DELBIOS
PHARMACEUTICALS

Extended Request for Quotation (RFQ) – In vivo pharmacokinetic bridging study (non-GLP)

Reference Code: SRD11-RFQ-TOX-009-2026

Date of Issue: 29/05/2026

Deadline for Submission: 15/06/2026

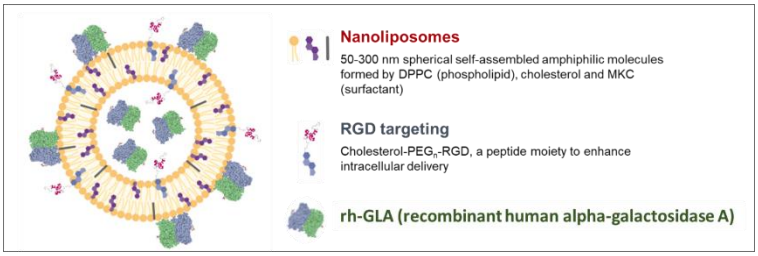
Contact Person: Nora Ventosa

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 for nanoGLA and given that the final pharmaceutical form will be a lyophilized product rather than a liquid dispersion, we require a pharmacokinetic (PK) bridging study in minipigs to demonstrate comparability between the two forms.

2. Scope of Work

NanoGLA is a drug candidate in which human α-galactosidase A (GLA) is encapsulated within liposomal nanovesicles. These nanovesicles are expected to protect the enzyme, enhance its stability and biodistribution, facilitate its transport throughout the body, and improve delivery to

target tissues, including the central nervous system (CNS). In addition, the nanovesicles may reduce toxicity and immune responses against the enzyme. This drug candidate is being developed as an enzyme replacement therapy for Fabry disease.

The **pharmacokinetic study in minipigs** has been considered essential **as a bridging study** to directly compare the in vivo PK profiles of the liquid and lyophilized nanoGLA formulations and to ensure detection of any potentially relevant formulation-related differences.

In vivo pharmacokinetic bridging study (non-GLP)

This study is conducted to compare the pharmacokinetics of the original (liquid nanoGLA) and new lyophilized nanoGLA formulation following a single intravenous infusion in minipigs.

The experimental design that we propose is as follows:

Group	Administration Route	Dosage	Infusion Rate	No. of Animals *	
				Males	Females
1 (NanoGLA - Liquid)	IV	0.1 mg/kg	1 mL/kg/h	2	2
2 (NanoGLA – Lyophilized)	IV	0.1 mg/kg	1 mL/kg/h	3	3

* 2 extra animals will be added

Biological samples will be collected on Day 0 at 10 predefined time points (up to 72 h) for subsequent pharmacokinetic evaluation. Pharmacokinetic analysis will be conducted separately by an external laboratory that has already developed the analytical method for the quantification of plasma GLA concentrations.

Additionally, animals will be clinically followed for 4 days, with necropsy performed on Day 4:

- Continuous assessment of animal welfare during the sampling period (Day 0–Day 3)
- Body weight measurements on Day 0 (baseline) and Day 3
- Gross macroscopic evaluation of organs and tissues during necropsy

3. Service Requirements (SRD06)

- Minimum 3 years' experience in toxicological studies in minipig or similar species.
- Experience with nanoformulations or biologicals preclinical development 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
- Provision of interim reports. If part of payment is on contract signature
- The final report shall be delivered no later than 4 weeks after the completion of the study.

- Payments shall be milestone-based and conditional upon the delivery and acceptance of agreed project deliverables. Initial payments may be linked to the submission of an appropriate documented deliverable.

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 %	Quality, clarity, and completeness of methodology	20%	Proposal clearly describes experimental steps, objectives, expected outcomes, and deliverables.
		Risk assessment and mitigation strategies	10%	Identification of potential risks and feasibility of proposed mitigation plans.
Relevant Experience	20 %	Experience with nanomedicines, biologics, or enzyme replacement therapies	10%	Relevant projects or publications demonstrating technical expertise.
		Experience in EU-funded projects or with regulatory bodies	10%	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	10%	Demonstrated ability to meet tight deadlines.
Cost Competitiveness	30 %	Price / total cost	20%	The final proposed cost, which will be an important 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 15/06/2026 to: info@delbios.com

Subject: SRD11-RFQ-TOX-009-2026

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.