DELBIOS
PHARMACEUTICALS

Extended Request for Quotation (RFQ) – Method validation for antiGLA in rat plasma

Reference Code: RFQ-TOX-001-2025

Date of Issue: 02/09/2025

Deadline for Submission: 24/09/2025

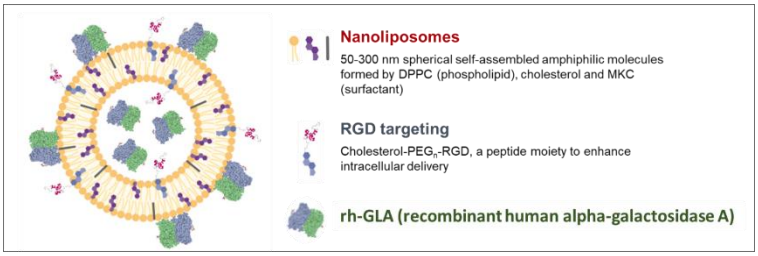
Contact Person: Nora Ventosa

Email: info@delbios.com

1. Background

Delbios Pharmaceuticals SL is developing a nanomedicine for the treatment of rare diseases under an EIC Transition project (Nano4Rare, n°101136772). The nanomedicine, called nanoGLA is a novel recombinant human GLA produced in Chinese Hamster Ovary (CHO) cell culture and integrated into nanoliposomes. This new delivery system is supposed to increase the plasma elimination half-life and tissue distribution, efficacy, and reduce the immunogenicity compared to the current standard of care. NanoGLA is administered by the intravenous route.

NanoGLA is composed of DPPC phospholipid, cholesterol, and cholesterol-Polyethylene Glycol (PEG)400-RGD targeting ligand, with a small amount of the quaternary ammonium surfactant MKC (Myristalkonium chloride).



As part of the preclinical development plan, we require the development and validation of a bioanalytical method to perform bioanalysis of toxicological programme supporting a first-in-human clinical study with nano-GLA.

This RFQ is issued to select the most suitable service provider for the validation of an analytical method called “Method Development of an ELISA Method for the Determination of Anti-GLA Antibodies in Rat Plasma” already developed at York Bioanalytical Solutions (YBS).

2. Scope of Work

NanoGLA is a drug candidate in which human α-Galactosidase A (GLA) is delivered through liposomal nanocapsule. The nanovesicles surrounding human GLA are expected to protect the enzyme; improve its movement in, through, and out of the body; provide better delivery to target tissues, including the central nervous system (CNS); and reduce its toxicity and immune responses against it. This drug candidate is being developed as an enzyme replacement therapy for Fabry disease.

In the preclinical development of the nanoGLA it has been a requirement the assessment of anti-drug antibodies production in preclinical species. Specifically, toxicological programs have been developed in wild-type rats, so an ELISA method to determine the production of anti-GLA Antibodies in Rat Plasma has been recently developed by YorkBio Analytical Solutions. The bioanalytical assay has been developed using the proposed ELISA format described below:

Microtiter plates coated with human GLA protein. After washing, the plate will be blocked with a blocking buffer. After washing, diluted sample is added to the wells and any antibodies against GLA present in the plasma samples bind to GLA on the plate. After washing, anti-rat or mouse IgG conjugated with horseradish peroxidase (HRP) is added which binds to any bound anti-GLA antibodies. After a final wash, tetramethylbenzidine (TMB) is added as a substrate to react with bound HRP added. After incubation, stop solution is added and the absorbance is measured. Results are reported as absorbance values measured at 450 nm and expressed as absorbance units. If necessary, the assay may be modified to employ an acid dissociation step.

Currently we request the validation of such method prior performing the analysis of the in vivo samples. Important considerations are listed below:

- Development of the aforementioned method.
- Validation of the method within a timeframe not exceeding 2 months.
- Provision of interim reports.
- The final report shall be delivered no later than 4 weeks following the completion of the study.

3. Service Requirements (SRD01)

- Minimum 3 years' experience in bioanalytical method development
- Experience with nanoformulations or biologicals is an advantage
- Audit readiness (including EU Commission or EIC bodies)
- Acceptance of confidentiality, ethics, and funding visibility clauses
- Retention of records for 5 years after project end

4. Submission Instructions

All proposals must include:

1. Technical proposal and study plan

2. Full cost breakdown
3. Timeline for study start and final report
4. Payment terms

If the proposal is selected, Delbios Pharmaceuticals will also need:

5. Signed declaration of no conflict of interest
6. Acceptance of audit rights and confidentiality terms

5. Evaluation Criteria

Main Criterion	Weight	Subcriterion	Sub-weight	Evaluation Indicators
Scientific & Technical Proposal	30%	Clarity and completeness of methodology	10%	Proposal clearly describes experimental steps, objectives, expected outcomes, and deliverables.
		Compliance with regulatory and GLP/GCP expectations	10%	Demonstrates adherence to relevant regulatory guidelines and best practices.
		Risk assessment and mitigation strategies	5%	Identification of potential risks and feasibility of proposed mitigation plans.
		Quality control measures and robustness of assay validation plan	5%	Adequacy of QC measures, reproducibility, and suitability of assay validation plan.
Relevant Experience	20%	Experience in bioanalytical method validation (ELISA-based assays)	8%	Documented track record in similar assay validations.
		Experience with nanomedicines, biologics, or enzyme replacement therapies	7%	Relevant projects or publications demonstrating technical expertise.
		Experience in EU-funded projects or with regulatory bodies	5%	Demonstrated capacity to meet EU project requirements and regulatory interactions.

Timeline	20%	Realism and feasibility of proposed schedule	10%	Schedule aligns with project milestones and deliverables.
		Capacity to meet 2-month validation window and 4-week reporting deadline	5%	Demonstrated ability to meet tight deadlines.
		Availability of resources and contingency planning	5%	Adequacy of staff, equipment, and contingency measures for potential delays.
Cost Competitiveness	30%	Price / total cost	20%	The final proposed cost, which will be the primary factor in the evaluation.
		Justification of costs in relation to scope and quality	5%	Costs must be reasonable and proportional to the proposed work and quality.
		Payment terms aligned with project needs	5%	Payment schedule must be aligned with project cash flow requirements.

Scoring Notes:

- Each subcriterion is scored 0–5 (0 = unacceptable, 5 = excellent).
- Weighted scores are calculated by multiplying sub-weight by the score.
- Total score = sum of all weighted sub-scores.
- **Technical criteria minimum threshold:** Scientific & Technical Proposal and Timeline must score at least 3/5 for a proposal to be considered in the cost evaluation.

6. Confidentiality

All RFQ contents and submitted proposals will be treated confidentially. Sensitive or proprietary information must be marked clearly by the applicants.

7. Submission Deadline

All quotations must be submitted by [24/09/2025, 23:59 CET] to: [info@delbios.com]

Subject: RFQ-TOX-001-2025

8. Legal and Funding Clauses

- A contract will be signed including obligations on confidentiality, audit rights, EU funding visibility, and ethics compliance.
- The European Commission, OLAF, EIC and the European Court of Auditors must be granted full audit rights.
- Costs must comply with the Horizon Europe eligibility rules.
- Subcontractor must retain all records for at least 5 years after the project ends.

9. Disclaimer

Delbios reserves the right to cancel or modify this RFQ, and is not obliged to award any subcontract as a result of this process.