REQUEST FOR QUOTATION no. 60/2026/M/RNA
Dated 16.09.2026 for CELON PHARMA SA with its registered office in Kiełpin

In connection with the implementation of the project no. 2021/ABM/05/00005 under the name **"Development of Innovative Therapeutic Solutions using RNA technology (TransformRNA - mRNA Therapeutics generation platform)"** co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers.

DATE OF PUBLICATION: 19.06.2026

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 September 2026

PROCEDURE
Request for quotation

CONTRACT AWARD PROCEDURE:

1. This contract award procedure is not governed by the provisions of the Act of 11 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 development services

Concerning the project: *" Transform RNA - mRNA Therapeutics generation platform.",* which is conducted by Celon Pharma S.A. (hereinafter "the Project"), we hereby request quotation for:

Conducting the following subcontracted general toxicology and analytical support studies program necessary to complete the Project:

The selected Contractor will be responsible for the planning, execution, and reporting of the following nonclinical studies and supporting activities:

1. General Toxicology

- Conduct Repeat-Dose Toxicity studies in one species (rodent- Wistar Han Rat),
- Test item to be administered via intramuscular injection,
- The studies must include full clinical observations, body weight and food consumption monitoring, clinical pathology, and comprehensive histopathology,
- Assessment of local tolerance,
- Safety Pharmacology: Respiratory, Nervous, and Ophthalmological Assessment,
- Toxicokinetic analysis

3. Genetic Toxicology

The following standard set of genotoxicity tests is required:

- In vivo bone marrow micronucleus test in the Wistar Han rat,
- In vitro chromosomal aberration assay using Chinese Hamster Ovary (CHO) cells,
- In vitro bacterial reverse mutation test (Ames test),

All studies must be performed in compliance with relevant **OECD** guidelines and **GLP** requirements.

4. Formulation Analysis

- Development, pre-validation, and full validation of an analytical method for the quantification of the test item (TI) in dose formulations.

5. Bioanalytical Method Development and Sample Analysis

- Development, validation, and application of a bioanalytical method suitable for the quantification of the test item in biological matrices (e.g., **LC/MS, qPCR**) in rodent- Wistar Han Rat.

6. Immunogenicity Assessment

- Determination of antigen-specific antibody response:
- ✓ Measurement of serum IgG antibodies specific to the antigen encoded by the mRNA construct, including antibodies directed against the S1 domain and the receptor-binding domain (RBD) (e.g. by ELISA)
- ✓ Assessment of neutralizing antibody titers using a pseudovirus neutralization assay
- Analysis of cytokines and complement factor activation

All studies must be conducted in accordance with the relevant OECD guidelines and in compliance with Good Laboratory Practice (GLP)

CELON PHARMA S.A.
Biuro: ul. Ogrodowa 2A, 05-092 Łomianki / Kiełpin, Dział R&D: ul. Marymoncka 15, 05-152 Kazuń Nowy / Czosnów,
tel.:+48 22 751 59 33; fax: +48 22 751 74 77 e-mail: info@celonpharma.com, www.celonpharma.com
Organ rejestrowy: Sąd Rejonowy dla m. st. Warszawy, XIV Wydział Gospodarczy Krajowego Rejestru Sądowego
Prezes Zarządu: Maciej Wieczorek, **Wysokość kapitału zakładowego:** 5.385.650 PLN
KRS: 0000437778, **NIP :** 118 16 42 061


Additional Information:

- The Purchaser declares readiness to commence the research program set forth herein starting from **no later than August 2026**.
- The planned study program will be conducted in accordance with **Good Laboratory Practice (GLP)** ,
- The program will also follow the **European Medicines Agency (EMA)** scientific guidelines on non-clinical testing of medicinal products.
- English shall be the language for all communication, documentation, and reporting.
- The detailed scope of work is provided in **Attachment No. 2 to this RfQ** and will be shared with the Bidder upon signing a Mutual Confidentiality or Non-Disclosure Agreement (**NDA**) with the Purchaser.
- All studies must be conducted in accordance with current scientific standards. Studies and supporting activities shall comply with applicable **ICH, EMA, FDA,** and **OECD** guidelines, including but not limited to: **ICH M3(R2), ICH S6(R1), ICH S6(R1) , ICH S7A/s7B** and other relevant documents. Where **GLP** compliance is required, studies must meet **EMA and FDA GLP standards**. A valid GLP certificate for the Bidder's facilities and laboratories must be provided. The Bidder must ensure ethical treatment of laboratory animals in line with animal welfare standards. A valid **AAALAC** accreditation is mandatory.
- All communication and documentation must be in English. Reports must comply with **FDA and EMA** non-clinical testing guidelines and be submitted in eCTD format, as per **ICH M4S(R2)**. The Bidder must deliver the Main Report and the following Subreports: Toxicokinetic, Pathology and Histopathology, Analytical Method Development and Validation (Formulation Analysis – DFA), Bioanalytical Method Development and Validation (BioA), and Anti-Drug Antibodies Assay Development and Validation (ADA). Reports must be delivered in both editable (.doc) and non-editable (.pdf) formats. Relevant raw data (e.g., body weight measurements, BioA raw data for TK analysis) must be delivered in separate files. The Purchaser reserves the right to review and request modifications to draft reports. Typically, two review cycles will be required before finalization

Additional Requirements and Bidder Qualifications

- The Bidder shall provide comprehensive project management support, including but not limited to: organization of weekly calls (if required) with meeting minutes, maintenance of up-to-date action and decision logs, preparation and updating of the Gantt chart, tracking of reports and budget, coordination of material and sample shipments, and management of on-site services. The Bidder shall support the Purchaser until the finalization of all reports and completion of the program. If project management services are already included in the study pricing, this must be clearly indicated.

- The Bidder acknowledges that the Purchaser is located in Poland (Central Europe) and agrees to ensure appropriate availability and communication adjusted for potential time differences.

- The Bidder shall demonstrate possession of appropriate infrastructure and resources necessary to conduct the non-clinical studies in compliance with Good Laboratory Practice (GLP), including but not limited to


animal facilities, experimental rooms, bioanalytical and analytical laboratories, archives, and storage areas **(Appendix 3 – Bidder's Statement).**

- The Bidder shall confirm access to an appropriate source of laboratory animals (certified and registered breeding facilities) and ensure adequate veterinary care **(Appendix 3 – Bidder's Statement).**

- The Bidder shall demonstrate relevant experience in conducting studies supporting the development of biological medicinal products, including at least three completed toxicology studies for vaccines. Experience with mRNA-LNP (lipid nanoparticle) vaccines will be considered an additional advantage **(Appendix 3 – Bidder's Statement).**

- The Bidder shall be responsible for procurement of all materials and reagents required for the execution of the study. The Purchaser will provide the Test Item for in vitro method development (e.g. bioanalytical, immunoassays including ADA where applicable) and for in vivo studies.

- The Purchaser reserves the right to modify the scope of work based on study progress and obtained results. Any changes (addition, removal, or modification of services) shall require mutual agreement of both Parties in the form of a written amendment (Purchase/Work Order Amendment).

- The Bidder shall submit, as part of the offer:
✓ a declaration confirming relevant experience as described above,
✓ at least three references for completed projects involving vaccines products (mRNA-LNP is a additional advantage),
✓ a declaration of no personal or capital links with the Contracting Authority,
✓ materials demonstrating scientific capabilities (e.g. brochure, presentation, or monograph).
- The Bidder must confirm that it possesses adequate financial and economic capacity to perform the contract.
- Interim and final reports shall be included in the offer, covering in particular: toxicokinetics, histopathology, analytical and bioanalytical method development and validation, formulation analysis, and (where applicable) anti-drug antibody assay development **(Appendix 1).**
- Unless otherwise agreed, invoices shall be payable within 30–60 days from the invoice date.

POINT SCORING SYSTEM:

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

No.	CRITERIA	WEIGHT IN %
1.	Price	80
2.	Study initiation date	20

Points scoring systems during selection process will be as follows:

No.	CRITERIA	Points scoring system
1.	Price	Price "P" – 100 points (weight of criterion 50%) Scoring in the price criterion will be as follows: the lowest price for conducting all studies proposed by the Tenderer will be considered as 100 points, which is the maximum number of points. The points will be given based on the formula: $\frac{Price_{lowest}}{Price\ _{service}} \times 100\ points$ Where: $Price_{lowest}$ – the lowest price among quotes. $Price_{service}$ – price for the given tenderer. *Criterion "P" = number of points x 50% (weight of criterion)*
2.	Study initiation date	Study initiation date "T" – 100 points (weight of criterion 20%) 100 points - will be given to the Bidder who will start the study by the September 2026 66 points - will be given to the Bidder who will start the study by the October 2026 33 points - will be given to the Bidder who will start the study by the November 2026 0 points - will be given to the Bidder who will start the study by the December 2026 *Criterion "T1" = number of points x 10% (weight of criterion)*

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

Total points = Criterion "P" + Criterion "T" + Criterion "M"

Address and deadline for the submission of tenders:

1. Tenders must be submitted to the Ordering Party to the address of its registered office: ul. Marymoncka 15, 05-152 Kazuń Nowy, Poland, if sent by traditional or courier mail, or to the e-mail address: przemyslaw.pietrasiuk@celonpharma.com , if sent by electronic mail.
2. Tenders must be submitted on **29.06.2026** at the latest. If a tender is sent by traditional or courier mail, it shall be deemed submitted on the day of its delivery to the registered office of the Ordering Party.
3. Tenders submitted after the expiry of the deadline shall not be processed.
4. Tenders shall be evaluated at the registered office of the Ordering Party by **10.07.2026** at the latest.
5. The tenders submitted in a foreign currency will be converted at the average exchange rate of the National Bank of Poland (NBP) applicable on the date of drawing up the protocol of the request for tender.

Presentation of tenders:

1. Each Bidder may submit only one bid.
2. The bid must be in English.
3. The bid must show the date of preparation, the Bidder's address, telephone number, email address, tax ID number NIP (if available).
4. 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.
5. The bid must remain valid for at least 3 months counted from the submission deadline.
6. The bid must contain:
7. The price:
   - should be presented for every single planned study including the total price for this study,
   - 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,
   - 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.
8. The Statement on the absence of personal or capital ties with the Purchaser should be submitted along with the bid.
9. Costs of preparing the bid shall be borne by the Bidder.

Note:

1. 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.
2. When substantiated, the purchaser reserves the right to cancel the bidding process.
3. 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.
4. 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.
5. The Bidder may alter or withdraw its bid before the submission deadline.
6. Bids submitted past the submission deadline will not be considered.
7. Bids that do not meet the formal requirements set forth herein will not be considered.
8. The Purchaser permits rejecting bids whose essential content clearly raises reasonable doubts.

VII. NOTIFICATION OF THE CONTRACT AWARD

Information about the result of the contract award procedure shall be published on the Celon Pharma website **https://celonpharma.com/category/zapof/**


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.