DELBIOS
PHARMACEUTICALS

Extended Request for Quotation (RFQ) – Investigator Brochure (IB), Investigational Medicinal Product Dossier (IMPD) and Phase I Synopsis

Reference Code: SRD12-RFQ-TOX-010-2026

Date of Issue: 05/06/2026

Deadline for Submission: 29/06/2026

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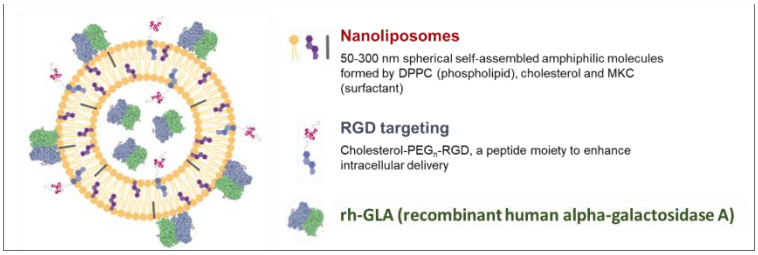
1. Background

Delbios Pharmaceuticals SL is developing nanoGLA, a nanomedicine intended for the treatment of Fabry disease under the EIC Transition Project Nano4Rare (Grant Agreement No. 101136772). NanoGLA is a recombinant human α-Galactosidase A (GLA) enzyme encapsulated in nanoliposomes designed to improve biodistribution, prolong circulation time and enhance therapeutic efficacy compared with conventional enzyme replacement therapies.



As the project advances towards first-in-human (FIH) clinical development, Delbios is preparing the key regulatory and clinical documentation required for a future Clinical Trial Application (CTA) submission.

To support this process, Delbios intends to subcontract specialized regulatory and scientific consulting services for the preparation and/or review and optimization of:

• Investigator Brochure (IB)

• Investigational Medicinal Product Dossier (IMPD)

• Phase I Clinical Study Synopsis

The objective is to ensure that these documents are scientifically robust, internally consistent and aligned with current EMA, ICH and EU Clinical Trial Regulation requirements prior to CTA preparation.

2. Scope of Work

Investigator Brochure Preparation

- Prepare the Investigator Brochure.
- Assess scientific consistency between IB and the supporting source documents.
- Review clinical, non-clinical, pharmacology, pharmacokinetic and safety sections.
- Evaluate compliance with ICH and EMA expectations.
- Provide recommendations and tracked changes.
- Participate in one review meeting with Delbios.

Deliverable:

- Prepared Investigator Brochure with tracked comments and recommendations.
- Participation in one scientific review meeting.

IMPD Review

- Review the draft IMPD.
- Review quality, non-clinical and clinical sections.
- Assess completeness and consistency of CMC information.
- Evaluate adequacy of pharmacology, toxicology and PK information.
- Assess readiness for future CTA submission.
- Provide recommendations and tracked changes.
- Participate in one review meeting.

Deliverable:

- Reviewed IMPD with tracked comments and recommendations.
- Participation in one review meeting.

Phase I Synopsis Review

- Review/update the draft Phase I clinical study synopsis.
- Assess overall study design.
- Review inclusion/exclusion criteria.
- Review objectives and endpoints.
- Review safety monitoring strategy.
- Review statistical considerations.

- Assess alignment with EMA expectations for first-in-human studies.
- Provide recommendations and tracked changes.
- Participate in one review meeting.

Deliverable:

- Reviewed synopsis with tracked comments and recommendations.
- Participation in one review meeting.

Deliverables

1. Prepared Investigator Brochure with annotated comments.
2. Reviewed IMPD with annotated comments.
3. Reviewed Phase I Clinical Study Synopsis with annotated comments.
4. Participation in up to three scientific review meetings (one per document).
5. Consolidated summary of key recommendations and identified risks.

Expected Timeline

- Kick-off meeting: within 2 weeks of contract signature.
- First draft completed within 6-8 weeks.
- Final version delivered no later than 16/10/2026.

3. Service requirements

- Minimum 5 years of experience in regulatory consulting for biologics, nanomedicines or advanced therapies.
- Demonstrated experience preparing or reviewing IBs, IMPDs and clinical study protocols/synopses.
- Experience supporting CTA submissions in Europe.
- Familiarity with EMA, ICH and EU CTR requirements.
- Audit readiness and compliance with Horizon Europe requirements.
- Ability to deliver within agreed timelines.

4. Evaluation Criteria

Main Criterion	Weight	Subcriterion	Sub-weight	Evaluation Indicators
Scientific & Technical Proposal	35%	Understanding of project objectives and regulatory context	15%	Demonstrated understanding of nanoGLA development stage, CTA requirements and project objectives.

		Methodology and review approach	15%	Clarity, completeness and feasibility of the proposed review strategy for the IB, IMPD and Phase I Synopsis
		Risk identification and mitigation	5%	Ability to identify scientific, regulatory or development risks and propose mitigation measures.
Relevant Experience	25%	Experience with nanomedicine, biologics or enzyme replacement therapies	10%	Documented experience in nanomedicine development, liposomal formulations, biologics or enzyme replacement therapies. Experience with rare diseases and nanopharmaceutical products will be positively evaluated.
		Experience with IB, IMPD, CTA or regulatory consulting activities	10%	Demonstrated experience in preparing or reviewing IBs, IMPDs, CTA documentation, scientific advice procedures or regulatory interactions with EMA/FDA.
		Team qualifications	5%	Seniority and suitability of proposed experts across regulatory, CMC, non-clinical and clinical disciplines.
Timeline	10%	Feasibility of proposed schedule	5%	Realistic timeline and resource allocation.
		Responsiveness and flexibility	5%	Ability to adapt to project needs and provide timely feedback.
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.

5. Confidentiality

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

6. Submission instructions

All proposals must include:

1. Technical proposal and study plan
2. Timeline for study start and final report
3. Team composition and relevant expertise.
4. Full cost breakdown
5. Payment terms

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

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

All quotations must be submitted by 29/06/2026 to: info@delbios.com

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7. 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.

8. 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.