

Request for Quotation (RFQ) – Development of a Lyophilized Nanoformulation

Reference Code: RFQ-FOR-001-2026

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Deadline for Submission: 25/02/2026

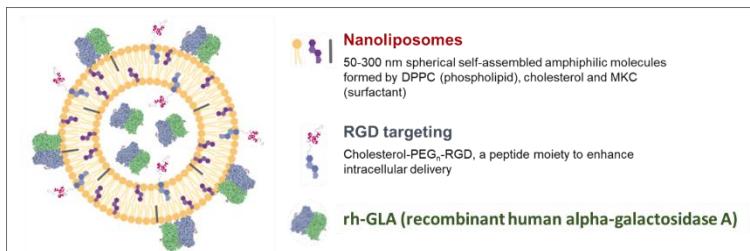
Contact Person: Nora Ventosa

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. As part of the preclinical development plan, the development and optimization of a final lyophilized product are required to enhance long-term stability.

This Request for Quotation (RFQ) is issued to identify and select the most suitable service provider for the development and characterization of a final lyophilized NanoGLA nanoformulation, intended for non-GMP preclinical use. This will be necessary to continue with the toxicity studies in second species and to test the efficacy in the final form.

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

While a liquid form (an aqueous dispersion) has already been developed and tested in vivo in rodent and non-rodent species, current efforts are focused on defining a final lyophilized formulation to extend shelf-life while preserving critical quality attributes, in particular GLA enzymatic activity and liposomal integrity.

The requested services include an optimization of a 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 process:

1. Optimization of cryo-/lyoprotectants and determination of critical temperatures (e.g. Tg', collapse temperature), using appropriate techniques such as lyophilization microscopy and thermal analysis (DSC).
2. Optimization of the lyophilization cycle parameters.

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 development timeline is approximately 1 month, subject to timely availability of samples and data. 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 development
- Experience with nanoparticles and sensitive protein formulations is an advantage
- Ability to lyophilize small batch sizes or low volume loads, appropriate for preclinical 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 formulation development | 15% | Documented track record in similar developments and optimizations. |
| | | 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. |

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|-------------------------------------|---|-----|---|
| Cost competitive ness 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 25/02/2026 at 23:59 CET to info@delbios.com.
Email subject: RFQ-FOR-001-2026

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.