REQUEST FOR QUOTATION no. 21/2023/M/FAiND2.0
dated 08.03.2023 for CELON PHARMA SA with its registered office in Kiełpin

In connection with the implementation of the project no. 2022/ABM/05/00005 under the name **"FGF1 analog: a novel therapeutic target for non-alcoholic fatty liver disease and related metabolic diseases"** co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers.

DATE OF PUBLICATION: 08.03.2023

LOCATION: Kazuń Nowy

ANNOUNCEMENT PUBLICATION: obligatory

ORDERING PARTY: Celon Pharma SA, ul. Ogrodowa 2a, 05-092 Kiełpin

OFFICIAL WEBSITE ADDRESS OF THE ORDERING PARTY
www.celonpharma.com, telephone: 22 7515933

TYPE OF THE ORDERING PARTY: Private entity

A PARTIAL TENDER ALLOWED - NO
A VARIANT TENDER ALLOWED - NO

DATE OF COMPLETION OF THE CONTRACT: until 30th June 2023

PROCEDURE
Request for quotation

CONTRACT AWARD PROCEDURE:

1. This contract award procedure is not governed by the provisions of the Act of 11th September 2019 – the Public Procurement Law.
2. This contract award procedure shall be conducted with due observance of the principles of competitiveness, openness, transparency and equal access.
3. The Ordering Party reserves itself the right to nullify the procedure at any stage thereof without stating the reason.
4. The Ordering Party shall inform Suppliers about any changes made by publishing relevant information on its website.
5. The Ordering Party reserves itself the right to request additional information, documents or explanations.
6. In justified cases, at any time before the expiry of the deadline for the submission of tenders, Celon Pharma SA may modify or supplement the content of the invitation to tender.
7. This invitation to tender imposes no obligation on Celon Pharma SA to conclude a contract.

DETAILS CONCERNING THE OBJECT OF A CONTRACT:
CPV CODE: 73100000-3 - research and experimental and development services

Deadline for completion: second quarter of 2023

Concerning the project: *" FGF1 analogue: a new therapeutic target for non-alcoholic fatty liver disease and related metabolic diseases." POIR.04.01.04-00-0117/15-00,* which is conducted by Celon Pharma S.A. (hereinafter "the Project"), we hereby request quotation for:

Conducting a subcontracted programme including: the manufacture of a non-GMP Active Substance (DS) system of candidate proteins for toxicology studies.

The scope of the project we are looking for spans for:

1. he Contractor shall, on the basis of the materials received, perform the documentation forming the basis for the transfer of the method for the production of the **three recombinant protein variants** in the E. coli T7 expression system,
   - Deliverables /Expected results of step 1Execution of the programme design with the relevant timetable and quotation of materials, virtual online access to the raw data and the resulting documents.

2. The Contractor shall obtain, together with the process documentation, a characterised RCB (Research Cell Bank) for each product variant. This material is to be used to multiply and produce the RCB required to supply the recombinant protein manufacturing process and for the Contractor's needs
   - deliverables /Expected delivery at step 2: delivery of at least 50 vials of characterised RCB with full documentation by ICH Topic Q5D, online access to raw data and generated documents.

3. Process development and production of demonstration batches with the production of reference material.

   a) Documentation development of Upstream processes: selection of raw materials to ensure comparability with future GMP process; inoculum optimisation; induction point assessment; process development with cell density to ensure adequate yield and quality of protein product; fermenter operating parameters assessment, development of feeding strategy during fermentation; lysis; IPC assessment,
   (b) Documentation development of Downstream processes: control of protein distribution (soluble vs. insoluble), applications of capture media technology transfer described in the documentation and screening of final product purification media; development; formation; virus removal and sterile filtration,
   (c) Demonstration of full process development (at least two runs) of fermentation and performance of a small scale protein purification process
   (d) Production of active reference protein in the formulation and product concentration in mg/ml as specified by the client
   - deliverables /expected achievement in step 3: Reports on the process carried out with the report on the generation of the reference material with SOP documentation, production of an active reference molecule of at least 200 mg of each variant, online access to the raw data and the generated documents.

4. Transfer to large scale and confirm process robustness.
   (a) Execution of one engineering batch at a scale to ensure an adequate amount of material produced,
   - Expected delivery at step 4: MBR, SOP documents engineering batch report, active reference molecule - at least 1 g, of each variant, completed Upstream and Downstream BPRs, online access to raw data and generated documents.

Until now we have generated laboratory data for expression and purification and analytics on a small laboratory scale – these data can be available after the execution of CDA.

Additional information:

- The planned program must be performed according to Good Manufacturing Practice and Good Laboratory Practice (GLP).
- The planned program will be performed according to EMA and FDA guidelines regarding manufacturing and preclinical and clinical assessment for biological drugs.
- All documentation associated with the Project must be in English.

Requirements to be met by bidders:

1. The Bidder must sign the Mutual Confidentiality and Nondisclosure Agreement with the Purchaser to get details enabling to create of a required bid.
2. The Bidder should demonstrate the ability to conduct the study referred to in this RfQ in the shortest possible term. *Submission of Bidder's experimental schedule (time plan) is required.* This is to include the estimated commencement date of the first study to the estimated primary completion date of the study program (date of DP release for Clinical Trial).
3. The Bidder should declare that he has all licenses required by law to perform the subject of the order.
4. The Bidder should declare that he has the necessary experience and potential to perform the subject of the order – additional point will be added for the submission of references from 2-3 pharmaceutical companies covering the experience in the execution of similar programs:
   a. *2-3 references -2 points, < 2 references 0 points.*
5. The Bidder should declare that he has the necessary technical and laboratory infrastructure to conduct the studies referred to in this RFQ and be able to conduct the selected studies following cGMP and GLP.
6. The Bidder should demonstrate it has scientific personnel specialized in areas related to the subject of this RfQ. *Submission of Bidder's folder, presentation or monograph is allowed*.
7. The Bidder should present together with a cost of each phase of the project estimated cost of consumables and raw materials needed to complete each part of the project.
8. "The Statement on the absence of personal or capital ties with the Purchaser" should be submitted along with the bid. The statement is an attachment to the inquiry.
9. Unless otherwise stated, all invoices will be payable within 30-60 days of the date of issuance of the invoice, this encompasses the invoices for service and consumables/materials.


10. Finally, the Bidder should declare that his financial and economic position can ensure successful implementation of the service.

Address and date for submitting the bids:

11. Bids must be submitted to the purchaser's office at Marymoncka 15 Str., 05-152 Kazun Nowy, if sent by traditional mail or by currier, or to przemyslaw.pietrasiuk@celonpharma.com if sent by electronic mail.
12. The bid must be submitted by 16.03.2023 at the latest. If sent by traditional mail or courier, the bid is deemed to be submitted on the day of its delivery to the purchaser's office.
13. Bids submitted after the aforementioned date will not be considered.
14. Bids will be evaluated at the Purchaser's office by 17.04.2023
15. For further information on the Project, please contact dr Tomasz Obtulowicz email: tomasz.obtulowicz@celonpharma.com
16. This request for quotation is available at: https://celonpharma.com/category/zapof/

Presentation of the bids:

17. Each Bidder may submit only one bid.
18. The bid must be in English.
19. The bid must show the date of preparation, the Bidder's address, telephone number, email address, tax ID number NIP (if available).
20. The bid must include the RfQ no. in the title. The RfQ no. must also appear in the titles of electronic, traditional and courier mail.
21. The bid must remain valid for at least 3 months counted from the submission deadline.
22. The bid must contain:
    a. The price:
        i. should be presented for every single planned study including the total price for this study excluding procedures specified in the section "Additional procedures to the above outline", which are to be priced separately (according to the Detailed Studies Scope – available after signing the confidentiality clause), the price for each study should contain the detailed estimation of the consumables and row materials costs needed for this study,
        ii. if submitted by a Bidder operating in Poland, the gross and net bid price and due VAT bided for delivery of the subject of the order by the requirements set forth herein,
        iii. if submitted by a Bidder operating outside Poland, the net bid price and information that not VAT or other taxes have been included in the price quotation.
    b. The Statement on the absence of personal or capital ties with the Purchaser should be submitted along with the bid.
23. Costs of preparing the bid shall be borne by the Bidder.

Note:

24. The Purchaser will place the order with the bidder whose bid meets all the requirements outlined in this RfQ and is deemed the best relative to the selection criteria set forth herein.
25. When substantiated, the purchaser reserves the right to cancel the bidding process.
26. The Purchaser reserves the right to close the bidding process without selecting the successful Bidder. The Ordering Party is not bound to give the reason for closing the procedure.
27. In the course of evaluation and assessment of the bids, the Purchaser may request that the bidders provide clarifications regarding their bids. In such a case, the Ordering party reserves the right to postpone the final evaluation and notification about the evaluation of quotes.
28. The Bidder may alter or withdraw its bid before the submission deadline.
29. Bids submitted past the submission deadline will not be considered.
30. Bids that do not meet the formal requirements set forth herein will not be considered.
31. The Purchaser permits rejecting bids whose essential content clearly raises reasonable doubts.
32. The absence of submission of the experimental schedule (time plan) both with the estimated commencement date of the first study and the estimated primary completion date of the studies program is the basis to reject the application and grant 0 points for the subsequent evaluation criteria.

The successful bid will be selected based on the following criteria:

No.	CRITERIA	WEIGHT IN %
1.	Price	49
2.	Price consumables/raw materials	19
3.	Time	29
4.	Additional criteria	3

Points scoring systems during selection process will be as follows:

No.	CRITERIA	Points scoring system
1.	Price	**Price "P" – 49 points (weight of criterion 49%)** Scoring in the price criterion will be as follows: the lowest price for conducting all studies proposed by the Tenderer will be considered as 49 points, which is the maximum number of points. The points will be given based on the formula:

		$\frac{Price_{lowest}}{Price\ _{service}} \times 49\ points$ Where: $Price_{lowest}$ – the lowest price among quotes. $Price_{service}$ – price for the given tenderer. ***Criterion "P" = number of points x 49% (weight of criterion)***
2.	Price consumables/raw materials	**Price "PC/R" – 19 points (weight of criterion 19%)** Scoring in the price criterion will be as follows: the lowest price for conducting all studies proposed by the Tenderer will be considered as 19 points, which is the maximum number of points. The points will be given based on the formula: $\frac{Price_{lowest}}{Price\ _{service}} \times 19\ points$ Where: $Price_{lowest}$ – the lowest price among quotes. $Price_{service}$ – price for the given tenderer. ***Criterion "P" = number of points x 19% (weight of criterion)***
3.	Time	**Time "T" – 29 points (weight of criterion 29%)** 29 points - will be given to the Bidder who will provide the estimated date of DS release for tox material, till the end of Q2 2023 (2023-06-30) The next Bidders will receive 29 points with subtracted 10 points for every month of delay in said DP release date – 2023-06-30. If the estimated DS release date will be later than 20 weeks from 2023-06-30, the Bidder will receive 0 points. ***Criterion "T" = number of points x 29% (weight of criterion)***
4.	Additional criteria	**References – 2 points** **Schedule and timeline – 1 point**

The final score will be calculated by substituting the data obtained above to the following formula:

1. ***Total points = Criterion "P" + Criterion "PC/R" + Criterion "T" + Additional criteria***

VII. NOTIFICATION OF THE CONTRACT AWARD

Information about the result of the contract award procedure shall be published on the Celon Pharma website

Please Note:

1. In connection with the entry into force of the Act of April 13, 2022 on special solutions in the field of counteracting aggression against Ukraine and serving the protection of national security (Journal of Laws, item 835), entities or citizens from the Russian Federation are excluded from participation in these proceedings, while subject to the sanctions specified in Art. 1 above of the Act, provided that on the day of submitting the offer they are on the list of persons and entities against which sanction measures should be applied, kept on the website of the Public Information Bulletin of the Minister of Internal Affairs and Administration,
2. The Contracting Party reserves the right to amend the agreement concluded with the awarded tenderer as a result of the procurement for the following reasons:
    a) justified changes in the manner of performance of the subject-matter of the order,
    b) objective reasons beyond the control of the Contracting Party or tenderer,
    c) changes in legal regulations in force on the day of signing the contract,
    d) force majeure,
    e) occurrence of another obstacle, beyond the control of the tenderer, which prevents the performance of works,
    f) in the event of changes to the Subject of the Agreement exceeding the material and/or financial scope indicated in the Tender, the Parties undertake that such changes will be introduced by way of an amending Annex and according to the "Guidelines on the eligibility of expenditure under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for 2014-2020".
3. Entities related to the Contracting Party either personally or by capital are excluded from participation in this procurement. Capital or personal relationships are understood as mutual relations between the Contracting Party or persons authorised to contract obligations on behalf of the Contracting Party or persons performing on behalf of the Contracting Party activities related to the conduct of the procedure for selecting a contractor and the contractor, consisting in particular of the following:
    a) participation in a company as a partner in a civil law partnership or a partnership,
    b) owning at least 10% of shares as long as the lower limit does not result from legal provisions or was not defined by IZ PO,
    c) fulfilling the duties of member of the supervisory body or as manager, proxy or power of attorney,
    d) being married, a direct family member, direct affinity, second-level relative or second degree affinity in lateral line or in relation to adoption, care or guardianship.
4. Each invoice issued should be due for at least 30 days.
5. Due to the necessity to maintain the continuity of tests, the Ordering Party provides for the possibility of submitting a supplementary order in the amount not exceeding 50% of the order value specified in the contract concluded with the Contractor.
6. The Ordering Party allows for the possibility of canceling the order or resigning from the order of goods and services included in the partial procedure or the entire procedure if funds are not obtained for the performance of this order or in other cases when the performance of the order will not be in the Ordering Party's best interest.
7. The Ordering Party admits the possibility of negotiating the presented offer.