EX-10.5 6 ex10-5.htm

EXPLANATORY NOTE: [***] INDICATES THE PORTION OF THIS EXHIBIT THAT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IN PUBLICLY DISCLOSED.

EXHIBIT 10.5

Response to AIM ImmunoTech's Request for
Proposal for Services to Support a Phase I/II Clinical Trial for Ampligen in Healthy Volunteers

August 4, 2020

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Important Information

This proposal for a Project Work Order is provided to AIM ImmunoTech, Inc (AIM) for the purpose of its evaluation and the information contained herein is not intended to be used by (AIM) for any other purpose than the subject of this proposal. (AIM) agrees not to voluntarily disclose any of the information contained herein to any third party without the prior written consent of Amarex Clinical Research, LLC (Amarex).

This proposal document is subject to negotiation and, when the final version is signed by both parties, shall create a Project Work Order with legal obligations on the part of both parties.

Proposal Expiration Date: August 22, 2020

Prepared for:

AIM ImmunoTech Inc
2117 SW Highway 484
Ocala, FL 34473

Prepared by:

Amarex Clinical Research, LLC
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Germantown, MD 20874
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Key Study Assumptions

Amarex understands that AIM would like to conduct a Phase I/II study in healthy volunteers of Ampligen to prevent COVID-19 infection.

Amarex will provide:

- Project Management
- Data Management
- Clinical Site Management
- Randomization
- Statistics
- Safety and Pharmacovigilance
- Data Management Committee (DMC)
- Medical Writing

As previously discussed, Amarex has identified a clinical site that will be able to handle the Phase I portion of the study. The site also believes they will be able to handle the Phase II portion of the study, as long as the enrollment is around 150 subjects. Additional sites may be added at AIM's discretion. It is assumed that all lab work can be managed and run through the site. Costs provided by the site and their projected enrollment times have been included in this proposal. The storage of serum samples is not included in the budget.

This proposal is based on the information provided by AIM and is subject to change based on the finalized protocol. We have assumed that the Phase I will have 4 cohorts with 6 subjects each conducted in parallel, with 3 active cohorts and 1 placebo cohort. It is assumed the subjects will receive treatments over a 28 day period. A follow up period of 28 days will occur after last treatment. A DMC will occur after the last treatment visit is complete to determine if the Phase II should commence. Amarex will conduct a remote initiation and interim monitoring visits during this Phase.

The Phase II estimates 3 cohorts of 50 subjects each, 2 active cohorts and 1 placebo. An initial DMC will be held after the first 6 subjects in each cohort are enrolled and treated. Once the DMC clears the study to continue, the remaining 132 subjects will be enrolled across the 3 cohorts. It is anticipated that some of the interim monitoring visits will be held at the site for this part of the study. The schedule of events is expected to be nearly identical between the two Phases, and therefore no additional programming would be needed to setup the EDC for the Phase II portion. A final analysis has been quoted in the budget below, but it is understood that AIM may like to conduct another analysis for sample size purposes prior to closing enrollment.

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Study Parameters

Following is a list of study parameters Amarex has used in order to prepare this proposal response:

Table 3. Study Parameters Used to Prepare This Proposal

STUDY PARAMETERS	Phase I	Phase II
Number of sites	***	***
Number of countries participating in study	***	***
Number of subjects screened	***	***
Number of subjects randomized/enrolled	***	***
SITE MONITORING AND AUDITING	***	***
Number of site qualification visits	***	***
Number of site initiation visits	***	***
Number of interim monitoring visits	***	***
Number of site closeout visits	***	***
Number of study sites audited	***	***
COMMITTEE FORMATION, INVESTIGATOR MEETING		
Number of DMC meetings to review data	***	***
Number safety listings for DMC meetings (uniques/replicates)	***	***
Number of Investigator meetings	***	***
MEDICAL MONITORING		
Estimated number of SAEs	***	***
Estimated number of reportable events	***	***
DATA MANAGEMENT		
Estimated Number of Adverse Events and Concomitant Medications to code	***	***
Number of unique pages in eCRF	***	***
Number of central labs	***	***
BIOSTATISTICS		
Number of stat. tables for interim analysis (uniques/replicates)	***	***
Number of listings for interim analysis (uniques/replicates)	***	***
Number of graphs for interim analysis (uniques/replicates)	***	***

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Number of stat. tables for final analysis (uniques/replicates)	***	***
Number of listings for final analysis (uniques/replicates)	***	***
Number of graphs for final analysis (uniques/replicates)	***	***
CLINICAL STUDY REPORT WRITING		
Write interim clinical trial report	***	***
Write final clinical trial report	***	***
PROJECT MANAGEMENT		
Number of months for project setup	***	***
Number of months for enrollment/treatment	***	***
Number of months for follow-up	***	***
Number of months for close out	***	***
Number of months of project management (including set up and close out)	***	***

*More sites may be added to the Phase II, if desired. Additional sites will increase the Phase II cost, and an amendment can be signed to make any such adjustments.

**Assumes DMC after Phase I will review the Interim Analysis report.

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Study Roles and Responsibilities

Clearly-defined roles and responsibilities are essential to project success, and Amarex will work closely with AIM to make sure all project tasks are covered. It is our current understanding that the tasks associated with this trial are assigned as shown in Table 1, below.

Table 1. Study Tasks and Responsibilities

Service	NA	Amarex	AIM
PROJECT MANAGEMENT			
Meetings, Training, and Study Start Up			
Prepare for and Attend Kick-off Meeting & Study Start-Up		X	
Communication and Tracking			
Coordinate Amarex's Internal Project Team		X	
Communicate with Sponsor (includes standard teleconferences with activities reports, emails, faxes)		X	
Manage Central Labs/Vendors	X		
Tracking Systems Setup		X	
Management of Payments to Sites, IRBs, and/or Vendors		X	
REGULATORY SERVICES	X		
PRODUCT MANAGEMENT			
Support Drug Shipments		X	
DATA MANAGEMENT SERVICES			
Data Management			
Develop Data Management Plan		X	
Standard Data Cleaning (Run edit checks; generate, process, and track data queries)		X	
Develop Edit Specifications		X	
Data Operations			
Program Edit Checks		X	
Set Up Transfer of Final SAS Data to Sponsor (in Amarex's format)		X	
Perform Data Transfer to Sponsor (Including export of final SAS Analysis Datasets)		X	
EDC Support			
Conduct Electronic Data Capture Site Training		X	

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Prepare EDC Manual and Completion Instructions (includes up to 1 round of edits)		X	
Prepare User Acceptance Testing (UAT) Management Plan		X	
Conduct QC of EDC Database		X	
Provide Electronic Data Capture Help Desk		X	
EDC PROGRAMMING			
Development of CRF Screen Shots		X	
EDC Programming		X	
EDC Maintenance		X	
CLINICAL SITE SERVICES			
Site Identification and Contracting			
Prepare Site Identification Plan	X		
Perform Site Identification	X		
Present Sites for Site Qualification Visits	X		
Develop Site Contracts (includes up to 2 rounds of edits)		X	
Negotiate Site Contract CTAs		X	
Negotiate Site Contract Budgets		X	
IRB and Ethics Committee Management		X	
Site Regulatory Document Collection			
Set Up Trial Master File		X	
Set Up, File, and Track Investigator/Site Regulatory Files		X	
Conduct Ongoing Regulatory Document Collection, Review, Tracking, and Maintenance of Trial Master File		X	
Monitoring Services			
Prepare Study Operations Manual (includes up to 2 rounds of edits)		X	
Prepare Monitoring Guidelines (includes up to 2 round of edits)		X	
Perform Site Management		X	
Prepare for Site Visit		X	
Prepare Documents for Site Initiation		X	
Conduct Site Qualification Visits		X	
Conduct Study Initiation Visits		X	
Conduct Interim Monitoring Visits		X	
Conduct Close Out Visits		X	

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SAFETY			
Set Up Tracking System and SAE Start Up		X	
Prepare Safety Management Plan		X	
Collect, Process, Evaluate, Prepare Narrative, and Report SAEs (CIOMS or MedWatch)		X	
Medical Monitoring (24/7)		X	
Distribute SAE "Dear Dr." Letters to Sites		X	
Submit Safety Reports to Regulatory Authorities		X	
Reconcile Safety Database with Clinical Database		X	
DATA MONITORING COMMITTEE (DMC)			
Establish and Manage 3-Member DMC		X	
Develop DMC Charter (includes up to 1 round of edits)		X	
Organize, Conduct and Participate in DMC Meetings		X	
Prepare Statistical Analysis Plan for DMC	X		
Program Tables, Listings and Graphs for DMC		X	
Prepare Statistical Report for DMC Meetings		X	
RANDOMIZATION AND ENROLLMENT		X	
BIOSTATISTICS			
Review the Protocol and Prepare Statistical Analysis Plan (1 draft and 1 final, mock templates for TLGs, and data set conventions)		X	
Program Tables, Listings and Graphs for Interim and Final Analysis		X	
Conduct QC Audit of Stats		X	
Production and Review of Tables, Listings, and Graphs for Interim and Final Analysis		X	
MEDICAL WRITING			
Prepare Interim Clinical Study Report (non-ICH Format) - includes up to one round of edits		X	
Prepare Final Clinical Study Report Shell (ICH Format) - includes up to one round of edits		X	
Prepare Final Clinical Study Report (ICH Format) with Appendices - includes up to two rounds of edits		X	
Conduct QC Audit of Clinical Study Report		X	

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Proposed Amarex Direct Services Budget

***

Estimated Pass-Through Costs

***

Estimated Third Party Costs

***

Payment Schedule for Services

The payment terms and obligations for the services outlined in this proposal are as follows:

Payment Description	Percentage Due	Phase I Amount	Phase II Amount
Execution of Project Work Order	20%	$ ***	$ ***
Monthly Unit-Based Billing	Balance Due	$ ***	$ ***
TOTAL		$ 514,391.29	$ 650,247.87

The Execution payment will be credited back to AIM as monthly invoices hit certain milestones against the expected total cost of Amarex services. Milestones will be on the *** totals have been billed to AIM. AIM will be billed each month for units of service performed in that month. If the study is terminated early, AIM will only be responsible for the units of work performed, and any remaining funds from the execution fee that have not been applied will be refunded to AIM.

Payment Schedule for Pass-Through Expenses

Pass-through expenses such as approved travel, document shipping and printing, and other reasonable expenses will be invoiced to AIM at cost. These expenses will be supported by acceptable documentation or actual receipts and will be invoiced on a monthly basis.

Payment Terms

***

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Project Work Order Signatures

In Witness Whereof, AIM ImmunoTech Inc. and Amarex Clinical Research, LLC agree to all items and payment terms and conditions presented in this Project Work Order as indicated by the signatures below of their respective duly authorized representatives as of the "Effective Date", appearing below.

ACKNOWLEDGED, ACCEPTED, AND AGREED TO:

For and on behalf of AIM ImmunoTech Inc.:		**For and on behalf of Amarex Clinical Research, LLC:**	
Print Name:	Peter Rodino	Print Name:	Kazem Kazempour
Signature:	*/s/ Peter Rodino*	Signature:	*/s/ Kazem Kazempour*
Title:	COO and General Counsel	Title:	President and CEO (Member)
Effective Date:	08/06/20	Effective Date:	