

REQUEST FOR PROPOSALS No 2025-60180-218170**I. NAME AND ADDRESS OF THE CONTRACTING AUTHORITY**

JJP Biologics Sp. z o.o.
ul. Bobrowiecka 6
00-728 Warszawa

II. MODE OF CONTRACT AWARD AND TYPE OF CONTRACT

The proceedings are being conducted in connection with the execution of a project entitled "Extension of a Phase I clinical trial to include a cohort of LAD patients as a step in the development of JJP-1212 (drug candidate)", for which the Contracting Authority is applying for funding under the National Recovery and Resilience Plan, Component D "Efficiency, accessibility and quality of the healthcare system", Investment D3.1.1 "Comprehensive research development in medical and health sciences", competitive mode (hereinafter referred to as the project).

The proceedings are conducted in accordance with the principle of competitiveness as defined in the document "Catalog of Eligible Expenditure" that constitutes Appendix No. 12 to the Terms and conditions for the selection of projects to receive support under the National Recovery and Resilience Plan, Component D "Efficiency, accessibility and quality of the healthcare system", Investment D3.1.1 "Comprehensive research development in medical and health sciences", competitive mode.

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

The announcement is conditional - the contract with the successful bidder will come into effect on condition of a positive audit covering the Bidder's facilities and standard operating procedures (the audit will not be required if the supplier was previously audited and qualified by JJP less than 3 years ago). Upon completion of the bidding process, a Conditional Agreement will be executed. The contract will enter into force on the date of fulfillment of the conditional.

III. CONTRACT SPECIFICATION

III.1. Category: Service

III.2. Subcategory: Research services

III.3. The object of the contract is the provision of supply chain services for collecting the Drug Product (DP) and Investigational medicinal product (IMP), relabelling of DP and IMP for new cohort in ongoing clinical trial and delivery to the destination points, in particular the arrangement of all aspects of the transportation, logistics, delivery process and labelling, ensuring timely, safe, and cost-effective movement of goods.

III.4. A detailed description of the order subject, is attached as Appendix 2 to this request for proposals.

III.5. Appendix 2 is subject to protection as business secrets within the meaning of the provisions of the Act on Combating Unfair Competition of 16 April 1993 (Polish Journal of Laws of 2022, item 1233, as amended), and its transfer requires the execution of an appropriate non-disclosure agreement (NDA), attached as Appendix 3 to this request for proposals.

Appendix 2 will be made available by the Contracting Entity within 1 business day after receiving by email the non-disclosure agreement signed with an electronic signature (e.g.

DocuSign) or a scanned copy with wet ink signature. The contract must be filled and signed by a person authorized to represent the Bidder or holding the appropriate power of attorney. The power of attorney and/or an excerpt from the relevant register, confirming representation authority, must be attached to the non-disclosure agreement.

The signed non-disclosure agreement should be sent to the e-mail address: tenders@jpp.bio not later than 2 working days prior to the bids submission deadline.

- III.6.** All results of the services and their copies (including in particular the documentation related to the process and product) and the intellectual property rights to them, including in particular sui generis database rights and industrial property rights, shall belong to the Ordering Party. To the extent that these rights do not arise initially in favor of the Ordering Party, they will be transferred to the Ordering Party at the earliest time permitted by law and to the widest extent permitted by law, without temporal and territorial restrictions, under the remuneration of the Contractor. As part of the Contractor's remuneration, the Contractor shall also unconditionally and exclusively transfer to the Ordering Party all economic copyright, related rights, and derivative rights to all works as defined in the Copyright and Related Rights Act created in the course of providing the services, regardless of the manner of their fixation and form of expression, to the widest extent permitted by law, without territorial and temporal restrictions, in all fields of exploitation known at the time of the conclusion of the agreement, and in particular the fields of exploitation referred to in Articles 50 and 74(4) of the Copyright and Related Rights Act. Documentation created during the provision of the service must be transferred to the Contracting Entity at the expense of the Bidder. Details of how and when the documentation will be transferred will be established in the contract concluded with the selected Contractor.
- III.7.** The announcement is conditional - the contract with the successful bidder will come into force on the condition of a positive result of an audit covering the Bidder's facilities and standard operating procedures (if necessary - the audit will not be required if the supplier was previously audited and qualified by JJP less than 3 years ago), according to the schedule:
- audit by the end of May 2025 at the latest.
The auditor will be selected and paid by the Procuring Entity. The cost of preparing and hosting the auditors is the responsibility of the Contractor.
- III.8.** Category of the subject of the contract according to the Common Procurement Vocabulary (CPV):

73000000-2 - Research and development services and related consultancy services

IV. PLACE OF CONTRACT PERFORMANCE

The place of contract performance will be in Poland, as well as in other selected European countries, as specified in the detailed description of the order subject (see Appendix no. 2).

V. CONTRACT COMPLETION AND PAYMENT TERMS

- V.1.** Order lead time, according to the current project schedule *:
- a). for label generation in polish: till May 2025
 - b). for label generation in other languages: till July 2025
 - c). for labelling for polish site is June 2025
 - d). for labelling for sites in other EU countries till July 2025.
 - e). shipment of IMP to polish site need to be finalized till July 2025.
 - f). shipment of IMP to foreign sites need to be finalized till August 2025.
- V.2.** Planned contract conclusion date: April 2025

V.3. The Contracting Entity allows for the possibility of remitting partial payments.

** please note that these periods are only estimates, cause they depend on the moment of CTA approval*

VI. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS AND GROUNDS FOR EXCLUSION

CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS.

VI.1. Bidders who meet the following conditions may apply for the contract:

6.1.1. license to carry out specific business or activities

The Contracting Authority will consider that the Bidder meets this requirement if the Bidder declares that the Bidder possesses the necessary licences and authorisations to carry out a specific professional activity, as required by the relevant regulations, necessary for the proper execution of the contract, including manufacturing authorization in the scope of labelling and shipment of IMP including relevant GMP certificate for both scopes

Condition verification manner:

Verification shall be based on the Bidder's statement on the fulfillment of the conditions for participation in the proceedings, included in Appendix 1 (Bid Form) and based on copies of manufacturing authorization and relevant GMP certificates for both scopes of services

6.1.2. knowledge and experience

The Contracting Entity shall consider that the Bidder meets this requirement, should the Bidder submit a statement that the Bidder has the knowledge and experience necessary for the proper execution of the contract and declare that the Bidder has at least 5 years' experience in the field of supply chain for the pharmacy sector.

Condition verification manner:

Verification shall be based on the Bidder's statement on the fulfillment of the conditions for participation in the proceedings, included in Appendix 1 (Bid Form).

6.1.3. technical potential

The Contracting Entity shall consider, that the Bidder meets this requirement, should the Bidder submit a statement that they have access to technical facilities necessary for the proper execution of the contract, including in particular:

- a. the capacity to transport the drug product to sites in EU countries named in Attachment no 2, while adhering to all applicable regulatory criteria.
- b. possibility to relabel vials with DP in conditions described in Attachment 2
- c. possibility to store vials with DP in 2-8 C

Condition verification manner:

Verification shall be based on the Bidder's statement on the fulfillment of the conditions for participation in the proceedings, included in Appendix 1 (Bid Form).

6.1.4. **economic and financial standing**

The Contracting Entity shall consider, that the Bidder meets this requirement, should the Bidder submit a statement that their economic and financial standing ensure proper execution of the contract; this includes, but shall not be limited to there being no pending bankruptcy, restructuring or liquidation proceedings against the Bidder.

Condition verification manner:

Verification shall be based on the Bidder's statement on the fulfillment of the conditions for participation in the proceedings, included in Appendix 1 (Bid Form).

GROUND FOR EXCLUSION FROM PARTICIPATION IN THE PROCEEDINGS

VI.2. Prerequisites for exclusion

6.2.1. Entities with personal or equity relationships with the Contracting Entity shall be excluded from participation in the proceedings.

Equity and personal relationships shall be defined as mutual relations between the Contracting Entity or the persons authorized to draw liabilities on behalf of the Contracting Entity or the persons performing activities connected with preparing and conducting the contractor selection procedure on behalf of the Contracting Entity on the one hand, and the Bidder on the other, including but not limited to:

- a) participation in an enterprise as a partner of a civil law partnership or a partnership,
- b) holding at least 10% of stock or shares, unless a lower threshold is required by law;
- c) serving the function of a member of a supervisory or managing authority, proxy or attorney in fact;
- d) remaining in a relationship of marriage, direct consanguinity or affinity, secondary consanguinity or affinity up to the second degree or an adoptive relationship, custody or guardianship;
- e) remaining in a cohabitation relationship with the Bidder, their legal representative or members of the management or supervisory bodies of the Bidder applying for the award of the contract;
- f) remaining in such a legal or factual relationship with the Bidder that could give rise to justified doubts as to whether they are impartial or independent in connection with the proceedings for the award of the contract.

Manner of verification of grounds/absence of grounds for exclusion:

Verification shall be based on a statement of the Bidder included in Appendix 1 (Bid Form), as well as statements of the Contracting Entity and persons performing activities on behalf of the Contracting Entity related to the preparation and conduct of the contract award procedure.

6.2.2. Entities that are subject to the following circumstances shall also be excluded from the proceedings:

- a) as defined under Article 7 section 1 of the Act of 13 April 2022 on special solutions to prevent support for the aggression against Ukraine and to protect national security;
- b) as defined under Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Official Journal of the EU No. L 229 of 31 July 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 destabilizing the situation in Ukraine (Official Journal of the EU No. L 111 of 8 April 2022, p. 1; as amended).

Manner of verification of grounds/absence of grounds for exclusion:

Verification will be based on the Bidder's statement included in Appendix 1 (Bid Form).

- VI.3.** Only bids from bidders who meet the required conditions and are not subject to exclusion will be considered and evaluated. Fulfilment of the conditions presented above will be evaluated according to the formula: 'fulfils - does not fulfil'. A bidder who does not meet any of the conditions will be excluded from the procedure and his bid will be rejected. Incomplete bids or bids that do not comply with the subject of the request for quotation will be rejected. (Subject to the one-time possibility of supplementing the submitted documents, as referred to in point XI.4).

VII. DESCRIPTION OF THE MANNER OF CALCULATING THE PRICE

- VII.1.** The price should be calculated as net and gross values and entered into the bid form.
- VII.2.** Prices expressed in a currency other than PLN shall be converted into PLN according to the average exchange rate of the National Bank of Poland on the day the deadline for submitting offers ends.
- VII.3.** **The price should include all the costs associated with the execution of the object of the contract.**
- VII.4.** Should the offered price or cost seem to be grossly understated compared to the object of the contract, i.e. differ by more than 30% from the arithmetic mean of the prices of all valid bids that are not subject to rejection or give raise to doubts on the part of the Contracting Entity as to whether it would be possible to perform the object of the contract as per the requirements stipulated in the request for proposals or as results from separate regulations, the Contracting Entity shall request the Bidder to submit explanations by a designated deadline, including the submission of evidence concerning the manner of calculation of the price or cost. The Contracting Entity shall assess these explanations in consultation with the Bidder and may reject the bid only where the explanations submitted along with the evidence do not substantiate the price or cost submitted in the particular bid.

VIII. DESCRIPTION OF THE CONTRACTING AUTHORITY'S BID SELECTION CRITERIA

- VIII.1.** When evaluating bids, the Ordering Party shall use the following criteria:

- Price – 100%

- VIII.2.** The score for the "Price" criterion (PC) will be calculated according to the following formula:

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

where:

- P_C - score for the "Price" criterion
- C_N - the lowest total net price from among the bids that are not rejected
- C_B - total net price of the examined bid

- VIII.3.** The bid that is awarded the highest score will be considered the most advantageous. The maximum score a bid may be awarded is 100 points. Calculations shall be made with two decimal places of accuracy.

VIII.4. If the highest number of points is awarded to more than one bid, the Contracting Authority will call on the Bidders who submitted these bids to submit additional bids, in which they will specify a new price. The price specified in the additional bid must not be higher than the price originally offered.

IX. PLACE AND DATE OF SUBMISSION AND OPENING BIDS

- IX.1.** Bids must be submitted by **March 14,2025**
- IX.2.** The bid must be submitted electronically through the Competitiveness Base service, in accordance with the requirements of the "Bidder's Instructions in BK2021"[https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction] in the form of documents signed by the Bidder or their scanned copies, in accordance with the requirements described under Section X.3.
- IX.3.** Whether the deadline has been adhered to shall be determined based on the date and time of submission of the bid to the Competitiveness Base service.
- IX.4.** Bids submitted in a manner other than described above shall not be considered.
- IX.5.** The Contracting Entity does not intend to open the bids publicly.

X. DESCRIPTION OF THE MANNER OF DRAFTING A PROPOSAL:

- X.1.** A Bidder may submit one bid. The submission of two or more bids will result in the rejection of all bids submitted by the Bidder.
- X.2.** A bid should be drafted in Polish or English. Documents written in a different language must be submitted together with a translation into Polish or English (a certified translation is not required).
- X.3.** Appendix No. 1 to the request for proposals - the Bid Form must be signed by persons authorized to represent the Bidder in accordance with the representation rules resulting from the entry into the relevant register or pursuant to a granted power of attorney.
- X.4.** If the person(s) signing the bid (representing the Bidder) is acting under a power of attorney, the power of attorney must be attached to the bid.
- X.5.** The bid must include the following components:
- a) Bid Form (drafted in accordance with Appendix No. 1 to the request for proposals);
 - b) statements and documents resulting from the provisions of Chapter VI of the request for proposals;
 - c) power of attorney to act on behalf of the Bidder (if applicable).
- X.6.** Should the Bidder include in their bid offer information that constitutes a business secret within the meaning of the Act on Combating Unfair Competition of 16 April 1993, they should clearly indicate which sections of the bid constitute a business secret and cannot be disclosed to third parties.
- X.7.** Prior to the deadline for submission of bids, the Bidder may amend their submitted bid or withdraw it. Amendments to the bid or its withdrawal shall be subject to the same conditions as its submission.
- X.8.** Bidders shall be required to carefully review the information contained in the request for proposals, as well as any amendments thereto, clarifications and responses published by the Contracting Entity during the proceedings and draft their bids in accordance with the requirements specified by the Contracting Entity.

XI. MANNER OF THE CONTRACTING AUTHORITY'S COMMUNICATION WITH BIDDERS

- XI.1.** No information, clarification or response to inquiries addressed to the Contracting Entity by telephone or e-mail shall be provided, except for the transmission of sensitive information in accordance with Section III.4. of the request for proposals, which shall be transmitted by e-mail.
- XI.2.** Questions regarding the request for proposals and requests for clarifications regarding the content of the request for proposals should be sent only through the Competitiveness Base via the "Questions" tab on the website of the request for proposals [<https://bazakonkurencyjnosci.fundusze europejskie.gov.pl/>], no later than 2 working days before the bids submission deadline.
- XI.3.** The Contracting Entity shall only provide responses to questions from Bidders and clarifications to the content of the request for proposals by publishing the content of the questions/requests for clarifications along with the provided answers/clarifications on the website of the request for proposals in the Competitiveness Base service [<https://bazakonkurencyjnosci.fundusze europejskie.gov.pl/>].
- XI.4.** Provided that this does not violate competition rules, in the course of examining the bids, the Contracting Entity shall have the right to request clarifications from Bidders regarding the content of submitted bids and to supplement documentation.
- XI.5.** The Contracting Entity shall have the right to request the Bidder to agree to correct obvious mistakes and calculation errors.
- XI.6.** Statements, requests, notifications and information under the proceedings shall be submitted by the Contracting Entity and Bidders in Polish or English.
- XI.7.** Any and all notices, statements, requests and information transmitted in electronic form shall require, at the request of either party, immediate acknowledgement of receipt.
- XI.8.** Where the Bidder fails to acknowledge receipt of correspondence, the Contracting Entity shall presume that correspondence sent to the email address provided by the Bidder in the bid form and through the Competitiveness Base service via the "Questions" tab [<https://bazakonkurencyjnosci.fundusze europejskie.gov.pl/>] has been delivered in a manner that makes it possible to review its contents.
- XI.9.** Correspondence related to these proceedings shall be sent to the following e-mail address: tenders@jpp.bio
- XI.10.** Bidders shall use the proceedings number in any correspondence related to these proceedings: Request for proposals No 2025-60180-218170.

XII. BIDS EVALUATION AND RESULTS ANNOUNCEMENT PROCEDURE

- XII.1.** The Contracting Entity reserves the right to additionally verify, in the course of bid evaluation, the credibility of the documents, statements, lists, data and information presented by the Bidders.
- XII.2.** Information on the outcome of the proceedings shall be published on the website of the request for proposals in the Competitiveness Base service under the "Bids" tab [<https://bazakonkurencyjnosci.fundusze europejskie.gov.pl/>].
- XII.3.** The selected Bidder shall be informed by phone or email about the date and place of signing the contract.
- XII.4.** Where the Bidder whose bid was selected does not proceed to the conclusion of the contract, the Contracting Entity shall have the right to sign the contract with the Bidder whose bid

received the next highest number of points, without conducting a new tender procedure. The provisions of Section VIII.4 shall apply accordingly.

XIII. CONTRACT AMENDMENT

XIII.1. The Contracting Entity reserves the right to introduce significant amendments to the provisions of the contract compared to the content of the bid, on the basis of which the Contractor was selected, within the following scope and in the following situations:

- 13.1.1. amendments to the European Union law or national law to an extent affecting the implementation of the Contract (including, but not limited to amendments of VAT rates);
- 13.1.2. to improve the technical parameters of the subject of the contract, without affecting the net lump sum price;
- 13.1.3. to extend the contract performance deadline 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 Entity, acting with due diligence, could not have foreseen earlier;
- 13.1.4. to extend the contract performance deadline due to Force Majeure, with all the consequences resulting from the extension;
- 13.1.5. to extend the contract performance deadline for other reasons beyond the control of the Contractor;
- 13.1.6. to amend the parameters of the subject matter of the contract, amend the material scope of the contract and to amend the manner of performing the contract without changing in the nature of the contract, in situation where the use of the previously indicated solutions would threaten non-performance or defective performance of the contract;
- 13.1.7. justified changes or additions to the scope of the contract and the subject of the research service (especially changes in timelines, changing the number of countries, removing a currently listed country, adding a new country), due to the nature of the subject of the Contract (R&D work);
- 13.1.8. changes listed in section 7.3 point 22 of the document 'Catalogue of eligible expenses'.

XIII.2. The Contracting Entity also provides for the possibility of introducing non-material amendments to the provisions of the contract compared to the content of the bid, on the basis of which the Contractor was selected.

XIII.3. Amendments to the contract shall be made in the form of an annex signed by both parties, and the possibility of their introduction is subject to the approval of the Contracting Entity.

XIV. OTHER INFORMATION

XIV.1. The Contracting Entity reserves the right to amend or supplement the contents of the request for proposals prior to the bids submission deadline. Information on any amendments or additions to the content of the call for proposals shall be published in the same places where the request for proposals was published.

XIV.2. Should the amendments or additions introduced into the content of the request for proposals require amendments to the content of the bids, the Contracting Entity shall extend the bids submission deadline by the time required to introduce amendments to the bid.

XIV.3. In the event of a discrepancy between the content of this document and the content of the announcement appearing in the Competitiveness Base form, priority shall be attached to the content of this document. Should there be 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 be binding. In case of discrepancies between language versions, the Polish version of the documentation shall prevail.

XIV.4. The Bidder shall bear any and all costs related to drafting and submitting their bid.

XIV.5. The Contracting Entity does not allow partial nor variant bids.

XIV.6. A Bidder submitting a bid shall remain bound by it for a period of 60 days counting from the deadline for submission of the bid.

XIV.7. Selection of the most favorable bid does not create a commitment on the part of the Contracting Entity to enter into a contract with the Contractor.

XIV.8. The Contracting Entity reserves the right to place additional orders with the Contractor, not included in the subject of the basic order, for an amount not exceeding 50% of the value of basic order, as necessary for their proper execution and resulting from, among others:

- where for technical or economic reasons the separation of the additional order from the basic order would require incurring disproportionately high costs;
- where performance of the basic order is dependent on the performance of the additional order.

XIV.9. The Contracting Entity reserves the right to award a supplementary contract to the Contractor (consistent with the description of the basic contract) in an amount not exceeding 50% of the value of the basic contract, as specified in the contract concluded with the Contractor.

XIV.10. PROTECTION OF PERSONAL DATA

With respect to personal data contained in bids, the Contracting Entity shall, upon submission of a bid, become the controller of such data within the meaning of Article 4 section 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 flow of such data and repealing Directive 95/46/EC ("GDPR"). The Contracting Entity shall process the data for the purpose of evaluating bids, concluding a contract with the selected Contractor and for the purpose of performing the concluded contract, i.e. on the basis of Article 6(1)(b) of the GDPR.

The Contracting Entity shall provide personal data contained in the submitted bids, subject to the relevant provisions of law, to authorized bodies and institutions authorized to inspect projects co-financed from the budget of the European Union. The data will be transferred to the Investment Support Unit - the Medical Research Agency, while the Director of the Medical Research Agency shall remain the controller for such data (in accordance with Appendix No. 15 to the competition terms and conditions), the Minister of Funds and Regional Policy (in accordance with Appendix No. 16 to the competition terms and conditions), the Minister of Health (in accordance with Appendix No. 17 to the competition terms and conditions).

The Contracting Entity shall process personal data for the period for which the applicable legal provisions impose onto them the obligation to retain all documentation related to a project co-financed from the EU budget. The Contractor agrees to discharge the disclosure duty on behalf of the Contracting Entity by providing each member of the Contractor's staff, whose data has been provided to the Contracting Entity in connection with the conclusion and performance of this contract, with information on how the Contracting Entity processes their data, including information on the rights of individuals, as set forth in the Contracting Entity's Information Clause, which shall be attached to the contract and the content of which shall be substantially consistent with the content of the clause attached to this inquiry as Appendix No. 4.

XIV.11. The Contracting Entity stipulates that:

- they shall have the right not to select any of the bids submitted;

- they shall have the right to cancel the bidding proceedings at any time without giving any reason or prior notice to Bidders;
- they shall have the right to amend or supplement the documents included in the request for proposals, which shall become an integral part thereof;
- they shall be authorized to extend the deadline for submission of bids,

whereby the Bidder shall not be entitled to any claims against the Contracting Entity on the above grounds.

XV. LIST OF APPENDICES

The following documents are attached to this request for proposals:

Appendix Designation	Appendix Name
Appendix no. 1	Template bid form
Appendix no. 2	Detailed Description of the Contract Subject (see section III.4)
Appendix no. 3	NDA - Non-Disclosure Agreement
Appendix no. 4	Information clause