturing and testing	X	
Label text development	X	X
Label text translation review		X
Patient card development	X	X
Patient card translation review		X
Primary packaging and labeling	X	
Secondary packaging and labeling		X
Procurement/Acquisition/Sourcing	N/A	N/A
Clinical supply chain management, coordination and consultancy		X
Inventory and expiry date tracking and monitoring		X
Import/Export license application management and consultancy		X
Monthly import/export management and consultancy	N/A	N/A
Import/Export coordination: country custom clearance		X
Export of patient samples	N/A	N/A
Depot set up		X
Depot management		X
Receipts at depots		X
Storage at PPD depots		X
Physical inventories of supplies stored at depots		X
Shipment preparation at depots		X
Re-labeling due to extension on expiry date at depot level	N/A	N/A
Sourcing and re-labeling of clinical supplies by depots	N/A	N/A
Returns of clinical supplies from sites for further delivery at depots		X

Task/Activity	Galectin	PPD
Reconciliation and accountability at depot level per patient kit/box		X
Final reconciliation and accountability per project		X
Clinical supply destruction		X

2.6 IVRS/IWRS

Task/Activity	Galectin	PPD
Personal Identification Number Packets/User Guides		X
Site Status Management Module		X
Screening Module		X
Randomization Module		X
Subject Visit and Drug Re-supply Module		X
Emergency Code Break Module		X
Subject Status Change Module		X
Study Drug Management Module		X
System Reports		X
System Support and Maintenance		X
Project Close-out/Archival		X
Interface to PPD System(s)		X

2.7 Data Management/Programming Ongoing Activities

Task/Activity	Galectin	PPD
Database Maintenance		X
Data Cleaning		X
Medical Terminology Coding		X
Serious Adverse Event Reconciliation		X
Data Imports From External Vendors (e.g., Central Labs)		X

Task/Activity	Galectin	PPD
Data Transfers		X
Archival		X

2.8 Pharmacovigilance

Task/Activity	Galectin	PPD
Safety Database - Set Up and Maintenance		X
Un-blinding Responsibility (e.g., emergency, regulatory reporting)		X
SAE Processing (receipt and follow-up assessment)		X
SAE Narrative Creation		X
SAE Database Entry		X
Medical Review of SAEs and Assign Preliminary Causality Assessment		X
Assign Final Causality Assessment	X	
Preparation of Analysis of Similar Events (AOSE)		X
Prepare Expedited Safety Reports		X
Prepare Development Safety Update Reports (DSUR)/Periodic Reports		X
Medically Review DSUR/Periodic Reports		X
Set Up and Manage a Data Monitoring Committee		X

2.9 Medical Monitoring

Task/Activity	Galectin	PPD
Consultation for Project-Related Inquiries		X
Review of Alert Labs and Physician Assessment Diagnostic Forms		X
Review of Coding Listings (AEs, concomitant medications, medical history)		X
Review of Safety Listings (AE listing with cross reference to medical history and concomitant medications)		X
Review of Medical Writing Deliverables - Safety Section (e.g., draft/final integrated study report)	X	
SMO CTA original review		X

Task/Activity	Galectin	PPD
SMO CTA-A review		X
SMO monthly maintenance		X

2.10 Pharmacovigilance Safety Reporting

Task/Activity	Galectin	PPD
Notify Expedited Safety Reports to Regulatory Authorities *		X
Notify Expedited Safety Reports to Ethics Committees		X
Notify Expedited Safety Reports to Investigators		X
Notify DSUR/Periodic Reports to Regulatory Agencies *		X
Notify DSUR/Periodic Reports to Ethics Committees/Investigators		X

* When contracted to PPD, expedited and periodic reporting to the US FDA is included in the Regulatory Affairs section of this proposal.

2.11 Biostatistics

Task/Activity	Galectin	PPD
Provide Randomization Schedule		X
Produce Statistical Analysis Plan (SAP) Text		X
Produce Table, Listing and Figure Shells		X
Produce and Validate Tables, Listings and Figures		X
Interim Statistical Analysis		n/a
Final Statistical Analysis		X
Provide Data Safety Monitoring Board Statistical Support		X

2.12 Medical Writing

Task/Activity	Galectin	PPD
Draft Final Integrated Report		X

Task/Activity	Galectin	PPD
Final Integrated Report		X
Serious Adverse Event Narratives		X

2.13 Quality Assurance

Task/Activity	Galectin	PPD
Information Governance & Compliance - Trial Master File (TMF) Set-Up, Maintenance, Archiving and Transfer		X
Information Governance & Compliance - Unblinded Investigator File Set-Up, Maintenance, Archiving and Transfer		X
Clinical QA - Clinical Investigator Site Audit		X
Clinical QA - Project Support		X
Clinical Supplies QA - Project Support		X

2.14 Regulatory Affairs

Task	Galectin	PPD
NA Region		
Preparation of Core dossier*	X	X
Compilation of Clinical Trial Study Documents for the Countries Participating in the Study		X
Submission of CTA to Regulatory Authorities in the Countries Participating in the Study including USA		X
IP Labels Country-specific Review		X
Maintenance of CTAs in the Countries Participating in the Study		X
Support of CTA Submission to ECs		X
Regulatory Compliance Review (Essential Documents Review) for IP Shipment to a Site and/or Site Initiation		X
Safety Reports Submission to Regulatory Authorities		X
Preparation of Quality Overall Summary (QOS) for ††		X
End of Trial Notifications		X

* This activity includes RAL management activities as described in Specification and Assumptions. It does not equate simply to preparation of IMPD and/or other ‘core’ documents common across participating countries.

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

2.15 EDC

Task/Activity	Galectin	PPD
Software Licensing {Other Direct Costs}		X
Start-up ad hoc Support		X
Access request management		X
Initial Training - Site, Clinical Team, Other		X
Medidata Help Desk Support		X
Site Training - Ongoing, Close-out		X
Database Lock Support		X
EDC Site Close out		X

2.16 Clinical Pharmacology (Pharmacokinetics)

Task/Activity	Galectin	PPD
Provide Input to Statistical Analysis Plan		X
Program and Validate PK Dataset		X
Generate PK TLFs		X
Write PK Section of Study Report		X
Prepare Population Modeling Analysis Plan		X
Program and Validate NONMEM Dataset		X
Perform Population PK Modeling		X
Prepare Population Modeling Report		X

2.17 Central Labs

Task/Activity	Galectin	PPD
Site Selection and Import/Export Permits	X	X
Kits, Supplies and Investigators Manual		X
Forward Samples to Third-party Lab		X
Traceability of Shipments		X
Patient Demographic Details into Database		X
Analysis		X
Laboratory Reports to Sites		X
PPD ClicksTM for Study Status and Reports	X	X

3 Central Labs Estimate

The Central Labs budget estimates are attached on the following pages.

PPD Central Labs
07-Nov-2014
Galectin Therapeutics, Inc.
GT-025
BC: 58004-01 Sc2 R2
Central Lab BC: 58004-02 **Revision #2**

Budget Summary GT-025	Total Charge (USD)
Laboratory Testing	$ ††
Sample Management	$ ††
Kits and Supplies	$ ††
Clinical Trial Services Fees	$ ††
Direct Costs Estimate:	$ ††
Logistics (Pass-Through) Estimate:	$ ††
Total Estimate:	$ ††

Regional Budget Summary GT-025	††	††	††	††
Laboratory Testing	$ ††	$ ††	$ ††	$ ††
Sample Management	$ ††	$ ††	$ ††	$ ††
Kits and Supplies	$ ††	$ ††	$ ††	$ ††
Clinical Trial Services Fees	$ ††	$ ††	$ ††	$ ††
Regional Direct Costs Estimate:	$ ††	$ ††	$ ††	$ ††
Regional Logistics (Pass-Through) Estimate:	$ ††	$ ††	$ ††	$ ††
Regional Total Estimate:	$ ††	$ ††	$ ††	$ ††

Countries	Sites	Screened Subjects	Enrolled Subjects	Completed Subjects	%
††	††	††	††	††	
††	††	††	††	††	
††	††	††	††	††	100%
TOTAL	††	††	††	††	

†† Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

PPD's Central Labs, LLC Budget Estimate

# Patients:				260	156	147	138	129	117	156	1103	100%	0%
				V2	V3	V4	V5	V6	V8	V9			
Laboratory Testing	**Assumptions**	**Shipping Frequency**	**Mode of Shipment**	**Screening (Week -8)**	**Randomization (Week 1)**	**Week 12**	**Week 26**	**Week 38**	**Week 52**	**Follow-up / Termination**	**Total**	††	††
LONG CHEMISTRY PANEL: > 15 tests plus calculated parameters - including Amylase		1:1	ambient	††	††	††	††	††	††	††	††	††	††
Cholesterol, High Density Lipoprotein (HDL direct)		1:1	ambient	††	††	††	††	††	††	††	††	††	††
HEMATOLOGY PANEL (Auto Differential)		1:1	ambient	††	††	††	††	††	††	††	††	††	††
ROUTINE URINALYSIS W/MICROSCOPIC PANEL		1:1	ambient	††						††	††	††	††
Prothrombin Time	Batch tested 3x weekly	1:1	frozen	††	††	††	††	††	††	††	††	††	††
Prothrombin Time, INR	Calculation - no charge	N/A	frozen	††	††	††	††	††	††	††	††	††	††
Partial Thromboplastin Time, Activated (APTT)	Batch tested 3x weekly	1:1	frozen	††	††	††	††	††	††	††	††	††	††
Drug Screen (Standard)	At screening	1:1	ambient	††							††	††	††
HIV 1&2 Antibody		1:1	ambient	††							††	††	††
HIV 1/2 Confirmation by Inno-Lia	To be performed at PPD EU	1:1	ambient	††							††		††
††		1:1	ambient	††							††	††	††
††		1:1	ambient	††							††	††	††
††	To be performed at PPD EU	1:1	ambient	††							††		††
††	Batch tested weekly	1:1	frozen	††	††	††	††	††		††	††	††	††
††	Batch tested weekly	1:1	ambient	††	††	††	††	††		††	††	††	††
††	Batch tested weekly	1:1	ambient	††	††	††	††	††		††	††	††	††
††	Performed at GCL EU; Batch tested at 40 samples	1:1	frozen		††	††	††	††		††	††		††
††		N/A	N/A	††	††	††	††	††		††	††	††	††
††	Batched 20 specimen testing	1:1	frozen/batch analysis		††	††	††	††		††	††	††	
Sample Management	**Assumptions**	**Shipping Frequency**	**Mode of Shipment**	**Screening (Week -8)**	**Randomization (Week 1)**	**Week 12**	**Week 26**	**Week 38**	**Week 52**	**Follow-up / Termination**	**Total**	††	††
PK samples		1:1	frozen		††		††		††		††	††	††
Serum samples	††	1:1	frozen		††	††	††	††	††	††	††	††	††
Plasma Samples		1:1	frozen		††	††	††	††	††	††	††	††	††
ADA samples	Anti-GR-MD-02 Antibodies	1:1	Frozen		††	††	††	††	††		††	††	††

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PPD's Central Labs, LLC
Budget Estimate

Estimate	US	EU
Screened:	††	††
Enrolled:	††	††
Completed:	††	††

Laboratory Testing	Assumptions	UOM	††	††	††	††	††	††	††
LONG CHEMISTRY PANEL: > 15 tests plus calculated parameters - including Amylase		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Cholesterol, High Density Lipoprotein (HDL direct)		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
HEMATOLOGY PANEL (Auto Differential)		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
ROUTINE URINALYSIS W/MICROSCOPIC PANEL		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Prothrombin Time	Batch tested 3x weekly	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Prothrombin Time, INR	Calculation - no charge	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Partial Thromboplastin Time, Activated (APTT)	Batch tested 3x weekly	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Drug Screen (Standard)	At screening	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
HIV 1&2 Antibody		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
HIV 1/2 Confirmation by Inno-Lia	To be performed at PPD EU	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Hepatitis B, Surface Antigen		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Hepatitis C, Antibody		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Hepatitis C Confirmation by Inno-Lia		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Microglobulin, Alpha-2	Batch tested weekly	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Haptoglobin	Batch tested weekly	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Apolipoprotein AI	Batch tested weekly	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
ELF Testing: Hyaluronic Acid; PIIINP; TIMP-1 & ELF score	Performed at GCL EU; Batch tested at 40 samples	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Fibrotest Score - sent to Biopredictive		result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Galectin-3	Batched 20 specimen testing	result	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
	Analysis Total (per region):				$ ††			€ ††	$ ††
Sample Management	**Assumptions**	**UOM**	††	††	††	††	††	††	††
PK samples		sample	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Serum samples	For ELF test, Galectin-3 and others	sample	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Plasma Samples		sample	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
ADA samples	Anti-GR-MD-02 Antibodies	sample	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Storage	Assume two months	sample month	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Sample Destruction Fee		sample	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
	Sample Handling & Storage (per region):				$ ††			€ ††	$ ††
Kits and Supplies	**Assumptions**	**UOM**	††	††	††	††	††	††	††
Collection Kit Tier 2	Visits: Screening, V3, V4, V5, V6, V8, and V9	kit	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Urine Cup W/Lid (25/sleeve)	Urine collection; assume 1 sleeve per site	sleeve	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Pregnancy Test Kits Quick View	Urine pregnancy; assume 1 box per site	box	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Box-Frozen Shipper-5lb. W/(1) Sample Bag Max/25 Samples (NA), 10lb. W/(2) Sample Bags Max/50 Samples (APAC)	Boxes for Frozen shipments	mailer	$ ††	††	$ ††	€ ††	††	€ ††	$ ††

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Box-Frozen Shipper-10lb.	Frozen PK samples - PPD CL US to PPD BioA: shipped quarterly	mailer	$ ††	††	$ ††				
Box-Frozen Shipper-20lb.	Frozen Serum samples - PPD CL US to referral lab: shipped quarterly	mailer	$ ††	††	$ ††				
Box-Frozen Shipper-20lb.	Frozen Plasma samples - PPD CL US to referral lab: shipped quarterly	mailer	$ ††	††	$ ††				
Box-Frozen Shipper-20lb.	Frozen ADA samples - PPD CL US to referral lab: shipped quarterly	mailer	$ ††	††	$ ††				
Cryo Box	Frozen samples - PPD CL US to referral lab	cryo box	$ ††	††	$ ††				
Bag-Large Single Cell W/Absorbent (Used w/cryboxes)	One per cryo box	bag	$ ††	††	$ ††				
Dry Ice < 44lb.	Frozen samples - PPD CL US to referral lab: 1 per shipment	dry ice	$ ††	††	$ ††				
	Supplies Total (per region):				$ ††			€ ††	$ ††
Clinical Trial Services Fees	**Assumptions**	**UOM**	**††**	**††**	**††**	**††**	**††**	**††**	**††**
Project Set-Up Fee	Study set-up	Project database	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Site Initiation Fee		site	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Project Management Fees	Includes 16 hours per month	month	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Accessioning Fee		visit	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Data Management Fee*	Assumes one transfer per month	transfer	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Estimated Logistics Management Fee		shipment	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
Kick-off/Investigator Meeting Attendance Fee (Domestic)	Including Preparation, 1 day of attendance for 1 attendee, 1 day of travel (actual travel costs will be billed as pass-through charges)	meeting	$ ††	††	$ ††	€ ††	††	€ ††	$ ††
	Clinical Trial Services Total (per region)				$ ††			€ ††	$ ††
Direct Costs Estimate per region:					$ ††			€ ††	$ ††

***If both PPD Central Labs and PPD Clinical/Data Management are awarded the opportunity this fee will be waived.**

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Exchange Rates:

SGD/USD	††
EUR/USD	††
USD/EUR	††

Global Logistics (Pass-Through)

			Outbound, supplies to sites					Inbound, Ambient/Refrig., sites to PPD					Inbound, Frozen, sites to PPD						Total Charge (USD)
Country	Sites	Unit Type	Unit Cost Courier	(Euro)	Unit Cost (USD)	# of Units	Sub-total	Unit Cost Courier	(Euro)	Unit Cost (USD)	# of Units	Sub-total	Unit Cost Courier	(Euro)	Unit Cost (USD)	# of Units	Sub-total	Dry ice and shippers	
††																			
††	††	awb	FedEx		$ ††	††	$ ††	††		$ ††	††	$ ††	††		$ ††	††	$ ††	Transport only	$††
††	††	awb	DHL		$ ††	††	$ ††	††		$ ††	††	$ ††	††		$ ††	††	$ ††		$††

Referral lab courier costs	Frequency	Courier	Unit Type	Unit Cost (Euro)	Unit Cost (USD)	# of Units	Sub-total	Comments	Total Charge (USD)
Outbound, PK specimens from GCL US to PPD BioA	Quarterly	FedEx	awb		$ ††	††	$ ††		$††
Outbound, Plasma specimens from GCL US to referral lab	Quarterly	FedEx	awb		$ ††	††	$ ††		$††
Outbound, Serum specimens from GCL US to referral lab	Quarterly	FedEx	awb		$ ††	††	$ ††		$††
Outbound, ADA specimens from GCL US to referral lab	Quarterly	FedEx	awb		$ ††	††	$ ††		$††
TOTAL PASS THROUGH COSTS	††		$††		††		$††	††	$††

* Transportation costs do not include Saturday delivery charges, taxes, tariffs, duties and fuel surcharge. This will be invoiced at the prevailing rate.
* Transportation fees are estimates only and based on primary cities.
* Client will be invoiced based on actual fees incurred.
* Laboratory kits may accommodate more than one patient visit/per inbound shipping box. For purposes of the estimate, 1 visit per inbound box has been assumed as average.
* Drive-away and trans-shipment to international port of departure may apply. Applicable customs fees charged as pass through cost.
* Inbound transport costs are based on Weekday priority overnight shipments.
* Outbound kits have standard transit time of 2-5 days. Overnight priority shipping provided with sponsor approval at additional shipping cost.

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Terms and Conditions

GENERAL

•Study set up will commence upon written acceptance of Contract and Central Laboratory Specification (CLS).
•The costs contained within this Proposal are valid for 45 days from date of proposal.
•The prices contained within this Proposal are estimates based upon information provided by the Sponsor. Cost will be revised if the Sponsor provides an amended protocol or updated information.
•Access to PPD Clicks or Clicks for Sites is included at no charge, regardless of number of users.
•All protocol materials will be archived for †† years from the end of PPD involvement. Requests for protocol materials will be shipped at the expense of the Sponsor/CRO.

SET-UP

•PPD Global Central Labs requires 20 business days from signed CLS for study initiation. Study initiation is defined as the first Investigational site to receive specimen collection kits.
•An acceleration fee will be applied, if study initiation is required within 20 business days of awarding the protocol. The acceleration fee will be invoiced at 25% of the set-up costs with a minimum charge of $5,000.
•Sponsor requested changes to the fully executed CLS will result in additional charges to be determined based upon the complexity of the revisions.
•PPD Global Central Labs has one global database that supports all regions within the study. Global set-up fees will be invoiced upon project initiation once database set-up activities are complete.

TRAINING/TRAVEL

•If requested to attend a Kick off meeting or Investigator meeting, a fee of US$ 2,000.00 per day per meeting for attendance of PPD Central Labs presenter at one meeting including preparation, excluding travel expenses billed as pass through. This cost assumes a one day meeting with one day for travel. Each additional day will be US$1,000 per day. Sponsor request of technical attendees will be charged additional fees of US$ 2,000.00 per day, plus travel expenses.
•Attendance at the investigator meeting via WebEx will be charged US$ 500.00 per meeting per attendee.
•Site training via conference call for protocol specific laboratory procedures is available at sponsor's request. This will be invoiced at US$ 200.00 per hour.
•On site training visits to outline protocol specific laboratory procedures at the sponsor's request, will be invoiced at a rate of US$ 750.00 per site visit, plus travel expenses.

TRANSPORTATION

•Transportation fees are based on primary cities only.
•Transportations costs do not include Saturday delivery charges, taxes, tariffs, duties and fuel surcharges. Sponsor will be invoiced at the prevailing rate.
•Dry ice supply is included in the estimated cost of all inbound frozen shipments except for those shipments originating in the United States and ††. Pass-through charges will equal the actual courier charge plus dry ice if supplied.
•Logistics Management Fee will be billed at 15% of the Indirect costs.

MODIFICATIONS

•Any services requested by Sponsor (or sites) and not included in this cost estimate will be charged separately. Services rendered will be invoiced as performed and a Contract Modification will be issued.
•Out of protocol testing will be invoiced per the unit price with an additional US$ 25.00 Project Management fee, per request.
•Additional charges will apply for any off-cycle or expedited testing.

•Specimens requiring off-hour technician/processing time, will be invoiced with an added service charge of US$ 65.00 per hour.
•Any sample that is UTP (Unable To Perform) will be charged a Sample Handling fee.

•A sample destruction fee will be invoiced for any sample that is required to be destroyed. This fee will be charged per sample destroyed.

•Expedited shipping fees will be applied at US$ 150.00 per shipment with less then 5 business days notice, plus shipping costs.
•Additional label sets provided at an additional fee of US$ 2.00 per set.
•Additional requisition forms provided at an additional fee of US$ 1.50 per requisition.
•Additional collection flow charts (CFC) provided at an additional fee of US$ 5.00 per chart.
•Set up of additional sites will incur additional site initiation fees and other applicable charges.
•Database modifications will be invoiced at $150 per hour.
•Non-Standard Services for Data Management and Custom programming will be supplied upon request and billed at a programming rate of US$ 200.00 per hour for services included but not limited to:
a. Custom data file formats
b. Custom data management reports c. Data reconciliation requirements
•Returned kit fee of US$ 4.00 each (break-down and disposal of kit contents) plus return shipping charges.
•Hard copy reports will be invoiced at US$ 5.00 per report
•Translation costs reflect the average cost to translate a typical manual. Translation costs for other documents besides the manual, will be charged to the client based on the actual translation fees plus 20%..
•Lab Manuals will be supplied to all sites upon initiation as part of the study set-up. Amended or revised manuals will be supplied at US$ 30.00 each.
•If adjustments to kits are required, the kit tier may be revised and billed at the following rates:

Kit Tier	NA & LATAM	EMEA	China	AsiaPac
Collection Kit Tier 1	$††	€ ††	$††	$††
Collection Kit Tier 2	$††	€ ††	$††	$††
Collection Kit Tier 3	$††	€ ††	$††	$††
Collection Kit Tier 4	$††	€ ††	$††	$††
Collection Kit Tier 5	$††	€ ††	$††	$††

This budget for central laboratory services is based upon protocol requirements provided at the time of the RFP and is an estimate only. PPD Central Labs will invoice Sponsor for actual services rendered and testing performed. Invoices may, therefore, differ from the Budget due to differences in actual services rendered versus those contained within this Budget

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Exhibit B
Budget

PPD

Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
Project Management										
GPD Consulting	protocol	††	††	††	††	††	††	††	††	††
Protocol Review	protocol	††	††	††	††	††	††	††	††	††
Review Data Validation Manual	protocol	††	††	††	††	††	††	††	††	††
Review CRF	protocol	††	††	††	††	††	††	††	††	††
Prepare CRF Completion Guidelines	case book	††	††	††	††	††	††	††	††	††
Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††
Develop Country Budget and Payment Schedule Template	country	††	††	††	††	††	††	††	††	††
ICF Local Customization - Review and Approve	country	††	††	††	††	††	††	††	††	††
ICF Local Customization - Review and Approve - Amendments	country	††	††	††	††	††	††	††	††	††
Review SAP (PPD or Client)	plan	††	††	††	††	††	††	††	††	††
Identify Third Party Vendors	vendor	††	††	††	††	††	††	††	††	††
Vendor Management - PPD Managed Vendors	vendor month	††	††	††	††	††	††	††	††	††
Develop and Negotiate Site Contract Language, Budget and Payment Schedule	site	††	††	††	††	††	††	††	††	††
Investigator Grant Payment Administration	payment	††	††	††	††	††	††	††	††	††
IND Safety Reports	report	††	††	††	††	††	††	††	††	††
Clinical Site Audits	audit	††	††	††	††	††	††	††	††	††
Final Analysis Review	report	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Face to Face Client Meetings	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Project Management - Start-up	month	††	††	††	††	††	††	††	††	††
Project Management - Enrollment	month	††	††	††	††	††	††	††	††	††
Project Management - Treatment	month	††	††	††	††	††	††	††	††	††
Project Management - Close Out	month	††	††	††	††	††	††	††	††	††
Study Newsletters	newsletter	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Site Intelligence and Activation										
Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††
CTMS Central Setup	protocol	††	††	††	††	††	††	††	††	††
CTMS Country Setup	country	††	††	††	††	††	††	††	††	††
CTMS Site Implementation	site	††	††	††	††	††	††	††	††	††
ICF Local Customization	country	††	††	††	††	††	††	††	††	††
Management of Translation of Protocol, Investigator Brochure, ICF & Technical Doc	translation	††	††	††	††	††	††	††	††	††
Review of Translation of ICF	translation	††	††	††	††	††	††	††	††	††
Clinical Site Identification	site	††	††	††	††	††	††	††	††	††
Pre-Study Visit Waiver	PSV waiver	††	††	††	††	††	††	††	††	††
Site Evaluation Visits - Prep/Admin/Follow-up	visit	††	††	††	††	††	††	††	††	††
Site Evaluation Visits - Time on Site	visit	††	††	††	††	††	††	††	††	††
Site Evaluation Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Collect and Verify Regulatory Docs	site	††	††	††	††	††	††	††	††	††
Local Ethics Submissions	site	††	††	††	††	††	††	††	††	††
Central Ethics Submissions - Country Specific	country	††	††	††	††	††	††	††	††	††
Develop and Negotiate Site Contract Language	site	††	††	††	††	††	††	††	††	††
Investigator Grant Payment Negotiation	site	††	††	††	††	††	††	††	††	††
Develop Site Budget and Payment Schedule	study	††	††	††	††	††	††	††	††	††
Legal Template Process Negotiation Activities	study	††	††	††	††	††	††	††	††	††
Negotiate CDA	site	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Site Intelligence and Activation Management	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Clinical Management										
Prepare Monitoring Plan	protocol	††	††	††	††	††	††	††	††	††
Review Protocol	protocol	††	††	††	††	††	††	††	††	††
Review CRF	protocol	††	††	††	††	††	††	††	††	††
Prepare CRF Completion Guidelines	case book	††	††	††	††	††	††	††	††	††
Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††

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Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
Unblinded Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††
Develop Country Budget and Payment Schedule Template	country	††	††	††	††	††	††	††	††	††
Design Master ICF	protocol	††	††	††	††	††	††	††	††	††
ICF Local Customization - Amendments	country	††	††	††	††	††	††	††	††	††
Review of Site-Specific ICF Post EC - Amendments	site	††	††	††	††	††	††	††	††	††
IRB/EC Annual Renewals	site	††	††	††	††	††	††	††	††	††
Collect and Verify Reg Docs - Amendments	site	††	††	††	††	††	††	††	††	††
Investigator Brochure - Annual Update to Ethics Committee	site year	††	††	††	††	††	††	††	††	††
Amendments - Management of Translation of Protocol, Investigator Brochure, ICF &	translation	††	††	††	††	††	††	††	††	††
Amendments - Review of Translation of ICF	translation	††	††	††	††	††	††	††	††	††
Clinical Site Identification	site	††	††	††	††	††	††	††	††	††
Site Evaluation Visits - Prep/Admin/Follow-up	visit	††	††	††	††	††	††	††	††	††
Site Initiation Visits - Prep/Admin/Follow-up	visit	††	††	††	††	††	††	††	††	††
Site Initiation Visits - Time on Site	visit	††	††	††	††	††	††	††	††	††
Site Initiation Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Interim Monitoring Visits - Prep/Admin/Follow-Up	visit	††	††	††	††	††	††	††	††	††
Interim Monitoring Visits - Time on Site	visit	††	††	††	††	††	††	††	††	††
Interim Monitoring Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Site Management	site month	††	††	††	††	††	††	††	††	††
Unblinded Site Management	site month	††	††	††	††	††	††	††	††	††
Annual Investigator File Audits	file audit	††	††	††	††	††	††	††	††	††
Vendor Management - PPD Managed Vendors	vendor month	††	††	††	††	††	††	††	††	††
Develop and Negotiate Site Contract Language, Budget and Payment Schedule	site	††	††	††	††	††	††	††	††	††
Investigator Payment Administration	payment	††	††	††	††	††	††	††	††	††
Management of Non-Drug Trial Supplies	shipment	††	††	††	††	††	††	††	††	††
Clinical Site Audits	audit	††	††	††	††	††	††	††	††	††
In-house CRF Review	CRF page	††	††	††	††	††	††	††	††	††
Query Resolution	query	††	††	††	††	††	††	††	††	††
Unblinded Drug Accountability Visits - Prep/Admin/Follow-up	visit	††	††	††	††	††	††	††	††	††
Unblinded Drug Accountability Visits - Time on Site	visit	††	††	††	††	††	††	††	††	††
Unblinded Drug Accountability Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Site Closeout Visits - Prep/Admin/Follow-up	visit	††	††	††	††	††	††	††	††	††
Site Closeout Visits - Time on Site	visit	††	††	††	††	††	††	††	††	††
Site Closeout Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Unblinded Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Unblinded Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Face to Face Client Meetings	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Unblinded Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
CRA Team Meetings	meeting	††	††	††	††	††	††	††	††	††
Unblinded CRA Team Meetings	meeting	††	††	††	††	††	††	††	††	††
Protocol Inquiry Forms Management	PIF	††	††	††	††	††	††	††	††	††
Clinical Team Management	month	††	††	††	††	††	††	††	††	††
Unblinded Clinical Team Management	month	††	††	††	††	††	††	††	††	††
Study Newsletters	newsletter	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Global Clinical Supplies										
Project Setup	protocol	††	††	††	††	††	††	††	††	††
Identify, Select and Negotiate Contracts with Clinical Supply Vendors	vendor	††	††	††	††	††	††	††	††	††
Label Text Development	label	††	††	††	††	††	††	††	††	††
Label Text Translation Coordination	country	††	††	††	††	††	††	††	††	††
Clinical Supply Forecasting	forecast	††	††	††	††	††	††	††	††	††
Monitor/Track Study Progress, Inventory Levels and Communication with Team/Spo	month	††	††	††	††	††	††	††	††	††
Final Drug Accountability and Destruction	randomized pati	††	††	††	††	††	††	††	††	††
Kick Off Meeting	meeting	††	††	††	††	††	††	††	††	††
Depot Management	depot month	††	††	††	††	††	††	††	††	††
Distribution Management	shipment	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
IVRS										
Base System Set-up	protocol	††	††	††	††	††	††	††	††	††
Code Break Module	protocol	††	††	††	††	††	††	††	††	††
Confirm Receipt Module	protocol	††	††	††	††	††	††	††	††	††

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Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
Randomization Module	protocol	††	††	††	††	††	††	††	††	††
Screening Module	protocol	††	††	††	††	††	††	††	††	††
Subject Status Change Module	protocol	††	††	††	††	††	††	††	††	††
Supplies Ordering Management - Site	protocol	††	††	††	††	††	††	††	††	††
Telephone Line Setup	protocol	††	††	††	††	††	††	††	††	††
User Acceptance Testing	protocol	††	††	††	††	††	††	††	††	††
Visit Tracking Module	protocol	††	††	††	††	††	††	††	††	††
Web Technical Setup	protocol	††	††	††	††	††	††	††	††	††
Project Closeout	protocol	††	††	††	††	††	††	††	††	††
User Information/Security Management (PINs)	site user	††	††	††	††	††	††	††	††	††
Site Based System Support	site month	††	††	††	††	††	††	††	††	††
Subject Based System Support	patient month	††	††	††	††	††	††	††	††	††
System Support - Base	month	††	††	††	††	††	††	††	††	††
User Guide Creation	user guide	††	††	††	††	††	††	††	††	††
Data Interfaces - Repeat	repeat interface	††	††	††	††	††	††	††	††	††
Data Transfers - Repeat	repeat transfer	††	††	††	††	††	††	††	††	††
Data Transfers - Unique	unique transfer	††	††	††	††	††	††	††	††	††
System Custom Coding	system custom	††	††	††	††	††	††	††	††	††
Standard Reports	Report	††	††	††	††	††	††	††	††	††
Configurable Reports	Report	††	††	††	††	††	††	††	††	††
Custom Reports	Report	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Project Team Meetings/Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
IVRS Team Management	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Data Management										
Database Design/Build/Validation	unique page	††	††	††	††	††	††	††	††	††
Coding Set-up	study	††	††	††	††	††	††	††	††	††
Mock Screen Layout Design	unique page	††	††	††	††	††	††	††	††	††
Project Start-Up	protocol	††	††	††	††	††	††	††	††	††
Transfer Activities - Set-Up	protocol	††	††	††	††	††	††	††	††	††
Data Validation System Design - DVM	DVM	††	††	††	††	††	††	††	††	††
Data Validation System Design - edits	edit check	††	††	††	††	††	††	††	††	††
Data Validation System Design - listings	output	††	††	††	††	††	††	††	††	††
Data Validation System Development - edits	edit check	††	††	††	††	††	††	††	††	††
Data Validation System Development - listings	output	††	††	††	††	††	††	††	††	††
Data Validation	page	††	††	††	††	††	††	††	††	††
Data Validation System Validation - edits	edit check	††	††	††	††	††	††	††	††	††
Data Validation System Validation - listings	output	††	††	††	††	††	††	††	††	††
Project Tracking	month	††	††	††	††	††	††	††	††	††
Medical Terminology Coding	verbatim term	††	††	††	††	††	††	††	††	††
Data Imports	import	††	††	††	††	††	††	††	††	††
Data Imports - Import Sources	import source	††	††	††	††	††	††	††	††	††
Data Reconciliation	import	††	††	††	††	††	††	††	††	††
Transfer Activities - Exports	export	††	††	††	††	††	††	††	††	††
Transfer Activities - Unique Page	unique page	††	††	††	††	††	††	††	††	††
Query	query	††	††	††	††	††	††	††	††	††
SAE	SAE	††	††	††	††	††	††	††	††	††
Discrepancies	discrepancy	††	††	††	††	††	††	††	††	††
Archive Study	study	††	††	††	††	††	††	††	††	††
Finalized Database	finalized databas	††	††	††	††	††	††	††	††	††
Data Review Meetings	meeting	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings	meeting	††	††	††	††	††	††	††	††	††
Quality Management	year	††	††	††	††	††	††	††	††	††
DM Project Management	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Pharmacovigilance										
Pharmacovigilance Set-up	protocol	††	††	††	††	††	††	††	††	††
Regulatory Reporting Set-Up	protocol	††	††	††	††	††	††	††	††	††
Data Safety Monitoring Board Set-up	protocol	††	††	††	††	††	††	††	††	††

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Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
Safety Database - Set-up	protocol	††	††	††	††	††	††	††	††	††
Analysis of Similar Events	analysis	††	††	††	††	††	††	††	††	††
Development Safety Update Report (DSUR) Preparation	report	††	††	††	††	††	††	††	††	††
Event Reconciliation	SAE	††	††	††	††	††	††	††	††	††
Expedited Report Submissions	submission	††	††	††	††	††	††	††	††	††
Medical Protocol Inquiries	inquiry	††	††	††	††	††	††	††	††	††
Protocol Deviation Reviews/Determine Evaluability Sets	month	††	††	††	††	††	††	††	††	††
Medical Review of Alert Labs	protocol	††	††	††	††	††	††	††	††	††
Medical Review of Coding	review	††	††	††	††	††	††	††	††	††
Medical Review of Safety Listings	review	††	††	††	††	††	††	††	††	††
Periodic Safety Report Preparation	report	††	††	††	††	††	††	††	††	††
Physician Assessment Diagnostic Forms	PADF	††	††	††	††	††	††	††	††	††
SAE/Event Processing	SAE	††	††	††	††	††	††	††	††	††
Senior Medical Officer for Canada - Start-up	protocol	††	††	††	††	††	††	††	††	††
Senior Medical Officer for Canada - Monthly Maintenance	month	††	††	††	††	††	††	††	††	††
Senior Medical Officer Review of Canadian CTA	CTA review	††	††	††	††	††	††	††	††	††
Senior Medical Officer Review of Canadian CTA Amendment	CTA amendmer	††	††	††	††	††	††	††	††	††
Pharmacovigilance Close-out	protocol	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Investigator Meeting	attendee	††	††	††	††	††	††	††	††	††
Data Safety Monitoring Board Face-to-Face Meeting	meeting	††	††	††	††	††	††	††	††	††
Data Safety Monitoring Board Teleconference Meeting	meeting	††	††	††	††	††	††	††	††	††
Pharmacovigilance Team Management	month	††	††	††	††	††	††	††	††	††
Data Safety Monitoring Board Project Management	month	††	††	††	††	††	††	††	††	††
Safety Database - Monthly Management	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Biostatistics										
DSMB meeting	meeting	††	††	††	††	††	††	††	††	††
Data Validation Manual	protocol	††	††	††	††	††	††	††	††	††
Design/Review Protocol	protocol	††	††	††	††	††	††	††	††	††
Initial Project Training	protocol	††	††	††	††	††	††	††	††	††
Produce/Review Statistical Analysis Plan (SAP)	plan	††	††	††	††	††	††	††	††	††
Randomization Schedule	protocol	††	††	††	††	††	††	††	††	††
Review CRF	protocol	††	††	††	††	††	††	††	††	††
Project Setup	protocol	††	††	††	††	††	††	††	††	††
DSMB - Produce/Review Statistical Analysis Plan (SAP)	plan	††	††	††	††	††	††	††	††	††
DSMB Analysis - Database	analysis dataset	††	††	††	††	††	††	††	††	††
DSMB - TLF Shells	shell	††	††	††	††	††	††	††	††	††
DSMB Analysis - Tables	table	††	††	††	††	††	††	††	††	††
DSMB Analysis - Listings	listing	††	††	††	††	††	††	††	††	††
IND Analysis - Database	analysis dataset	††	††	††	††	††	††	††	††	††
IND Analysis - Tables	table	††	††	††	††	††	††	††	††	††
Full Analysis - Database	analysis dataset	††	††	††	††	††	††	††	††	††
Full Analysis - TLF Shells	shell	††	††	††	††	††	††	††	††	††
Full Analysis - Tables	table	††	††	††	††	††	††	††	††	††
Full Analysis - Listings	listing	††	††	††	††	††	††	††	††	††
Full Analysis - Figures	figure	††	††	††	††	††	††	††	††	††
Full Analysis - Report	report	††	††	††	††	††	††	††	††	††
Project Archiving	study	††	††	††	††	††	††	††	††	††
Data Review Meetings	meeting	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Biostats Team Management	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Medical Writing										
DSUR	study	††	††	††	††	††	††	††	††	††
Review CRF	protocol	††	††	††	††	††	††	††	††	††
Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††
Prepare SAE Narratives for Final Report	narrative	††	††	††	††	††	††	††	††	††
Prepare Final Integrated Report	report	††	††	††	††	††	††	††	††	††
Prepare Mock Final Integrated Report	report	††	††	††	††	††	††	††	††	††
Prepare Draft 1 Final Integrated Report	report	††	††	††	††	††	††	††	††	††
Prepare Final Integrated Report - Appendices	appendices set	††	††	††	††	††	††	††	††	††
Prepare Final Integrated Report - Publishing	publishing	††	††	††	††	††	††	††	††	††

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Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
Data Review Meetings	meeting	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings	meeting	††	††	††	††	††	††	††	††	††
Medical Writing Project Maintenance	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
QA										
Clinical QA - Project Familiarization & Initial Team Training	protocol	††	††	††	††	††	††	††	††	††
Clinical QA - Clinical Investigator Site Audit	audit	††	††	††	††	††	††	††	††	††
Clinical QA - Project Support	month	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Investigator Files Set-up	site	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Investigator File Maintenance	site month	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Investigator Files Archiving and Transfer	site	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Unblinded Investigator Files Set-up	site	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Unblinded Investigator File Maintenance	site month	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Unblinded Investigator Files Archiving and	site	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Country File Set-up	country	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Country File Maintenance	month	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Country File Archiving and Transfer	country	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Central File Set-up	protocol	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Central File Maintenance	month	††	††	††	††	††	††	††	††	††
Information Governance & Compliance - Central File Archiving and Transfer	protocol	††	††	††	††	††	††	††	††	††
Clinical Supplies QA - Project Agreements	study	††	††	††	††	††	††	††	††	††
Clinical Supplies QA - Project Support	study	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Regulatory Affairs										
Clinical Trial Application/Authorization - Country Specific Submissions	country	††	††	††	††	††	††	††	††	††
Clinical Trial Application/Authorization - Variations and Amendments	country	††	††	††	††	††	††	††	††	††
Clinical Trial Application/Authorization - Management	month	††	††	††	††	††	††	††	††	††
Clinical Trial Application/Authorization - Annual/Progress Reports	report	††	††	††	††	††	††	††	††	††
Registration of Clinical Trials - Initial	protocol	††	††	††	††	††	††	††	††	††
Registration of Clinical Trials - Maintenance	month	††	††	††	††	††	††	††	††	††
Regulatory Review of Clinical Trial Labeling	protocol	††	††	††	††	††	††	††	††	††
Regulatory Compliance Review	site	††	††	††	††	††	††	††	††	††
Regulatory Compliance Review - Amendments	site	††	††	††	††	††	††	††	††	††
Safety Report Submissions	submission	††	††	††	††	††	††	††	††	††
Notification of End of Trial (Health Authority)	protocol	††	††	††	††	††	††	††	††	††
Kick-off Meeting with Client	meeting	††	††	††	††	††	††	††	††	††
Client Teleconferences	teleconference	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Clinical Pharmacology (PK)										
Clean and Format Bioanalytical and CRF Data for NONMEM Datasets - POP	study	††	††	††	††	††	††	††	††	††
Project Setup - POP	study	††	††	††	††	††	††	††	††	††
Produce/PK Input to Population PKPD Analysis Plan - POP	plan	††	††	††	††	††	††	††	††	††
Generation of NONMEM datasets - POP	dataset	††	††	††	††	††	††	††	††	††
Generation of PKPD Datasets - NCA	analysis dataset	††	††	††	††	††	††	††	††	††
Generation of PKPD TLFs - NCA	PKPD TLF set	††	††	††	††	††	††	††	††	††
Population PK Analysis, Covariate Analysis, Model Evaluation - POP	analyte	††	††	††	††	††	††	††	††	††
Produce Population PKPD Study Report - POP	report	††	††	††	††	††	††	††	††	††
PK Project Team Meetings - POP	month	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
EDC										
EDC Project Set-up	protocol	††	††	††	††	††	††	††	††	††
EDC Study Closeout	protocol	††	††	††	††	††	††	††	††	††
Internal Team Meetings and Ongoing Training	meeting	††	††	††	††	††	††	††	††	††
Sub Total		††			††	††			††	††
Total Direct Costs					**				**	**
Consulting Services Discount					**				**	**
Total Discounted Direct Costs					**				**	8,866,490.71
Pass Through Costs										

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Department/Activity	Unit Type	Total Hours NA	Unit Cost NA (USD)	# of Units NA	Budget NA (USD)	Total Hours EMEA	Unit Cost EMEA (USD)	# of Units EMEA	Budget EMEA (USD)	Total Budget (USD)
BioA Quote	report	††	††	††	††	††	††	††	††	††
Central Laboratory Fees	protocol	††	††	††	††	††	††	††	††	††
Central Labs Quote EMEA	report	††	††	††	††	††	††	††	††	††
Clinical Site Audit - Travel	audit	††	††	††	††	††	††	††	††	††
Data Safety Monitoring Board Meetings	meeting	††	††	††	††	††	††	††	††	††
EDC CD Building Material	site	††	††	††	††	††	††	††	††	††
Face to Face Client Meetings - Travel	attendee	††	††	††	††	††	††	††	††	††
Host Investigator Meeting	study	††	††	††	††	††	††	††	††	††
Importation costs for Supplies	study	††	††	††	††	††	††	††	††	††
Interim Monitoring Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Investigator Fees	patient	††	††	††	††	††	††	††	††	††
IRB/EC Fees	site	††	††	††	††	††	††	††	††	††
IVR - Courier Charges for PIN Packets	site user	††	††	††	††	††	††	††	††	††
IVR - System Translations & Voice Recordings	translation per la	††	††	††	††	††	††	††	††	††
IVR - Telephone Line Charges	call	††	††	††	††	††	††	††	††	††
Kick-off Meeting With Client - Travel	attendee	††	††	††	††	††	††	††	††	††
Management of Packaging and Labeling	packaging run	††	††	††	††	††	††	††	††	††
Medidata Rave Services	site month	††	††	††	††	††	††	††	††	††
Site Closeout Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Site Evaluation Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Site Initiation Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Study Drug Label Text Translations Fees	protocol	††	††	††	††	††	††	††	††	††
Third Party Depot Costs	protocol	††	††	††	††	††	††	††	††	††
Translation of various documents (excluding protocol)	document	††	††	††	††	††	††	††	††	††
Unblinded Drug Accountability Visits - Travel	visit	††	††	††	††	††	††	††	††	††
Total Pass Throughs					††				††	††
Total Study Costs					††				††	14,941,804.16

Should Galectin Therapeutics, Inc. require assistance from PPD in responding to a Sponsor or investigative site regulatory inspection, Galectin Therapeutics, Inc. and PPD will mutually agree the scope of services to be provided in writing. For these services Galectin Therapeutics, Inc. will compensate PPD based on the unit pricing table below, unless the inspection occurs as a result of PPD's inadequate service delivery or negligence. Each unit represents 8 hours of PPD effort to aid in Galectin Therapeutics, Inc.'s response to the inspection(s).

	Unit Cost NA (USD)	Unit Cost EMEA (EUR)	Unit Cost APAC (USD)	Unit Cost LA (USD)
Regulatory Inspection of Sponsor - 8 Hour Unit	$††	$††	$††	$††
Inspection of Site - 8 Hour Unit	$††	$††	$††	$††

*Inspection costs will be converted to the contract currency at the time of invoicing.

** The units and unit prices for the following service areas represent global units and the services associated with these units will be performed utilizing PPD's global resource pool: IVRS, Data Management, Pharmacovigilance, Biostatistics, Medical Writing, Regulatory Affairs, Writing and Editorial Services, Electronic Data Capture.

This cost estimate is based upon the estimated study timeline included in PPD's proposal dated 16 Dec 2014. Should there be a subsequent change to the estimated study timeline, PPD will apply resulting inflation as appropriate

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Exhibit C

PPD Payment Schedule
Galectin
BC Number: 58004-01
Protocol : GT026

	GALT proposal
Execution of Contract	††
Monthly	
Project Management Fee	
$†† per month beginning ††	††
Milestones:	
50% Site Qual Visits Completed	††
First Site Initiated - NA	††
50% Sites Initiated	††
First Patient In	††
10% MV Completed	††
20% MV Completed	††
30% MV Completed	††
40% MV Completed	††
50% MV Completed	††
60% MV Completed	††
70% MV Completed	††
80% MV Completed	††
90% MV Completed	††
Database Set-up	††
20% eCRFs verified	††
40% eCRFs verified	††
60% eCRFs verified	††
80% eCRFs verified	††
DB Lock & all Queries Resolved	††
Draft Tables & Listings	††
Final Tables & Listings	††
Draft ICSR	††
Final ICSR	††
Total Direct Costs	8,866,490.71
Clinical Grants due at execution of agreement (note 1)	††
Clinical Grants invoiced monthly in advance of payout to sites (note 1)	††
Total Clinical Grants	
Investigator meeting billed upfront	††
Remaining pass through amounts will be billed monthly at actual costs	††
Total Pass Through Costs	6,075,313.45
Project Grand Total	14,941,804.16

1 PPD will not release payment for investigator grants or investigator meeting costs until sponsor has remitted the applicable amount.

2 In the event that the study is delayed or put on hold for a period of greater than 30 days, PPD may invoice Sponsor on a prorated basis for all milestones partially completed and other services partially performed, such proration to be reasonably computed and within the limitations of the Study Budget.

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MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (the ***"Agreement"***) is effective as of 8 January, 2015 (the ***"Effective Date"***) by and between **PPD DEVELOPMENT, L.P.**, a Delaware limited partnership, with its principal executive offices located at 929 North Front Street, Wilmington, North Carolina (***"PPD"***) and **GALECTIN THERAPEUTICS, INC.**, a Nevada corporation with its principal executive offices located at 4960 Peachtree Industrial Boulevard, Suite 240, Norcross Georgia 30071 (***"Sponsor"***).

WHEREAS, Sponsor is engaged in the development, manufacture, distribution and sale of pharmaceutical products; and

WHEREAS, PPD is a clinical research organization engaged in the business of managing clinical research programs and providing clinical development and other related services; and

WHEREAS, Sponsor may wish to retain the services of PPD from time to time to perform clinical development services in connection with certain clinical research programs Sponsor is conducting (individually, a ***"Project"***), in which case the terms and conditions for each such Project shall be set forth in a project addendum to be attached to this Agreement and incorporated herein by reference (individually, a ***"Project Addendum"*** and collectively, the ***"Project Addenda"***); and

WHEREAS, PPD is willing to provide such services to Sponsor in accordance with the terms and conditions of this Agreement and the attached Project Addenda.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. SERVICES.

1.1 Services to be Provided by PPD. PPD hereby agrees to provide to Sponsor the services identified and described in the Services section of each Project Addendum attached to this Agreement (the ***"Services"***). PPD shall perform the Services for each Project set forth in the applicable Project Addendum in compliance with (i) the protocol for the Project (***"Protocol"***), which may be attached to and as amended or updated from time to time, and made a part of, the applicable Project Addendum, (ii) the terms and conditions of this Agreement, (iii) the terms and conditions of the applicable Project Addendum and Sponsor's written instructions, (iv) PPD's standard operating procedures (***"SOPs"***), which will be available for review upon written request, and (v) all applicable laws, rules and regulations. Sponsor agrees that PPD is responsible only for those Services set forth on a properly executed Project Addendum.

1.2 Project Addendum. In the event that the parties hereto shall reach agreement with respect to the provision of Services for a Project, PPD and Sponsor shall execute a Project Addendum evidencing such Services. Each Project Addendum shall be attached to this Agreement and incorporated into and made a part of this Agreement by reference, and each such Project Addendum and this Agreement shall constitute the entire agreement for the applicable Project. To the extent any terms set forth in a Project Addendum conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise specifically set forth in the Project Addendum.

1.3 Mutual Cooperation. Sponsor and PPD will each cooperate with the other party in providing reasonably requested information to the other party, taking action and executing documents, as appropriate, to achieve the objectives of this Agreement and any Project Addendum executed under this Agreement. Sponsor acknowledges and agrees that PPD's performance under this agreement is dependent on Sponsor and Sponsor's representatives

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timely and effective cooperation with PPD. Accordingly, Sponsor acknowledges that any delay by Sponsor to provide information information necessary to PPD to meet an obligation or deadline may result in PPD receiving an extension to meet an obligation to meet an obligation or schedule deadline or in Sponsor having to pay additional fees in order for PPD to meet a specific obligation or deadline despite the delay. In addition, PPD shall not be responsible for any delays due to (1) Sponsor or its agents, employees and contractors other than PPD, (2) any third party except for those who have been selected by PPD and research sites, (3) a force majeure event, or (4) any other factors outside of the direct and reasonable control of PPD. In the event of any such delays, the study timelines will be revised accordingly. Sponsor and PPD each shall comply with all applicable laws, rules and regulations governing the performance of its obligations hereunder and the subject matter of this Agreement.

1.4 Serious Adverse Event and Medical Management Plan. Notwithstanding anything to the contrary herein, in the event PPD and Sponsor agree upon a serious adverse event and medical management plan relating to a specific Project ("SMMP"), the parties shall comply with the terms and conditions of any such SMMP. In the event of any conflict between the terms and conditions of the SMMP and the relevant Project Addendum, the terms and conditions of the SMMP shall control. Sponsor shall be responsible for any additional costs associated with compliance with the SMMP, which will be captured in an amendment to the applicable Project Addendum.

1.5 Patient Enrollment. The parties agree that enrollment numbers are good faith estimates and that various factors outside of PPD's control can affect the rate of enrollment. PPD shall exercise all reasonable efforts to meet such enrollment estimates, but cannot guarantee that enrollment numbers or enrollment timelines will be met. The Parties agree that incentives around enrollment based milestones may be addressed in an applicable Project Addendum.

1.6 Final Protocol. Subject to section 9.2 of this Agreement PPD shall not be liable or responsible for the final review, approval, adoption and content of the Protocol.

1.7 PPD Representations and Warranties. PPD represents and warrants to Sponsor that:

a. It 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;

b. All aspects of PPD's facilities which may be used in the performance of any Services, including without limitation the databases to be used by PPD for the tracking, handling, recording, reporting and transmitting of data generated during the Projects have been fully verified and validated according to applicable industry standards;

c. It is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement and that during the term of this Agreement it will not enter into any agreement to provide services that would in any way prevent it from providing the Services contemplated under this Agreement;

d. It has the experience, capability and resources, including but not limited to sufficient personnel and supervisors to perform the Services under any Project Addenda in a competent manner and that it shall at all times devote the necessary personnel and supervisors to perform the Services in a competent manner; and

e. 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. § 312 and the International Conference on

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Harmonisation Good Clinical Practice Guidelines and including all requirements on clinical research organizations, including as designees of trial sponsors that relate to Services provided hereunder.

2. COMPENSATION AND PAYMENT.

2.1 Charges for Services. Sponsor shall pay PPD for all Services performed under this Agreement and any Project Addendum (***"Direct Fees"***) in accordance with the rates for such Services set forth in such Project Addendum, including any cap in fees agreed upon by the parties and identified in the Project Addendum. Sponsor shall also reimburse PPD for all out-of-pocket expenses incurred in connection with the performance of the Services with respect to a Project, including, without limitation, investigator grants and fees, travel expenses, shipping and postage costs, copying and printing fees, copyright fees, third party drug storage and distribution fees, required Institutional Review Board or similar board or committee fees, and other "pass through" expenses reasonably expected to be incurred in connection with performing the Services to the extent such expenses have been approved by Sponsor in advance (collectively, the ***"Pass Through Costs"***). Except as otherwise expressly provided in a Project Addendum, PPD shall submit to Sponsor for each Project a monthly invoice describing the Services performed on such Project, the Direct Fees due for such Services, and all Pass Through Costs paid by PPD. Sponsor shall pay each invoice within thirty (30) days of receipt of said invoice. If payment is not received by PPD within such thirty-day period, PPD shall provide notice to Sponsor in writing (e-mail is sufficient) of such unpaid invoice. Should Sponsor fail to make payment to PPD on such unpaid amounts within ten (10) days of Sponsor's receipt of such written notice, Sponsor's nonpayment thereof shall be considered a default. PPD shall have no obligation to pay Subcontractor (as defined in Section 14.11) costs, vendor costs, or investigator grant payments to any Subcontractor, vendor or investigator site (the ***"Site"***) for conduct of services by such Site related to a Project until PPD has received payment of such Pass Through Costs from Sponsor. Notwithstanding anything to the contrary contained herein, Sponsor acknowledges and agrees that certain vendor and Subcontractor contracts, including without limitation, contracts for investigator meetings and patient recruitment services, must be advanced and paid up front by Sponsor. PPD shall be under no obligation to incur any such vendor or Subcontractor fees until such fees are received from Sponsor. In addition, all investigator grants, if applicable and if approved in advance by Sponsor, shall be advanced by Sponsor at timeframes mutually agreed upon by the parties.

2.2 Payment after Termination. Upon termination of any Project Addendum or this Agreement pursuant to Section 3 below, Sponsor shall pay PPD all Direct Fees and Pass Through Costs for all Services, and any portion of Services, performed through the termination date. In addition, Sponsor shall reimburse PPD for all future non-cancelable obligations (where such obligations were reasonably created as a result of a Project being authorized by Sponsor and were approved in advance by Sponsor). Any funds held by PPD which are unearned shall be returned to Sponsor within sixty (60) days following conclusion of the Project including any wind down services, as long as no further funds are due to PPD from Sponsor are outstanding. Sponsor acknowledges that certain services of PPD require greater utilization of resources at the outset such that compensation for such services based on a percentage of milestones completed prior to PPD fully completing the milestones would work to the detriment of PPD. Accordingly, the parties agree that in the event of early termination that PPD shall be entitled to compensation for all completed and partially completed Services on a time and materials basis according to a calculation agreed upon by both parties.

2.3 Pre-Execution Services. In the event Sponsor requests PPD to begin providing the Services for a Project prior to the execution by Sponsor of a Project Addendum or other mutually agreed upon writing, Sponsor agrees that PPD shall be compensated on a time and materials basis for Services performed at Sponsor's request in accordance with the PPD Proposal for Services.

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2.4 Taxes. All fees stated in this Agreement or any Project Addendum are net of Value Added Tax ("VAT") or similar taxes. If any VAT or similar taxes are due, these will be payable by Sponsor in addition to the fees paid to PPD.

2.5 Payments. Unless otherwise set forth in a Project Addendum, all payments to PPD under this Agreement or any Project Addendum shall be made as follows:

If made by check, payment mailed to:	PPD Development, L.P. 26361 Network Place Chicago, IL 60673-1263 Tax ID# †† Overnight Address: JPMorgan Chase 131 S. Dearborn, 6th Floor Chicago, IL 60603 Attn: PPD Development, L.P./Box 26361
If made by wire transfer, payment wired to:	JPMorgan Chase Acct: †† R/T Number: ††(ACH & Wire) SWIFT/BIC: †† Beneficiary: PPD Development, L.P.

Any changes to the payee information set forth above require a writing signed by PPD's Treasurer or Chief Financial Officer.

3. TERM AND TERMINATION.

3.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue for a period of five (5) years unless extended by mutual written agreement by the parties; provided however, the term shall be extended as to any Project Addendum ongoing on the fifth anniversary of the Effective Date until the Services contemplated by the Project Addendum have been completed. Each Project Addendum shall be effective upon the date set forth in such Project Addendum and shall terminate upon (i) the completion of the Services to be provided thereunder, and (ii) PPD's receipt of all Direct Fees, Pass Through Costs, and any other payments due to PPD related to the Services provided thereunder, unless earlier terminated in accordance with this Section 3.

3.2 Early Termination. This Agreement or any Project Addendum may be terminated by Sponsor with or without cause upon thirty (30) days prior written notice to PPD. PPD may terminate any Project Addendum upon Sponsor's breach of Agreement upon thirty (30) days prior written notice, provided that such breach is not cured within such thirty (30) day period.

3.3 Insolvency. Either party hereto may terminate this Agreement immediately upon the occurrence of an "Insolvency Event" with respect to the other party. For purposes of this Agreement, ***"Insolvency Event"*** shall mean (1) a party or any of its subsidiaries shall commence a voluntary proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any action to authorize any of the foregoing; (2) an involuntary case or other proceeding shall be commenced against a party or any of its subsidiaries seeking

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liquidation, reorganization or other relief with respect to it or its debts under bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain un-dismissed and un-stayed for a period of sixty (60) days; or (3) an order for relief shall be entered against a party or any of its subsidiaries under the federal bankruptcy laws now or hereafter in effect.

3.4 Effect of Termination. The termination of this Agreement by either party shall not automatically terminate all Project Addenda, unless otherwise agreed in writing. In the event of termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to all Project Addenda still in effect after such termination or expiration.

3.5 Wind Down. Upon the termination of this Agreement or a Project Addendum, PPD shall reasonably cooperate with Sponsor to provide for an orderly wind-down of the Services provided by PPD hereunder, including assisting Sponsor in assigning agreements (if applicable) related to the Project (e.g., with Sites) and transferring duties for Services to Sponsor or its designee. Costs associated with such wind-down activities shall be billed to Sponsor on a time and materials basis, based on the rates in the Project Addendum for the Services and if not identified in the Project Addendum, the then-current PPD rates.

3.6 Provisions Surviving Termination. The expiration, termination or cancellation of this Agreement will not extinguish the rights of either party that accrue prior to expiration, termination or cancellation or any obligations that extend beyond expiration, termination or cancellation, either by their inherent nature or by their express terms, including, without limitation, the obligations contained in Sections 2 (Compensation and Payment), 3.4 (Effect of Termination), 3.5 (Wind Down), 3.6 (Provisions Surviving Termination), 6 (Confidentiality), 7 (Data Privacy), 8 (Intellectual Property), 9 (Indemnification), 10 (Limitation of Liability), 11 (Insurance) 12.2 (Record Maintenance after Expiration or Termination), 14.2 (Publicity), 14.5 (Notices), 14.6 (Governing Law), 14.7 (Severability), 14.10 (Assignment), 14.11 (Subcontracting), 14.12 (Arbitration) and 14.13 (Construction) hereof and herein shall survive termination of this Agreement.

4. CURRENCY MANAGEMENT

4.1 Direct Fees. All Direct Fees owed to PPD for Services performed under this Agreement or any Project Addendum shall be invoiced to and paid by Sponsor in the “Contract Currency”, which shall be defined as the currency, or currencies, designated in any budget or payment schedule set forth in a Project Addendum. The parties agree that where possible, PPD will provide its budget for each Project Addendum in US Dollars (“USD”) globally with the exception of Services performed in Europe, Middle East and Africa (the “EMEA Region”), which will be in Euros.

In the event Sponsor desires to be invoiced in any currency other than Euros for Services performed in the EMEA Region, and other than USD for Services performed in all other regions, the parties shall specify in the Project Addendum the exchange rate or rates (“Contracted Exchange Rate”) to be used for the Project Addendum. The Contracted Exchange Rate will be used for the preparation of each invoice for Services and payment by Sponsor. The “Spot Rate” for purposes of reconciliation, shall mean the actual spot rate in the Wall Street Journal for the date on which the invoice is raised. At the conclusion of each calendar year, a reconciliation shall be undertaken by PPD. PPD shall compare the total value of the invoices billed to Sponsor at the Contracted Exchange Rate to the value of the same invoices when converted using the Spot Rates. In the event the comparison demonstrates that the total difference in such amounts is five percent (5%) or more of the annual invoice value or is greater than USD $50,000 (or the contracted currency equivalent when measured against the current spot rate), such difference shall be invoiced or credited, as the case may be, to Sponsor. The reconciliation invoice or credit note will be issued by PPD in Contract Currency. The process of reconciliation is not cumulative, but shall be conducted on a calendar year basis and completed by the end of March in the subsequent year.

4.2 Pass Through Costs. Where PPD incurs Pass Through Costs in a currency other than the Contract Currency, PPD shall, for Sponsor invoicing and payment purposes, convert such costs to the Contract Currency based on an average exchange rate between the local currency and the Contract Currency for the month in which such costs were incurred. This average exchange rate will be based on the monthly average of the daily exchange rates as published in the Wall Street Journal.

4.3 Investigator Fees. At the beginning of each study Sponsor shall advance PPD a pre-agreed value for the sole purpose of paying Investigator Fees. All future amounts invoiced to Sponsor will be based upon an accrual of costs owed to investigators, with the pre-agreed advance serving to provide available funds for PPD to make payments to investigator sites, while said invoices are processed by Sponsor. PPD shall pay investigator fees in the currency specified in the investigator agreements. For Sponsor invoicing and payment purposes, PPD shall convert all investigator fees that are to be paid in a currency other than the Contract Currency to the Contract Currency based on the average exchange rate between the currencies for the month prior to the month the invoice is raised. As each Project Addendum comes to a close, the original advance will be used to pay the final Investigator Fees with a reconciliation provided by PPD at the conclusion of the study reflecting how the funds were applied. This reconciliation will also compare the estimated exchange rate used for the purposes of invoicing on the basis of accrued costs versus the exchange rate when the actual payment was made to the investigator sites, and any variation will be invoiced or credited to Sponsor as applicable.

5. PERSONNEL.

5.1 Project Management. The Services with respect to each Project shall be performed by PPD under the direction of the person identified as the operational lead in the applicable Project Addendum or such other person acceptable to Sponsor as PPD may from time to time designate as the Project Manager, such Sponsor acceptance of the designated Project Manager not to be unreasonably withheld or delayed in all instances.

5.2 Covenant Not to Interfere. During the term of a Project Addendum, neither party will solicit for employment any employee of the other party who is providing services under that Project Addendum. As used in this section “solicit” means the initiation by a party or its agent of a contact with any of the other party’s then current employees who are performing services under this Agreement for the purpose of offering employment to such employees, but shall not include the circumstance where any such employee initiates a contact with the other party for the purpose of obtaining employment whether in response to a general advertisement of employment or where such contact is initiated by a third party who was not instructed to contact such employee by the hiring party.

5.3 Personnel Retention. In the event of delays in the performance of the Project which are caused solely and directly by Sponsor, i.e., after PPD is authorized to commence work or delays beyond the reasonable control of PPD and where Sponsor desires for PPD to keep PPD Project personnel assigned to the Project, after PPD notifies Sponsor in writing (email to suffice) that additional fees will apply, Sponsor agrees that Sponsor shall pay a personnel fee calculated on an FTE-day basis. Said personnel fees shall be invoiced by PPD on a monthly basis, and shall be due and payable by Sponsor within 30 days of receipt of invoice.

6. CONFIDENTIALITY.

6.1 Sponsor Confidential Information. PPD shall treat all information obtained from Sponsor and all Sponsor Property (as defined below) and any revisions improvements or enhancements thereto (***“Sponsor Confidential Information”***) as the confidential and exclusive property of Sponsor.

6.2 PPD Confidential Information. Sponsor shall treat all information obtained from PPD or any of PPD's Affiliates including, without limitation, any PPD bids or proposals, standard operating procedures, third party confidential information, personnel information, all PPD Property (as defined below) and any revisions, improvements or enhancements thereto (***"PPD Confidential Information"***) as the confidential and exclusive property of PPD. In addition, any affiliate of Sponsor receiving information pursuant to this Agreement or any Project Addendum hereunder from PPD or any PPD Affiliate shall be bound by these confidentiality obligations. Further, any information disclosed, obtained, or observed by Sponsor or any affiliate of Sponsor during an audit of PPD or an Affiliate of PPD, or the facilities of either, with the exception of Sponsor Confidential Information, shall be treated as confidential by Sponsor in accordance with the terms contained herein. For the purposes of this Agreement, Sponsor Confidential Information and PPD Confidential Information shall collectively be referred to as "**Confidential Information**."

6.3 Use of Sponsor Confidential Information and PPD Confidential Information. Each party shall use the other's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of the other party. Neither party shall publish, disseminate or otherwise disclose Confidential Information of the other to any third party without first obtaining the written consent of such other party. Each party shall restrict the dissemination of the other's Confidential Information with its organization to only those persons who have a need to know, and shall ensure that all of its directors, officers, employees, agents, representatives and advisors (collectively, ***"Associates"***) are aware of this Agreement and bound by terms of confidentiality no less stringent than those stated herein. In addition, prior to providing any Confidential Information to a permitted third party other than an Associate, the receiving party will ensure that such third parties are bound to written obligations of confidentiality that are not less stringent than those contained herein.

6.4 Exceptions to Confidential Information. The above provisions of confidentiality shall not apply to that part of disclosing party's Confidential Information which the receiving party is able to demonstrate by documentary evidence: (i) was in the receiving party's possession prior to receipt from the disclosing party or is independently developed by or for the receiving party; (ii) was in the public domain at the time of receipt from disclosing party; (iii) subsequently becomes a part of the public domain through no fault of the receiving party or its Associates; or (iv) is lawfully received by the receiving party from a third party having a right of further disclosure.

6.5 Disclosure Required by Law. The non-disclosure obligations pursuant to this Agreement shall not apply to Confidential Information that a receiving party is required to disclose pursuant to any judicial action, order of the court or other governmental agency or requirement of the Securities and Exchange Commission or applicable securities exchange; provided, however, that the receiving party shall make all reasonable efforts to notify the disclosing party prior to the disclosure of Confidential Information and allow the disclosing party the opportunity to contest and avoid such disclosure, and further provided that the receiving party shall disclose only that portion of such Confidential Information that it is legally required to disclose. Notwithstanding the foregoing, Sponsor may disclose the existence and terms of this Agreement and any Project Addendum as needed to comply with any requirement of the Securities and Exchange Commission or applicable securities exchange, but subject to redactions as permitted by applicable rules without consent from PPD. However, Sponsor will provide reasonable notice to PPD that such disclosure is occurring.

6.6 Return of Information. Upon termination or expiration of this Agreement or at the disclosing party's earlier written request, the receiving party shall return, and shall cause its Associates to return, all documentary, electronic or other tangible forms of Confidential Information provided by the disclosing party including, without limitation, any and all copies

thereof, or, at the disclosing party's request, destroy all or such parts of the disclosing party's Confidential Information as the disclosing party shall direct. Notwithstanding the foregoing, the receiving party may retain copies of such of the disclosing party's Confidential Information as is reasonably necessary for regulatory and business archival purposes, subject to the ongoing obligation to maintain the confidentiality of such information.

6.7 Remedy. Each party agrees that its obligations hereunder are necessary and reasonable in order to protect the other party and the other party's business, and expressly agrees that monetary damages would be inadequate to compensate the other party for any breach of the terms of this Agreement. Accordingly, each party agrees and acknowledges that any such violation or threatened violation will cause irreparable injury to the other party, and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the other party shall be entitled to obtain injunctive relief against the threatened breach of this Agreement or a Project Addendum or the continuation of any such breach, without the necessity of proving actual damages.

6.8 Survival. The obligations contained herein shall survive for a period of ten (10) years from the date of the disclosure of the Confidential Information.

7. DATA PRIVACY.

7.1 Definitions. For the purpose of this Section 7, 'Personal Data', 'Process/Processing', 'Data Controller', 'Data Processor' and 'Data Subject' shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("Directive 95/46/EC") as implemented in the law of any EU Member State which is applicable to the provision of the Services or as defined in the law of any other country which is applicable to the provision of the Services (including, as applicable, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, 45 C.F.R. Parts 160-164, and the Health Information Technology for Economic and Clinical Health Act (HITECH), P.L. No. 111-005, Part I, Title XIII, Subpart D, 13401-13409, and state privacy laws) (collectively referred to as the "Applicable Data Privacy Laws").

7.2 Compliance. Each party warrants to the other that it will Process the Personal Data in compliance with all Applicable Data Privacy Laws.

7.3 Data Processing. Sponsor and PPD acknowledge that Sponsor is the Data Controller and PPD is the Data Processor with respect to the Processing of Personal Data relating to the Services provided under this Agreement. In the event that the Services are performed by any PPD Affiliate then such PPD Affiliate shall be a sub-Processor. PPD shall Process the Personal Data only in accordance with instructions from Sponsor or as may be required or permitted by law. (The instructions may be specific instructions or instructions of a general nature as set out in this Agreement, a Project Addendum, Protocol, SOP or SMMP or as otherwise notified by Sponsor to PPD during the Term).

7.4 Representative. If Sponsor needs to appoint a representative to comply with Applicable Data Privacy Law in any EU Member State pursuant to Article 4 of Directive 95/46/EC and PPD is willing to provide such services to Sponsor, Sponsor and PPD shall enter into a mutually acceptable agreement for such representative purposes. Unless and until such an agreement is entered into, PPD shall not be deemed to be a representative under any Applicable Data Privacy Law.

7.5 Security. PPD shall implement appropriate technical and organisational measures to protect the Personal Data as required by ICH-GCP and Applicable Data Privacy Laws.

7.6 Data Privacy Requests. PPD shall promptly notify Sponsor in writing if it receives any communication with regard to data privacy relating to the Services from a Data Subject, a privacy authority or other regulatory authority, and provide Sponsor with cooperation and assistance in relation to any such communication. PPD shall be entitled to charge Sponsor for such assistance, at its usual hourly rate, unless the communication relates to a breach or violation by PPD or a PPD Affiliate of its obligations under this Section 7. However, PPD and Sponsor recognize that any fees charged to the requesting party must comply with Applicable Data Privacy Laws.

7.7 Security Breaches. If PPD becomes aware of any breach of an Applicable Data Privacy Law relating to the Services, then it shall promptly notify Sponsor and, if requested, assist Sponsor in meeting any obligations under Applicable Data Privacy Law to notify Data Subjects, regulatory authorities or other required parties. PPD shall be entitled to charge Sponsor for such assistance, at its usual hourly rate, unless PPD or a PPD Affiliate was solely responsible for such breach.

7.8 Data transfers. PPD shall only Process or otherwise transfer Personal Data outside the European Economic Area ("EEA") (member states of the European Union plus, Norway, Iceland & Liechtenstein) as necessary to provide services under this Agreement, or any Project Addendum, Protocol, SOP or SMMP, or where otherwise instructed by Sponsor. Where Personal Data are transferred to PPD's US based Affiliates, they shall be protected by PPD's membership of the US Department of Commerce Safe Harbor scheme. In providing services, it may be necessary to sub-contract certain tasks to one or more third party vendors, including cloud based service providers, whose servers may be located outside the EEA. Transfers of Personal Data to said vendors shall be proceed on the basis of Data Subject consent and/or through a commitment by the vendor to comply with the Principles of the Safe Harbor scheme. Sponsor as Data Controller shall in any event take necessary measures to ensure data transfers are lawful.

8. INTELLECTUAL PROPERTY.

8.1 No License. Neither anything contained herein, nor the delivery of any information to a party hereto, shall be deemed to grant the receiving party any right or license under any patent or patent application or to any know-how, technology or invention of the disclosing party.

8.2 Sponsor Property.

a. All budgets, proposals, Protocols and other materials, documents, information and programs of every kind and description supplied to PPD or investigators by on or on behalf of Sponsor, and all materials, documents and information prepared or developed by PPD or investigators in the course of performing the work provided for in this Agreement including the inventions, technology, know-how and other intellectual property assigned under Section 8.2(b) (collectively "Sponsor Property") and all revisions, improvements or enhancements thereto shall be the sole and exclusive property of Sponsor and PPD shall have no rights, title or interest in such Sponsor Property. PPD waives an renounces any rights to file or assert a lien on any Sponsor Property, including without limitation, any lien that may arise on account of non-payment.

b. Subject to Section 8.3 below, PPD hereby assigns to Sponsor all rights PPD or its Associates may have in any invention, technology, know-how or other intellectual property relating to a Project drug, Protocol or Sponsor Confidential Information or which is (i) a direct result of PPD's provision of the Services or (ii) specifically set forth as a deliverable under a Project Addendum, and PPD shall assist Sponsor, at Sponsor's sole cost and expense, in obtaining or extending protection therefor. PPD warrants that it has and will continue to have agreements with its Associates to effect the terms of this Section 8.2.

8.3 PPD Property. PPD possesses certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and assets, including, without limitation, those related to business or product plans or proposals, marketing strategies, standard operating procedures, data, composition of matter, research, experimental results, personnel data, financial information and conditions, pricing information, customer information, supplier/vendor information, raw materials, data collection and data management processes, laboratory analyses, analytical, biotechnology and clinical methods, procedures and techniques, computer technical expertise and software (including code) which have been independently developed without the benefit of the Sponsor Property (collectively, ***"PPD Property"***). Sponsor and PPD agree that any PPD Property or revisions, improvements or enhancements thereto shall be the sole and exclusive property of PPD, and Sponsor shall have no rights, title and interest to such PPD Property.

9. INDEMNIFICATION.

9.1 Sponsor Indemnity. Sponsor shall indemnify, defend, and hold harmless PPD, PPD Affiliates (as that term is defined in Section 14.10), and their Associates ("***PPD Indemnitees***") from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorneys' fees, expert witness fees, court costs, and amounts incurred by PPD Indemnitees in connection with any third party claim, demand, action, proceeding, investigation or hearing resulting from (i) any personal injury or death caused by the use of Sponsor's study drug, or other materials supplied by Sponsor, or anyone acting on the Sponsor's behalf, in connection with a Project Addendum, or any deviations from the applicable Protocol necessary to preserve the health, safety and welfare of the study subjects; (ii) any claims for patent infringement related to a study drug, compound or other materials supplied by Sponsor, or anyone acting on Sponsor's behalf, to PPD in connection with a Project Addendum; (iii) the negligent acts, omissions or willful misconduct of any subcontractor selected by Sponsor; or (iv) the negligence or willful misconduct of a Sponsor Indemnitee or a material breach of this Agreement by Sponsor; provided however, that Sponsor shall have no obligation of indemnity hereunder with respect to any claim to the extent such claim arises from the negligence, intentional misconduct or material breach of the Agreement or any Project Addenda on the part of PPD or its Associates or any PPD Indemnitee.

9.2 PPD Indemnity. PPD shall indemnify, defend and hold harmless Sponsor and its Associates ("Sponsor Indemnitees") from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, cost and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorney's fees, expert witnesses and court costs, arising out of the negligence, willful misconduct, or breach of this Agreement or any Project Addenda by PPD or its Associates; provided however, that PPD shall have no obligation of indemnity hereunder with respect to any claim to the extent such claim arises from the negligence or intentional misconduct or material breach Agreement or any Project Addenda on the part of Sponsor or its Associates.

9.3 Indemnification Procedure. Each indemnified party shall give the indemnifying party prompt notice of any claim for which indemnification is sought hereunder; provided however that the failure to provide prompt notice shall not release the indemnifying party of its obligations hereunder except to the extent it is irrevocably prejudiced in defending or settling the claim. The indemnifying party shall have the right to control the defense and settlement of a claim, at its sole expense, provided the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the claim, and the indemnified party shall reasonably cooperate in the investigation, defense and settlement of such claim at the indemnifying party's expense. Neither party will enter into any settlement agreement that attributes fault or negligence to the other party, requires any payment by the other party, or restricts the future actions or activities of the other party, without the other party's prior written consent, which shall not be unreasonably withheld. Any indemnified party shall have the right to

participate in, but not control, the defense and settlement of a claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the indemnified party's own expense, unless (i) the employment thereof has been specifically authorized by the indemnifying party, or (ii) the indemnifying party has failed to assume the defense and employ counsel (in which case the indemnified party shall control the defense and settlement of such claim). The costs and expenses, including reasonable fees and disbursements of counsel, incurred by any indemnified party in connection with any claim shall be reimbursed on a monthly basis by the indemnifying party subject to refund in the event the indemnifying party is ultimately held not to be obligated to indemnify the indemnified party.

10. LIMITATION OF LIABILITY.

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PROJECT ADDENDUM, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR ANTICIPATED SALES, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

11. INSURANCE.

11.1 Sponsor and PPD will each undertake to purchase and maintain insurance of such types and amounts reasonably adequate to cover any liabilities arising out of its obligations hereunder. Sponsor further undertakes to purchase and maintain insurance of such types and amounts and coverage reasonably adequate (including but not limited to that required by law) to cover any liabilities arising in relation to all clinical trials contracted to PPD pursuant to this Agreement. The following sets forth the minimum thresholds of insurance each party will maintain:

11.2 PPD Insurance. PPD shall, at its own cost and expense, obtain and thereafter maintain in full force and effect and with properly licensed and financially secure insurers (AM Best rating of A-VII in the United States and reasonably equivalent in countries outside the United States) the following insurance during the term of this Agreement and for a period of not less than three (3) years following termination of this Agreement:

Worker's Compensation. In amounts as required by applicable law.

Automobile Liability Insurance. One Million Dollars ($1,000,000) per occurrence covering all owned, leased and hired vehicles.

General Commercial Liability Insurance. One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) in the aggregate.

Professional Liability Insurance. Five Million Dollars ($5,000,000) per occurrence and Five Million Dollars ($5,000,000) in the aggregate.

11.3 Sponsor Insurance. Sponsor shall, at its own cost and expense, obtain and thereafter maintain in full force and effect, and with properly licensed and financially secure insurers (AM Best rating of A-VII in the United States and reasonably equivalent in countries outside the United States) the following insurance during the term of this Agreement and for a period of not less than three (3) years following termination of this Agreement: [

Worker's Compensation. In amounts as required by applicable law.

General Commercial Liability Insurance. One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) in the aggregate.

Products Liability or Clinical Trial Insurance with a minimum limit of Ten Million Dollars ($10,000,000) per occurrence and Ten Million Dollars ($10,000,000) in the aggregate.

11.4 Sponsor and PPD will each undertake, upon request, to provide the other party a certificate (or certificates) of insurance setting forth the liability limits, exclusions and deductibles of the insurance such party is required to carry pursuant to this Agreement. Each party shall obtain the prior written consent of the other party before implementing any material change or cancellation of the insurance coverage agreed upon herein. Neither party will make any material changes to coverage thresholds that bring such party's required coverage below the minimum requirements stated in this Agreement. Unapproved reductions in any coverage threshold is a breach of this Agreement and at the non-breaching party's option, can result in termination of this Agreement.

12. RECORD STORAGE, AUDITS, AND INSPECTIONS.

12.1 Record Maintenance during Project. During the term of this Agreement, PPD shall maintain all materials and all other data obtained or generated by PPD in the course of providing the Services hereunder, including all computerized records and files. PPD shall cooperate with any reasonable internal review or audit by Sponsor and make available to sponsor for examination and duplication, during normal business hours, all documentation, data and information relating to a Project.

12.2 Record Maintenance after Expiration or Termination. Upon the expiration or termination of the Services other than for Sponsor's breach of required payment hereunder, all materials and all other data and information obtained or generated by PPD in the course of providing the Services hereunder (collectively, the ***"Records"***) shall, as directed by Sponsor (and at Sponsor's cost and expense), be (i) delivered to Sponsor at Sponsor's risk to its offices identified herein in such form as is then currently in the possession of PPD, (ii) retained by PPD for Sponsor for five (5) years after the expiration or termination of the Services, or (iii) disposed of as directed by written request of Sponsor, unless the Records are otherwise required to be stored or maintained by PPD under applicable law. If PPD is required or requested to maintain and/or store the Records in excess of the five (5) year period beyond the termination or expiration of the Services under the applicable Project Addendum, Sponsor shall reimburse PPD for its maintenance and storage costs. Sponsor will give PPD at least thirty (30) days prior written notice prior to the end of the agreed upon storage period if it wishes for PPD to return the Records which shall be at Sponsor's expense, provided however, in no event shall PPD dispose of Records without first giving Sponsor thirty (30) days prior written notice. PPD shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Section 6 above.

12.3 Sponsor Audits. Representatives of Sponsor (who shall not be competitors of PPD) shall be permitted to review all documents, information, data and materials in the possession of PPD directly relating to the work performed hereunder, upon reasonable advance notice and at mutually agreeable times, for the sole purpose of determining PPD's compliance with the applicable Project Addendum. PPD and Sponsor agree to one (1) no-cost audit per year, to include no more than three (3) days on-site at PPD's facilities. All other audits shall be charged according to PPD's personnel billable rates. All Sponsor representatives shall, in advance of such audit, execute a mutually agreeable confidentiality and non-disclosure agreement with PPD. Notwithstanding the foregoing, Sponsor shall not be permitted to review any such documents, information, data and/or materials that contain information deemed, in good faith by PPD, to be confidential, privileged, or proprietary and not directly related to the performance of this Agreement or any Project Addendum. Sponsor and its agents and consultants shall observe all confidentiality obligations concerning all documents, information, data or materials that it comes in contact with in connection with the audit.

12.4 Regulatory Inspections.

a. Inspections of Investigator Sites. Both parties shall promptly notify the other party of any regulatory inspections of investigator sites of which it becomes aware. Where reasonable practicable and permitted by the Regulatory Authority, Sponsor will have the right to be present at any inspections which are directly related to the Services. PPD shall reasonably act to secure the cooperation of investigators with respect to regulatory review.

b. Inspections of PPD. PPD agrees to promptly notify Sponsor of a regulatory inspection of PPD in which Sponsor's project is the scope, in whole or in part of the inspection may be affected by such inspection. PPD shall permit Sponsor to be present for any inspection in which Sponsor's project is the scope, in whole or in part, of the inspection. Sponsor agrees to provide PPD support during the inspection as needed relative to the Services contracted and Project. PPD agrees to provide updates to Sponsor as to the progress of the inspection relative to the Services and Sponsor project. PPD shall provide to Sponsor copies of any correspondence from any regulatory or governmental agency relating to such inspection related to, or which may affect Sponsor's study, including by not limited to, Form FDA 483 notices and warning letters (regardless of whether such documents reference Sponsor). PPD shall notify Sponsor before referring to any Sponsor or any Project in any regulatory correspondence, however PPD may respond independently if required by applicable law or regulation. PPD shall ensure that it discloses information related to the Sponsor or the Project only to the extent required by the regulatory authority and shall not disclose more information than the minimum necessary to comply with the request of the regulatory authority. PPD shall not disclose information and materials that are not required to be disclosed to such authority without the prior consent of Sponsor which shall not be unreasonably withheld. Notwithstanding the foregoing, PPD shall not be obligated to take any action prohibited by a regulatory authority.

c. Inspection of Sponsor. Sponsor agrees to notify PPD of a regulatory inspection of Sponsor which are directly related to the Services. PPD agrees to provide Sponsor with support relative to the Services. Sponsor agrees to provide PPD with updates of inspection activities relative to the Services.

d. In the event that the inspection relates to the activities being performed on behalf of Sponsor, PPD's participation in any regulatory inspection shall be subject to reimbursement by Sponsor of the cost of PPD's personnel time and expense. The parties shall review costs associated with participation and shall agree to a reasonable rate of compensation in advance of the performance of any regulatory services.

12.5 PPD Audits. As part of PPD's Quality Management System, Global Quality & Compliance conducts audits of PPD processes and systems. If the outcome of such audits identify significant findings that impact the Services and/or Sponsor Project, PPD agrees to inform Sponsor of such findings.

12.6 Suspected Scientific Misconduct. Both parties agree to notify the other party of instances of suspected scientific misconduct as it relates to the Services. Sponsor will consult with PPD on response to suspected scientific misconduct, including investigation and reporting. The parties agree that Sponsor will determine and direct the appropriate response to any such suspected scientific misconduct. Notwithstanding the foregoing, in the event of regulatory or governmental inquiry into suspected scientific misconduct, PPD may respond independently to any such regulatory correspondence or inquiry if PPD is required by applicable law to respond independently. Notwithstanding the foregoing, Sponsor may review or respond to any PPD response.

12.7 Non-Compliance of Clinical Investigators and Related Parties. Notwithstanding anything to the contrary herein, in the event PPD or Sponsor identify continued non-compliance on the part of the clinical investigator/institution or related supporting staff, Sponsor agrees to support all reasonable actions required of the clinical investigatory/institution by PPD procedures/actions to secure compliance. Should the decision be made by Sponsor to terminate or suspend the trial at the site as a result of serious and persistent non-compliance by these parties, Sponsor agrees to report the clinical investigator according to applicable regulatory requirement and authorizes PPD to report in the absence of such appropriate Sponsor action. Sponsor will consult with PPD on addressing any such non-compliance. The parties agree that Sponsor will determine and direct the appropriate response to any such non-compliance. Notwithstanding the foregoing, in the event of regulatory or governmental inquiry into any non-compliance (if applicable), PPD may respond independently to any such regulatory correspondence or inquiry if PPD is required by applicable law to respond independently. Notwithstanding the foregoing, Sponsor may review or respond to any PPD response; however PPD shall still be required to respond independently.

13. DEBARMENT.

13.1 PPD hereby certifies that it has not been debarred, and, to the best of its knowledge, is not under any type of investigation which it reasonably believes could lead to debarment, under any applicable law, rule or regulation including without limitation, the Generic Drug Enforcement Act of 1992. If PPD or any of its Associates who perform Services for a Project is debarred or receives notice of an action or threat of action of debarment during the term of this Agreement and for three (3) years thereafter, PPD shall immediately notify Sponsor of same. The debarment of PPD or any of its Associates (which are providing services to Sponsor on a Project under this Agreement) that remains in place for a period of at least thirty (30) days shall be deemed to be a material breach of this Agreement, unless with respect to the debarment of an Associate which is providing services hereunder, PPD is able to replace the Associate within such 30-day period, in which case the debarment of the replaced Associate shall not be a material breach of this Agreement.

13.2 PPD hereby certifies that it has not utilized, and will not use the services of any individual or entity in the performance of services under this Agreement or any Project Addendum that has been debarred or that has been convicted of a crime that could lead to debarment under any applicable law, rule or regulations, including without limitation, the Generic Drug Enforcement Act of 1992. In the event that PPD receives notice of the debarment or threatened debarment of any such individual or entity, PPD shall notify Sponsor immediately and Sponsor shall have the right to terminate this Agreement pursuant to Article 3.

14. MISCELLANEOUS.

14.1 Independent Contractor Relationship. The parties hereto are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to place the parties in the relationship of partners, principal and agent, employer/employee or joint venturer. Neither party shall have any right, power or authority to bind or obligate the other, nor shall either hold itself out as having such right, power or authority.

14.2 Publicity. Neither party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of the other party in each instance. The restrictions imposed by this Section shall not prohibit a party from making any disclosure identifying the other party that is required by any applicable law, rule or regulation.

14.3 Publication. PPD may not publish any articles or make any presentations relating to the Services provided to Sponsor hereunder with respect to a Project or referring to data, information or materials generated as part of the Services without the prior written consent of Sponsor.

14.4 Force Majeure. If either party shall be delayed, hindered, or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather, or other cause beyond such party's reasonable control (each, a ***"Disability"***), then performance of such act shall be excused for the length of time necessary to cure such Disability and resume performance. A party shall not be liable for any delays resulting from a Disability, and any affected timelines shall be extended for a period at least equal to that of the Disability. The party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability.

14.5 Notices. Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date delivered if delivered (i) personally, (ii) on the first business day after the date sent if sent by recognized overnight courier, (iii) on the date transmitted if sent via facsimile (with confirmation of receipt generated by the transmitting machine), or (iv) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each party shall be sent to the address for said party set forth in the applicable Project Addendum. If no address is provided in the Project Addendum, then notices shall be sent to the following address:

If to PPD:	PPD Development, L.P. 929 North Front Street Wilmington, North Carolina 28401 Attention: CEO Tel: (910) 251-0081 Fax: (910) 558-5820
If to Sponsor:	Galectin Therapeutics, Inc. 4960 Peachtree Industrial Blvd. Suite 240 Norcross, Georgia 30071 Attention: Chief Operating Officer Tel: (678) 615-3213 Fax:

Either party may change its notice address by notice to the other party hereto in the form and manner provided in this Section 14.6.

14.6 Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the State of North Carolina without reference to its conflicts of laws provisions.

14.7 Severability. If any provision of this Agreement or any Project Addendum is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party hereto under this Agreement or such Project Addendum will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement or such Project Addendum will be construed and enforced as if such illegal, invalid or unenforceable provision had never compromised a part hereof, (c) the remaining provisions of this Agreement or such Project Addendum will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a party of this Agreement or such Project Addendum, a legal, valid and enforceable provision as similar in terms as to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties herein.

14.8 Waiver. Any term or condition of this Agreement or a Project Addendum may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement or a Project Addendum, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement or such Project Addendum on any future occasion.

14.9 Amendments. No amendment, change or modification to this Agreement or any Project Addendum shall be effective unless in writing and executed by the parties hereto.

14.10 Assignment. This Agreement and any Project Addendum may not be assigned by either party without the prior written consent of the other party; provided, however, that (i) a party hereto may assign this Agreement or a Project Addendum hereunder to a successor-in-interest to the party's business and (ii) PPD may assign this Agreement or a Project Addendum or subcontract all or part of the Services to be performed hereunder to PPD Affiliates. "PPD Affiliates" shall mean entities which can provide the Services and which controls, is controlled by or is under common control with PPD or PPD's parent company Pharmaceutical Product Development, LLC. In the event the Services shall be performed by a PPD Affiliate, such PPD Affiliate may be the contracting party to any Project Addendum for the Services.

14.11 Subcontracting. PPD may use a subcontractor in the performance of any services under this Agreement only with the prior written approval (email to suffice) of Sponsor. In the event that PPD subcontracts all or part of the Services under a Project Addendum to a third party Subcontractor, PPD shall be responsible and retain primary liability for the performance of all obligations of Subcontractors selected, managed and contracted by PPD. When used in this Agreement, the term "Subcontractor" shall mean and refer to any third party to whom PPD has subcontracted or delegated PPD's obligation to perform any portion of the Services hereunder, but shall exclude any third party vendor whose expenses are considered a Pass Through Cost.

14.12 Arbitration. Except for disputes regarding breaches of Section 6 and the right to pursue the remedies set forth in Section 6.7 above, the parties hereby agree to submit any dispute arising hereunder to binding arbitration pursuant to the Commercial Arbitration Rules of the American Arbitration Association. The arbitration shall be conducted in Charlotte, North Carolina. The decision of the arbitrator or arbitration panel shall be final and binding upon the parties hereto and shall be enforceable by any court of competent jurisdiction. By agreeing to arbitration, the parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any party to respect the court of arbitration's order to that effect. The expenses of any arbitration shall be borne by the parties in proportion as to which each party prevails or is defeated in arbitration. Each party shall bear the expenses of its counsel and other experts.

14.13 Construction. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.

14.14 MedDRA and WHODrug Dictionary License. The parties acknowledge that MedDRA and Uppsala Monitoring Centre product licenses are required by all parties who wish to distribute or receive MedDRA or WHODrug dictionary terminology. Each party represents and warrants that it possesses a current MedDRA and/or Uppsala Monitoring Centre product license. In the event Sponsor requests that PPD perform services which require PPD to distribute MedDRA terminology or WHODrug dictionary to third parties, Sponsor shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

14.15 Counterparts and Electronic Signatures. This Agreement, any Project Addendum hereunder, and all associated amendments may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement, any Project Addendum, and all amendments by facsimile transmission or in Portable Document Format sent by electronic means. Signatures of authorized signatories of the parties transmitted by facsimile or sent by electronic means in Portable Document Format shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement, any Project Addendum, or any amendments hereunder.

14.16 Representative. With regard to any Project conducted under this Agreement, Sponsor represents and warrants that it shall not name any PPD employee, contractor, or other PPD representative on Line 16 of Form FDA 1571. Sponsor acknowledges and understands that if Sponsor desires that any PPD employee, contractor, or other PPD representative be named as the Senior Medical Officer in Canada on Line 89 of Form HC/SC 3011 or in any similar capacity for clinical trials conducted in other countries, Sponsor must first submit such a request to PPD in writing for the performance of services pursuant to such naming, including, without limitation, responsibility for review and evaluation of information relevant to the safety of the study drug. If PPD agrees to perform such services, the parties shall enter into good faith negotiations and enter into either a separate agreement or written amendment to the applicable Project Addendum prior to PPD initiating the services.

14.17 Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, with respect to the subject matter hereof.

IN WITNESS WHEREOF, this Agreement has been executed and delivered by the parties hereto by their duly authorized officers as of the date of last signature below.

PPD DEVELOPMENT, L.P. **BY: PPD GP, LLC** **ITS: GENERAL PARTNER**	**GALECTIN THERAPEUTICS, INC.**
By: /s/ Paul Colvin	By: /s/ Harold H. Shlevin
Name: Paul Colvin, RPh.	Name: Harold H. Shlevin
Title: Exec. V.P. Global Clinical Development	Title: Chief Operating Officer
Date:	Date:

Galectin Therapeutics Engages PPD to Conduct GR-MD-02 Phase 2 Trial in NASH, Submits Special Protocol Assessment to FDA

Study Enrollment to Begin in the Second Quarter

NORCROSS, Ga. (March 12, 2015) – Galectin Therapeutics (Nasdaq: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces it has engaged the contract research organization Pharmaceutical Product Development, LLC (PPD) to conduct the Phase 2 trial with GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with non-alcoholic steatohepatitis (NASH) cirrhosis (the NASH-CX trial). Galectin also announces it has submitted the protocol for a Special Protocol Assessment (SPA) to the U.S. Food and Drug Administration (FDA) with the goal of accepting the NASH-CX results, if positive, as one of the trials to support approval of the drug candidate.

“We are very pleased to have finalized our engagement of PPD, one of the leading contract research organizations in the world, and are excited to take this step toward the beginning of our Phase 2 program,” said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. “PPD’s extensive experience in conducting clinical trials in liver-related diseases will serve us well. We are particularly attracted to their work with clinical trial sites possessing familiarity with hepatic venous pressure gradient (HVPG), as the FDA has indicated that HVPG may serve as a surrogate primary endpoint for NASH cirrhosis. We look forward to the prospect of bringing this new drug to the millions of people in the U.S. with NASH.”

As previously announced, Galectin’s Phase 2 program for GR-MD-02 currently consists of two clinical trials. The NASH-CX trial is designed as a multicenter, randomized, placebo-controlled, double-blind, parallel-group study with 156 patients at up to 60 sites to evaluate the safety and efficacy of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in NASH patients with cirrhosis. Enrollment is expected to commence in the second quarter of 2015, and data readout is expected in the fourth quarter of 2017. In addition, the Company will conduct a smaller trial of shorter duration in 30 NASH patients with advanced fibrosis (the NASH-FX trial). This randomized, placebo-controlled, blinded study will be conducted at Brooke Army Medical Center with enrollment expected to begin in mid-2015 and top-line data readout in mid-2016. In this study, the safety and efficacy of GR-MD-02 on liver stiffness will be evaluated by magnetic resonance-elastography and FibroScan score, and by imaging liver fibrosis using multi-parametric magnetic resonance imaging (LiverMultiScan®, Perspectum Diagnostics).

About GR-MD-02

GR-MD-02 is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease and fibrosis. Galectin-3 plays a major role in diseases that involve scaring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH), also known as fatty liver disease, has become a common disease of the liver with the rise in obesity rates. NASH is estimated to affect up to 28 million people in the U.S. Fatty liver disease is characterized by the presence of fat in the liver along with inflammation and damage in people who consume little or no alcohol. Over time, patients with fatty liver disease can develop fibrosis, or scarring of the liver, and it is estimated that as many as 1-2 million individuals in the U.S. will develop cirrhosis, a severe liver disease for which liver transplantation is the only treatment available. Approximately 6,300 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

About Galectin Therapeutics

Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect" and others. They are based on management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for GR-MD-02 will lead to the first therapy for the treatment of fatty liver disease with cirrhosis. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development. The Company's current clinical trial and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove time consuming and costly. Plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. There is no certainty that FDA and Company will agree on a SPA or that a SPA would ultimately be acceptable to FDA nor result in approval of GR-MD-02. Regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report

on Form 10-K for the year ended December 31, 2013, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

Contacts

Galectin Therapeutics Inc.
Peter G. Traber, M.D.
President, CEO & CMO
(678) 620-3186
ir@galectintherapeutics.com

LHA
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

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