

**REQUEST FOR QUOTATION No. 2.2.****QTPP and non-clinical studies needed for the registration of the medicinal product Insulin N in EMA****I. NAME AND ADDRESS OF THE CONTRACTING AUTHORITY**

BIOTON S.A. ul. Starościńska 5, 02-516 Warsaw.

Factory address: Macierzysz, ul. Poznańska 12, 05-850 Ożarów Mazowiecki

**II. PROCEDURE FOR AWARDING THE CONTRACT AND TYPE OF CONTRACT**

The proceedings are conducted in connection with the implementation of the Project entitled **"Development of Human Insulin (intermediate-acting insulin) (ATC code: A10AC01) (hereinafter referred to as "Insulin N")"** as part of the implementation of the drug safety strategy in accordance with the list of critical drugs included in the document **"Union list of critical medicines - version 1" (EMA/528805/2023)** as part of the competition for entrepreneurs for the implementation of research in the area of drug safety, innovative therapies and drugs of the future (2024/ABM/05/KPO) as part of the call for proposals KPOD.07.07-IW.07-003/24, as part of the National Recovery and Resilience Plan, Component D "Efficiency, accessibility and quality of the health care system", Investment D3.1.1 "Comprehensive development of research in the field of medical sciences and health sciences", competition mode (hereinafter referred to as: **the Project**).

The procedure is conducted in accordance with the principle of competitiveness set out in the document entitled "Catalogue of eligible expenditures" constituting Appendix No. 12 to the Regulations for the selection of projects to be covered by support under the National Recovery and Resilience Plan, Component D "Efficiency, accessibility and quality of the health care system", Investment D3.1.1 "Comprehensive development of research in the field of medical sciences and health sciences", competition mode.

The procedure is conducted in accordance with the principle of competitiveness set out in subsection 3.2 of the *Guidelines on the eligibility of expenditure for 2021-2027* of 18 November 2022.

The provisions of the Act of 11 September 2019 do not apply to these proceedings. Public Procurement Law.

**III. DESCRIPTION OF THE SUBJECT OF THE CONTRACT**

- 3.1. Category: CPV: 73000000-2 Research and development services and related consultancy services**
- 3.2. The subject of the contract is execution of QTPP and non-clinical studies needed for the registration of the medicinal product Insulin N in EMA**
- 3.3. The result of the work carried out will be a report or a document approved by the Contracting Authority in accordance with the Scope of Works** constituting Appendix No. 2 to this request for quotation.
- 3.4. All results of the services and their copies (including in particular the documentation produced) and intellectual property rights to them, including in particular the rights to sui generis databases, industrial property rights, will be vested in the Contracting Authority. To the extent that these rights do not arise in the original manner for the benefit of the Contracting Authority, they will be transferred to the Contracting Authority at the earliest time permitted by law and to the widest extent permitted by law, without time and territorial limitations, as part of the Contractor's**

remuneration. As part of the Contractor's remuneration, the Contractor will also transfer to the Contracting Authority unconditionally and exclusively all proprietary copyrights, related rights and derivative rights to all works within the meaning of the Act on Copyright and Related Rights, created as part of the provision of services, regardless of the manner of their recording and the form of expression, to the widest extent permissible, without territorial and time limitations, in all fields of exploitation known at the time of conclusion of the agreement, and in particular the fields of exploitation referred to in Article 50 and Article 74(4) of the Act on Copyright and Related Rights.

- 3.5. The documentation created as part of the service must be handed over to the Contracting Authority at the Tenderer's expense.

#### IV. PLACE OF ORDER EXECUTION

- 4.1. No limits.

#### V. ORDER PROCESSING AND PAYMENT DEADLINE

- 5.1. Contract completion date: in accordance with the Scope of works constituting Appendix No. 2 to this request for proposal.
- 5.2. Planned date of concluding the contract: by March 2025
- 5.3. The Contracting Authority allows for partial payment.

#### VI. CONDITIONS FOR PARTICIPATION IN THE PROCEDURE AND GROUNDS FOR EXCLUSION

##### CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

- 6.1. Tenderer who meet the following conditions may apply for the award of the contract:

6.1.1. **authorisation to carry out a specific activity or activity**

The Contracting Authority will consider that the Tenderer meets this condition if they submit a statement that they have the necessary authorizations to properly perform the contract. Tenderer declares that the laboratory operates in a GMP-compliant environment, provides validation of analytical methods, release methods, as well as stability testing in accordance with GMP to ensure compliance with regulations in line with ICH guidelines.

6.1.2. **knowledge and experience**

The Contracting Authority will consider that the Tenderer meets this condition if it submits a statement that it has the knowledge and experience necessary for the proper performance of the contract, i.e. within the last 3 years before the expiry of the deadline for submission of tenders (and if the period of conducting business activity is shorter – during this period) it has performed, and in the case of recurring or continuous services it also performs, whose subject was execution of QTPP and non-clinical studies required for the registration in EMA (European Medicines Agency) in the centralised procedure of a biosimilar product using microorganisms such as *E.coli* for the production of the active substance for at least 2 medicinal products. By 2 medicinal products, it is understood two biosimilar medicinal products differing in the active substance, managed by Tenderer under two separate contracts. In the case of services still being performed by the Tenderer, their completed scope must correspond to the last stage of the registration procedure in EMA.

#### 6.1.3. technical potential

The Contracting Authority will consider that the Tenderer meets this condition if it submits a statement that it has the technical facilities necessary for the proper performance of the contract and that the tests will be carried out exclusively by the Tenderer.

#### 6.1.4. persons capable of performing the contract

The Contracting Authority will consider that the Tenderer meets this condition if they submit a statement that they have or will have the human resources necessary to properly perform the contract meeting the following requirements on the day the service begins:

##### i. Project Manager

- higher education
- served as a project manager in at least one successfully completed QTPP and/or non-clinical studies executed for medicinal product successfully registered in EMA for a period of not less than 6 months in the last 10 years
- experienced in coordinating biopharmaceutical projects, ensuring optimal communication, timeline adherence, and budget management

##### ii. Analytical Chemists/Scientists

- higher education
- at least 3 years of experience in execution of analytical methods used for testing of biological products
- skilled in method development, validation, and execution of analytical testing for biosimilars

##### iii. Quality Assurance Specialists

- ensure compliance with GMP and regulatory standards

##### iv. Technical Experts

- Proficient in advanced analytical techniques listed in Appendix No. 2 (Scope of work with expected completion date)

**The Contracting Authority does not allow the same person to perform different functions during the performance of the service (as above).**

#### 6.1.5. economic or financial situation

The Contracting Authority will consider that the Tenderer meets this condition if it submits a statement that it is in an economic and financial situation that ensures proper performance of the contract, in particular it is not in bankruptcy, restructuring or liquidation.

### GROUND FOR EXCLUSION FROM PARTICIPATION IN THE PROCEDURE

#### 6.2. Conditions for exclusion

##### 6.2.1. Entities related personally or by capital to the Contracting Authority are excluded from participation in the procedure.

Capital or personal ties are understood as mutual connections between the Contracting Authority or persons authorized to incur liabilities on behalf of the Contracting Authority, or persons performing on behalf of the Contracting Authority activities related to the preparation and conduct of the contractor selection procedure and the Tenderer, consisting in particular in:

- a) participation in the company as a partner in a civil law partnership or partnership,

- b) holding at least 10% of shares, unless a lower threshold results from the provisions of law,
- c) performing the function of a member of the supervisory or management body, proxy, proxy,
- d) being married, in a relationship of kinship or affinity in a direct line, kinship or affinity in the collateral line to the second degree or binding by adoption, guardianship or guardianship,
- e) being in common life with the Tenderer, its legal representative or members of the management or supervisory bodies of the Tenderers applying for the award of the contract,
- f) being in such a legal or factual relationship with the Tenderer that there is a justified doubt as to impartiality or independence in connection with the procurement procedure.

Method of verification of the grounds for exclusion or lack of grounds:

*The verification will take place on the basis of the Tenderer 's statement and the statements of the Contracting Authority and persons performing activities related to the preparation and conduct of the contractor selection procedure on behalf of the Contracting Authority.*

6.2.2 Entities in relation to which the following circumstances occur:

- a) described in Article 7(1) of the Act of 13 April 2022 on special solutions for counteracting support for aggression against Ukraine and for the protection of national security;
- b) described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (OJ L 2014, p. EU No. L 229, 31.07.2014, p. 1), as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (OJ L 229, p. EU No. L 111, 8.04.2022, p. 1, as amended. as amended).

Method of verification of the grounds for exclusion or lack of grounds:

*The verification will take place on the basis of the Tenderer 's statement.*

- 6.3. Offers submitted by entities that do not meet the conditions for participation in the procedure or in relation to which there are grounds for exclusion from participation in the procedure are subject to rejection and will not be evaluated.

## VII. UNDERSTAND HOW THE PRICE IS CALCULATED

- 7.1. The price should be calculated in net and gross value and entered in the offer form.
- 7.2. Prices expressed in a currency other than PLN will be converted into PLN according to the average exchange rate of the National Bank of Poland as of the date of initiation of the proceedings.
- 7.3. The price should include all costs related to the performance of the subject of the contract.
- 7.4. In the event that the offered price or cost seems grossly low in relation to the subject of the contract, i.e. differs by more than 30% from the arithmetic average of the prices of all valid offers not subject to rejection or raises doubts of the Contracting Authority as to the possibility of

performing the subject of the contract in accordance with the requirements specified in the request for proposal or resulting from separate regulations, The Contracting Authority shall request the Tenderer to provide explanations within the specified period, including the submission of evidence regarding the calculation of the price or cost. The Contracting Authority will assess these explanations in consultation with the Tenderer and may reject this offer if the submitted explanations together with evidence do not justify the price or cost given in this offer.

## VIII. DESCRIPTION OF THE CRITERIA TO BE FOLLOWED BY THE CONTRACTING AUTHORITY WHEN SELECTING THE TENDER

8.1. When evaluating the offers, the Contracting Authority will be guided by the following criteria:

8.2. Price – 100%

Number of points (PC) in the "Price" criterion will be calculated according to the formula:

$$P_C = \frac{C_N}{C_B} * 100$$

where:

- PC - number of points under the criterion "Price"
- CN - among the non-rejected offers, the lowest net price covering the implementation of the subject of the basic contract and the optional contract,
- C<sub>B</sub> - the net value of the examined offer covering the performance of the subject of the contract.

8.3. The offer that receives the highest number of points will be considered the most advantageous. The offer can receive a maximum of 100 points. Calculations will be made with an accuracy of two decimal places.

8.4. If several offers receive the highest number of points, the offer with the lowest price will be considered the most advantageous among them. In the event that several offers receive the highest number of points and at the same time are for the lowest price, the Contracting Authority will call on the Tenderer who submitted these offers to submit additional offers in which they will specify the new price. The price specified in the additional offer cannot be higher than the price originally offered.

## IX. PLACE AND DATE OF SUBMISSION AND OPENING OF TENDERS

9.1. Offers should be submitted by 03.03.2025 r.

9.2. The offer should be submitted in electronic form via the Competitiveness Database website, in accordance with the requirements of the "Tenderer's Instruction in BK2021" [[https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction)] in the form of documents signed by the Tenderer or their scans, in accordance with the requirements described in point 10.3.

9.3. The date and time of submitting the offer on the Competitiveness Database website determines whether the deadline is met.

9.4. Offers submitted in a manner other than described above will not be considered.

9.5. The contracting authority does not plan to open the Offers to the public.

## X. DESCRIPTION OF HOW TO PREPARE THE OFFER

- 10.1. The Tenderer may submit one offer. Submission of two or more offers will result in the rejection of all offers submitted by a given Tenderer .
- 10.2. The offer should be prepared in Polish or in English.
- 10.3. The offer with attachments must be signed by persons authorized to represent the Tenderer in accordance with the representation resulting from the relevant register or on the basis of the power of attorney granted, in the case of companies from outside Polish, a document confirming the appropriate authorization should be attached.
- 10.4. If the person(s) signing the offer (representing the Tenderer ) acts on the basis of a power of attorney, this power of attorney must be attached to the offer.
- 10.5. The offer must include:
- a) offer form (in accordance with Appendix No. 1 to the request for proposal),
  - b) statements and documents resulting from chapters III and VI of the request for proposal,
  - c) power of attorney to act on behalf of the Tenderer (if applicable)
  - d) in the case of foreign entities – a document confirming the proper authorization.
- 10.6. If the Tenderer presents in the offer information constituting a trade secret within the meaning of the Act of 16 April 1993 on combating unfair competition, it should clearly indicate which sections of the offer constitute a trade secret and cannot be disclosed to third parties.
- 10.7. Before the deadline for submission of offers, the Tenderer may make changes to the submitted offer or withdraw it. Changes to the offer or its withdrawal are made on the same terms as its submission.
- 10.8. The Tenderer are obliged to carefully read the information contained in the request for proposal and any changes in the content of the inquiry, explanations and answers published by the Contracting Authority during the procedure and preparation of the offer in accordance with the requirements specified by the Contracting Authority.

## **XI. MANNER OF COMMUNICATION BETWEEN THE CONTRACTING AUTHORITY AND TENDERER**

- 11.1. No information, explanations or answers to inquiries addressed to the Contracting Authority by phone or e-mail are provided, except for the provision of sensitive information in accordance with point 3.5 of the request for proposal, which will be provided by e-mail.
- 11.2. Questions regarding the request for proposal and requests for explanations regarding the content of the inquiry should be sent only via the Competitiveness Database through the "Questions" tab on the request for proposal page [<https://bazakonkurencyjnosci.fundusze.europa.eu/>], no later than 5 working days before the deadline for submitting offers.
- 11.3. Answers to the Tenderer ' questions and explanations to the content of the request for proposal will be provided to the Tenderer only in such a way that the Contracting Authority will publish the content of the questions/requests for clarifications along with the answers/explanations



provided on the request for proposal page on the Competitiveness Database website [<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>].

- 11.4. Unless it violates competitiveness, in the course of the examination of Offers, the Contracting Authority has the right to demand explanations from the Tenderer regarding the content of the submitted Offers and supplementing the documentation.
- 11.5. The contracting authority has the right to ask the Tenderer for permission to correct obvious mistakes and accounting errors.
- 11.6. In the procedure, statements, applications, notifications and information shall be submitted by the Contracting Authority and the Tenderer in Polish or in English.
- 11.7. All notices, statements, requests and information provided in electronic form shall require immediate confirmation of receipt at the request of each party.
- 11.8. If the Tenderer does not confirm receipt of the correspondence, the Contracting Authority presumes that the correspondence sent to the e-mail address provided by the Tenderer in the offer form and via the Competitiveness Database through the "Questions" tab [<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>] has been delivered in a way that allows reading its content.
- 11.9. Correspondence related to these proceedings should be sent to the following e-mail address: [przetarg@bioton.com](mailto:przetarg@bioton.com)
- 11.10. In correspondence related to this procedure, the Tenderer should use the procedure number:  
**Request for Quotation No. 2.2 QTPP and non-clinical studies needed for the registration of the medicinal product Insulin N in EMA**

## XII. PROCEDURE FOR EVALUATING OFFERS AND ANNOUNCING RESULTS

- 12.1. The Contracting Authority reserves the right to additionally verify the credibility of the documents, statements, lists, data and information presented by the Tenderer in the course of the evaluation of the offer.
- 12.2. Information about the result of the procedure will be published on the request for proposal page on the Competitiveness Database website in the "Offers" tab [<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>].
- 12.3. The selected Tenderer will be informed by phone or e-mail about the date and place of signing the contract.
- 12.4. If the Tenderer whose offer has been selected does not proceed to conclude the contract, the Contracting Authority has the right to sign the contract with the Tenderer whose bid has received the next highest number of points, without conducting another bid procedure. The provisions of Section 8.4 shall apply mutatis mutandis.

## XIII. AMENDMENT OF THE AGREEMENT

- 13.1. The Contracting Authority reserves the right to make significant changes to the provisions of the concluded contract in relation to the content of the offer, on the basis of which the Contractor was selected, in the following scope and situations:
  - 13.1.1. changes in the provisions of the European Union law or national law to the extent affecting the performance of the Agreement (in particular changes in VAT rates);

- 13.1.2. extension of the deadline for the performance of the contract due to the need to perform additional works, the performance of which is necessary for the proper performance of the contract, and the performance of which the Contracting Authority, acting with due diligence, could not have foreseen in advance;
  - 13.1.3. extension of the deadline for the performance of the order as a result of force majeure occurrence of a fortuitous event caused by external factors that could not have been predicted with certainty, in particular directly threatening human life or health or threatening to cause significant damage;
  - 13.1.4. extension of the deadline for the performance of the contract due to the actions of third parties preventing the performance of works, which are not a consequence of the fault of any of the parties to the contract. Each time, the change of the order performance date depends on its acceptance by the Contracting Authority and, possibly, the intermediary institution in financing the project (in accordance with the provisions of the grant agreement).
  - 13.1.5. extension of the deadline for the performance of the contract in the event of the occurrence of another legal, economic or technical circumstance that is unforeseeable at the time of conclusion of the contract, for which neither party is responsible, resulting in the inability to properly perform the contract, in accordance with the provisions of the request for proposal.
  - 13.1.6. extension of the deadline for the performance of the contract for other reasons beyond the Contractor's control;
  - 13.1.7. changes listed in section 3.2.4 point 4 of the Guidelines on the eligibility of expenditure for 2021-2027.
- 13.2.** The Contracting Authority also provides for the possibility of making insignificant changes to the provisions of the concluded contract in relation to the content of the offer on the basis of which the Contractor was selected.
- 13.3.** Amendments to the contract will be introduced in the form of an annex signed by both parties, and the possibility of their introduction depends on the acceptance by the Contracting Authority.

#### **XIV. OTHER INFORMATION**

- 14.1.** The Contracting Authority reserves the right to change or supplement the content of the request for proposal before the deadline for submitting offers. Information about the introduction of changes or additions to the content of the request for proposal will be published in the places where the request is published.
- 14.2.** If the introduced changes or additions to the content of the request for proposal require a change in the content of the offers, the Contracting Authority will extend the deadline for submitting offers by the time needed to make changes to the offer.
- 14.3.** In the event of any discrepancies between the content of this document and the content of the announcement appearing in the Competitiveness Database form, the content of this document shall prevail. In the event of any discrepancies between the content of this document and the content of other documents included in the tender documentation, the content of this document shall prevail.
- 14.4.** The Tenderer bears all costs related to the preparation and submission of the offer.
- 14.5.** The Contracting Authority does not accept partial or variant offers.
- 14.6.** The Tenderer submitting the offer remains bound by it for a period of 90 days from the date of expiry of the deadline for submitting the offer.



- 14.7. The selection of the most advantageous offer does not mean that the Contracting Authority incurs an obligation to conclude a contract with the Contractor.
- 14.8. The Contracting Authority reserves the right to award the Contractor additional contracts, not covered by the subject of the basic contract, in the amount not exceeding 50% of the value of the subject of the basic contract, necessary for its proper performance and resulting m.in:
- for technical or economic reasons, separating the additional contract from the subject of the basic contract would require incurring disproportionately high costs,
  - the performance of the subject of the basic contract depends on the performance of the additional contract.
- 14.9. The Contracting Authority reserves the right to award the Contractor a supplementary contract (in accordance with the description of the subject of the basic contract) in the amount not exceeding 50% of the value of the basic contract specified in the contract concluded with the Contractor.

#### 14.10. PERSONAL DATA PROTECTION

With regard to personal data included in the offers, the Contracting Authority will become the controller of such data within the meaning of Article 4(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR"). The Contracting Authority will process this data for the purpose of evaluating Offers, concluding a contract with the selected Contractor and for the purposes of performing the concluded contract, i.e. on the basis of Article 6(1)(b) of the GDPR.

The contracting authority will transfer personal data contained in the submitted offers, on the basis of relevant legal provisions, to authorized bodies and institutions authorized to control projects co-financed from the European Union budget. These data will be transferred to the Unit supporting the implementation of the Investment – the Medical Research Agency, and their administrator will be the Director of the Medical Research Agency (in accordance with Appendix No. 15 to the competition regulations), the Minister of Development Funds and Regional Policy (in accordance with Appendix No. 16 to the competition regulations), the Minister of Health (in accordance with Appendix No. 17 to the competition regulations).

The contracting authority will process personal data for the period in which it is obliged by applicable law to store all documentation related to the project co-financed from the EU budget. The Contractor undertakes to fulfil the information obligation on behalf of the Employer by providing each of the Contractor's staff members, whose data have been provided to the Employer in connection with the conclusion and performance of this contract, information on how the Employer processes their data, including information on the rights of natural persons, specified in the Employer's Information Clause, which will constitute an appendix to the contract, and the content of which will be substantially consistent with the content of the clause attached to this inquiry as Appendix No. 3.

#### 14.11. The Contracting Authority stipulates that:

- has the right not to select any of the submitted offers,
- has the right to cancel the tender procedure at any time without giving a reason or informing the Tenderer in advance,
- has the right to change or supplement the documents included in the request for proposal, which will become its integral part,
- may extend the deadline for submission of tenders,

however, the Tenderer is not entitled to any claims against the Contracting Authority on the above grounds.

## XV. LIST OF ATTACHMENTS

The attachments to this request for proposal are the following documents:

Attachment designation	Attachment Name
Appendix No. 1	Template of the offer
Appendix No. 2	Scope of work with expected completion date
Appendix No. 3	Data protection