DELBIOS
PHARMACEUTICALS

Request for Quotation (RFQ) – Scale-up methodology and production of a Lyophilized Nanoformulation

Reference Code: RFQ-FOR-002-2026

Date of Issue: 25/06/2026

Deadline for Submission: 09/07/2026

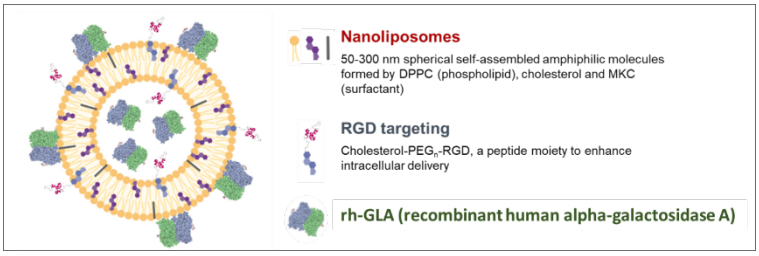
Contact Person: Nora Ventosa

Email: info@delbios.com

1. Background

Delbios Pharmaceuticals SL is developing a nanomedicine for the treatment of rare diseases. 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).



This nanoformulation is currently formulated as a liquid dispersion of nanoliposomes and then lyophilized with a developed method. As part of the preclinical development plan, an optimized scale-up methodology for the final lyophilized product is required to produce higher amounts of nanoGLA lyophilized product, maintaining a long-term stability.

This Request for Quotation (RFQ) is issued to identify and select the most suitable service provider for scaling up the lyophilization procedure and produce, under aseptic conditions, lyophilized nanoGLA samples for a non-GLP PK bridging study in minipigs to evaluate and compare the in vivo performance of the nanoGLA final form with the former liquid dispersion tested in previous stages of preclinical development.

2. Scope of Work

NanoGLA is a drug candidate in which human α-Galactosidase A (GLA) is delivered through a liposomal nanocapsule. The nanovesicles surrounding human GLA are expected to protect the enzyme, improve biodistribution, enhance delivery to target tissues, including the central nervous system (CNS), and reduce toxicity and immunogenicity. NanoGLA is being developed as an enzyme replacement therapy for Fabry disease

A liquid form (an aqueous dispersion) has already been tested in vivo in rodent and non-rodent species. Meanwhile, a lyophilized formulation has been developed to extend shelf-life while preserving critical quality attributes, in particular GLA enzymatic activity and liposomal integrity. Current efforts are focused on scaling up the lyophilization process to obtain larger amounts of the lyophilized nanoGLA formulation in aseptic conditions required to be tested in vivo in a second species.

The requested services include an optimization scale-up and production of our final lyophilized formulation under aseptic, non-GMP conditions, and the characterization needed in each step of the process for quality control purposes.

3. Development and Characterization Requirements

Key requirements include:
Development and optimization of the lyophilization scale-up process:

1. Scale-up production and characterization of critical temperatures (e.g. Tg', collapse temperature), using appropriate techniques such as lyophilization microscopy and differential scanning calorimetry (DSC).
2. Optimization of the lyophilization cycle parameters for the scale-up process.
3. Preparation of a scaled-up lyophilized nanoGLA batch intended for a preclinical PK bridging study in a second species.

In-process and/or post-lyophilization characterization may include, but is not limited to:

1. Visual inspection of the lyophilized cake (appearance, collapse).
2. Residual moisture determination (Karl Fischer titration).
3. Reconstitution time and ease of re-dispersion.
4. Qualitative assessment of vial closure and sealing integrity.

The target timeline:

- Scale up completion before 15th August 2026.
- Lyophilization cycle to obtain lyophilized nanoGLA batch intended for PK bridging study on second half August 2026.

Interim reports are expected. The final report must be delivered no later than 1 week after completion of the study.

4. Service Requirements

- Demonstrated experience in lyophilized formulation scale-up process from 4R vials to 50R vials.
- Experience with nanoparticles and sensitive protein formulations is an advantage

- Ability to lyophilize batch products of 20-30 vials 50R, appropriate for non-GLP pre-clinical studies.
- Capacity to perform lyophilization under aseptic or near-aseptic conditions.
- Availability of relevant analytical techniques for in-process and post-lyophilization quality control.
- Audit readiness for public grant bodies
- Acceptance of confidentiality, ethics, and funding visibility clauses
- Retention of project records for at least 5 years after project completion
- 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.

5. Submission Instructions

Proposals must include:

1. Technical proposal and study plan
2. Full cost breakdown
3. Timeline for study initiation and final reporting
4. Payment terms

If selected, the provider must also submit:

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

6. Evaluation Criteria

Main Criterion	Weight	Subcriterion	Sub-weight	Evaluation Indicators
Scientific & Technical quality	30%	Clarity and completeness of methodology	10%	Proposal clearly describes experimental steps, objectives, expected outcomes, and deliverables.
		Risk assessment and mitigation strategies	5%	Identification of potential risks and feasibility of proposed mitigation plans.
		Quality control (QC)	15%	Adequacy of QC, reproducibility, and of fit-for-purpose analytical methods.
Relevant Experience	25%	Experience in lyophilized nanoformulations	15%	Documented track record in similar developments and optimizations.

		and lyophilization scale-up		
		Experience with nanomedicines, biologics, or enzyme replacement therapies	10%	Relevant projects or publications demonstrating technical expertise in nanomedicine or biologics.
Timeline feasibility	20%	Realism and feasibility of proposed schedule, resources and contingency planning	10%	Alignment with project milestones; adequacy of staff, equipment, and contingency measures for potential delays.
		Capacity to meet the targeted development, optimization and sample characterization timeline (≈1 month) and 1-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 are reasonable and proportional to the proposed work and technical 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 Quality and Timeline must score at least 3/5 for a proposal to be considered in the cost evaluation.

7. Confidentiality

All RFQ contents and submitted proposals will be treated as confidential. Proprietary information must be clearly marked.

8. Submission Deadline

All quotations must be submitted by 09/07/2026 at 23:59 CET to info@delbios.com. Email subject: RFQ-FOR-002-2026

9. Legal and Funding Clauses

- A contract will be signed including obligations on confidentiality, audit rights, Spain and EU funding visibility, and ethics compliance.
- The Public bodies related to this subcontracting must be granted audit rights.
- Subcontractor must retain all records for at least 5 years after the project ends.

10. 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.