DELBIOS
PHARMACEUTICALS

Extended Request for Quotation (RFQ) – Method development, validation and bioanalysis for antiGLA antibodies in minipig plasma

Reference Code: RFQ-TOX-003-2025

Date of Issue: 06/10/2025

Deadline for Submission: 30/10/2025

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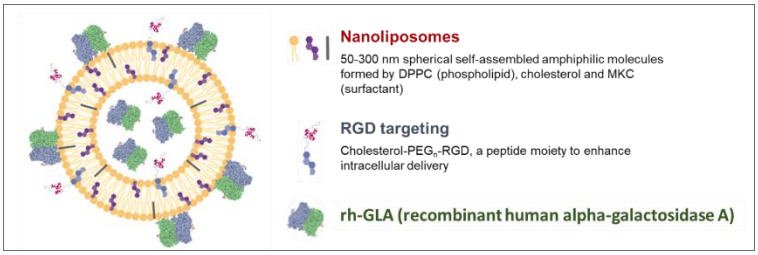
1. Background

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 program supporting a first-in-human clinical study with nano-GLA.

This RFQ is issued to select **the most suitable service provider for the development and validation of an analytical method for the determination of antiGLA in minipig plasma after the administration of the nanoGLA. This work is related to Task 1.1 in the work plan of the Nano4Rare project (as detailed in GA 101136772),** included in the subcontracting item "Analytical methods development - Development and Validation in plasma and tissues of all preclinical species, bioanalysis of important preclinical and clinical biomarkers."

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 two ELISA methods have been developed so far to determine the GLA concentration in rat plasma as well as the production of anti-GLA Antibodies in Rat Plasma. The bioanalytical assay has been developed using the proposed ELISA format described below:

Currently we request the development of two new bioanalytical methods for the determination of GLA and **anti-GLA** antibodies in minipig plasma. Important considerations are listed below:

- Development of the aforementioned method within a timeframe not exceeding 2 months.
- Validation of the method within a timeframe not exceeding 1 month.
- Sample bioanalysis of antiGLA in 100 minipig plasma samples.
- Provision of interim reports.
- The final report shall be delivered no later than 4 weeks following the completion of the study.

3. Service Requirements (SRD03)

- 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	25%	Experience in bioanalytical method development and validation (ELISA-based assays)	10%	Documented track record in similar assay developments and validations.
		Experience with nanomedicines, biologics, or enzyme replacement therapies	10%	Relevant projects or publications demonstrating technical expertise in the specific field of nanomedicine-related assays.
		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. Adequacy of staff, equipment, and

		Availability of resources and contingency planning		contingency measures for potential delays.
		Capacity to meet 3-months development, validation and sample bioanalysis window and 4-week reporting deadline	10%	Demonstrated ability to meet tight deadlines.
Cost Competitiveness	25%	Price / total cost	15%	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 sub criterion 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 [30/10/2025, 23:59 CET] to: [info@delbios.com]

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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.