

## **SRD08: Extended Request for Quotation (RFQ) – Target Product Profile and Asset Valuation for nanoGLA**

Reference Code: RFQ-BUS-001-2026

Date of Issue: 20/03/2026

Deadline for Submission: 01/04/2026

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### **1. Background**

Delbios Pharmaceuticals SL is developing nanoGLA, a nanomedicine intended for the treatment of Fabry disease. nanoGLA consists of a recombinant human  $\alpha$ -Galactosidase A (GLA) enzyme encapsulated in nanoliposomes designed to enhance enzyme stability, prolong plasma half-life, and improve tissue distribution compared with conventional enzyme replacement therapies.

As the program advances through nonclinical development and prepares for future clinical and investment milestones, Delbios aims to further define the Target Product Profile (TPP), clinical development strategy and its potential positioning in the Fabry disease therapeutic landscape. Delbios plans to subcontract expert consultants to develop a Target Product Profile (TPP) and conduct an asset valuation for nanoGLA, clarifying its clinical positioning, competitive advantages, development strategy, and commercial potential.

The outcome of this work will support strategic decision-making, fundraising activities, and preparation for interactions with potential partners and investors.

### **2. Scope of Work**

Delbios seeks to subcontract expert consulting services to support the strategic development and evaluation of nanoGLA through the preparation of a Target Product Profile (TPP) and an asset valuation analysis.

The objective is to define the desired clinical and product characteristics for nanoGLA, assess its positioning within the Fabry disease treatment landscape, and estimate the potential value of the asset based on development assumptions, market opportunity, and comparable benchmarks.

The scope of work is expected to include the following activities:

### **2.1 Target Product Profile (TPP) Development**

Development of a structured TPP outlining the key clinical, regulatory, and product attributes expected for nanoGLA.

Activities may include:

- Review of available background documentation and scientific data related to nanoGLA.
- Analysis of the Fabry disease treatment landscape, including current and emerging therapies.
- Identification of unmet medical needs and therapeutic goals in Fabry disease.
- Definition of key product characteristics including:
  - Indication and patient population
  - Route of administration and dosing strategy
  - Efficacy targets and clinical endpoints
  - Safety considerations
  - Quality of life and patient-reported outcomes
  - Pharmaceutical and formulation considerations
  - Regulatory positioning and potential special designations
- Development of both a **base TPP** and an **aspirational TPP** aligned with the long-term strategic objectives of Delbios.

### **2.2 Competitive Landscape and Benchmarking**

Assessment of current and emerging therapies for Fabry disease to benchmark relevant product characteristics and development strategies.

Activities may include:

- Review of approved and pipeline therapies.
- Benchmarking of efficacy, safety, and development endpoints.
- Analysis of clinical trial designs and regulatory precedents.

### **2.3 Asset Valuation Analysis**

Development of an asset-level valuation analysis for nanoGLA to estimate its potential economic value under defined development scenarios.

Activities may include:

- Assessment of epidemiology and market opportunity in relevant geographies.

- Development of key assumptions regarding clinical development, timelines, and probability of success.
- Market and pricing considerations based on comparable therapies.
- Financial modelling to estimate potential asset value under different investment and deal scenarios. Definition of full financial plans from present stage to commercialization.
- Calculation of the total timelines and cost for nanoGLA development from the actual position to the clinical value inflection point (Phase II/POC) to the product entrance to the market.

## **2.4 Deliverables and Timeline**

The subcontractor is expected to deliver the following outputs:

### **Kick-off meeting**

Initial meeting to align on project scope, timelines, and information requirements.

### **Target Product Profile (TPP) report**

A structured document summarizing the recommended base and aspirational Target Product Profiles for nanoGLA, including supporting analysis and assumptions.

### **Competitive landscape summary**

Overview of the Fabry disease treatment landscape, including benchmarking of key product attributes and development considerations.

### **Asset valuation report**

A report summarizing the methodology, assumptions, and estimated asset value based on the defined development and commercial scenarios.

### **Final presentation**

Presentation of the key findings, conclusions, and strategic recommendations to the Delbios team.

The expected total project duration is approximately **4–8 weeks from project kick-off**, depending on the proposed methodology and work plan.

## **3. Service Requirements (SRD08)**

The subcontractor must demonstrate:

- Proven experience ( $\geq 5$  years) in **biopharmaceutical strategy, product development consulting, or asset valuation**.
- Demonstrated expertise in **rare diseases, biologics, or advanced therapies**.
- Experience in developing **Target Product Profiles (TPPs)** and strategic development plans for pharmaceutical assets.

- Experience performing **biotech asset valuation, market analysis, and commercial strategy assessments**.
- Strong understanding of **drug development processes, clinical development strategy, regulatory considerations** and timelines and costs estimation
- Ability to deliver clear and structured strategic reports suitable for **investor communication or partnership discussions**.
- Compliance with **public financial agencies (i.e. EIC, CDTI, etc..) ethics requirements**

#### 4. Submission Instructions

All proposals must include:

- **Technical proposal** and work plan detailing methodology, expected outcomes, and deliverables.
- **Timeline** including milestones and submission of final deliverable.
- **Cost breakdown** and **payment terms**.
- Team expertise summary highlighting relevant experience with EMA, EIC-funded, or nanomedicine projects.

Proposals must be submitted by **1st april 2026, 23:59 CET** to:

**info@delbios.com**

Subject: *RFQ-BUS-001-2026 – Target Product Profile and Asset Valuation for nanoGLA*

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

1. Signed declaration of no conflict of interest
2. Acceptance of audit rights and confidentiality terms

#### 5. Evaluation Criteria

Main Criterion	Weight	Subcriterion	Sub-weight	Evaluation Indicators
<b>Technical &amp; Scientific Proposal</b>	40%	Clarity and relevance of the proposed approach	15%	Understanding of project objectives
		Completeness and methodology	15%	Coherence and feasibility of the plan
		Risk identification and mitigation	10%	Ability to anticipate and address project risks
<b>Experience &amp; Expertise</b>	30%	Relevant experience in biologics/nanomedicines	15%	Documented previous projects. Rare disease experience, project and

				contact with specialized centers.
		TPP and asset valuation experience	10%	Documented previous projects.
		Team qualifications	5%	Seniority and adequacy of proposed experts
<b>Timeline &amp; Deliverables</b>	5%	Feasibility of completion of the project	3%	Realistic planning and resource allocation
		Flexibility and responsiveness	2%	Adaptability to project needs
<b>Cost competitiveness</b>	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 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.

**8. Legal and Funding Clauses**

- A contract will be signed including obligations on confidentiality, audit rights, and ethics compliance.
- Public financing entities must be granted full audit rights.
- Costs must comply with public financing 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.