Request for Bids No. 01/WPD107/2020

announced on the 07th August 2020

on the implementation of the project under working title: "*Development of an innovative drug candidate for the treatment of solid tumor metastasis to the lungs"* applying for funding in the competition "Fast track" under the Smart Growth Operational Program 2014-2020, Priority I Support for R&D work by enterprises, Measure 1.1 R&D projects of enterprises, Sub-measure 1.1.1 Industrial research and development works carried out by enterprises, Competition No. 6/1.1.1/2020.

I. Awarding Entity.

Awarding Entity's name and address:

WPD Pharmaceuticals sp. z o. o. with its registered office in Warsaw

address: ul. Żwirki i Wigury 101, 02-089 Warsaw

entered in the Register of Entrepreneurs of the National Court Register kept by the District Court for the capital city of Warsaw in Warsaw, 12th Commercial Division of the National Court Register, under No. KRS 0000693186, Tax ID No.: 5252721500, initial capital of PLN 888 950

Phone: +48 515 262 381

www.wpdpharmaceuticals.com

Awarding Entity's authorized representative:

Mariusz Olejniczak – President of the Management Board

Contact person for the Request for Bids authorized by the Awarding Entity:

Mariusz Olejniczak

e-mail: oferty@wpdpharmaceuticals.com

II. Contract award procedure

The contract award procedure will be organized as a request for bids compliant with the Competitiveness Rule set out in the *Guidelines on the Eligibility of Expenses under the European Regional Development Fund, European Social Fund and Cohesion Fund for 2014-2020* of 22 August 2019, version valid from 09 September 2019 (reference no.: MIiR/2014-2020/12(4)), issued pursuant to Article 5(1) of the Act of 11 July 2014 on the rules of implementation of cohesion policy programs funded in the 2014-2020 financing perspective (consolidated text: Journal of Laws of 2018, item 1431), available from:

https://www.poir.gov.pl/strony/o-programie/dokumenty/wytyczne-w-zakresie-kwalifikowalnosci-wydatkow-w-ramach-europejskiego-funduszu-rozwoju-regionalnego-europejskiego-funduszu-spolecznego-oraz-funduszu-spojnosci-na-lata-2014-2020/.

.

III. Description of the Contract Object.

1. **Order type:** service
2. **Name and code according to the Common Procurement Vocabulary (CPV):**

   Research services

   CPV: 73110000-6

3. **Contract Object.**

   1) The contract object is a research service, involving the synthesis of an active pharmaceutical ingredient (API) which is a doxorubicin analog (hereinafter referred to as the "Product"), for the purpose of the planned research and development work and for clinical trial, as well as preparation of documentation compliant with the EU GMP regulations for this active pharmaceutical ingredient (API).

   2) The Product must be wholesome, free from any physical and legal defects or damage and must meet European regulatory requirements of Good Manufacturing Practice (GMP) for active pharmaceutical ingredients and medicinal products, as well as must have appropriate documentation, including Qualified Person (QP) release, according to the Article 48 of Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67, with updates).

   3) Contractor will provide the Product at his own expense and risk in conditions in accordance with specification, along with the necessary documentation, including release certificate (for batches manufactured in the GMP standard), confirming that the Product meets the requirements specified in the Article 48 of Directive 2001/83/EC.

   4) The scope of the service has been presented in the form of two (**2**) task Packages:

      a) **Package No 1** – Synthesis of the key intermediate material – which is an intermediate necessary for API synthesis, in accordance with cGMP guidelines and QA release for the purpose of API synthesis;

      b) **Package No 2** – Synthesis of the active pharmaceuticals ingredient (API), which is a small molecular weight cytotoxic compound – a doxorubicin analog (High potent API), with the use of the key intermediate, in cGMP standard with preparation of complete regulatory documentation necessary for the active pharmaceutical ingredient and the analytical standards in adequate format.

   5) The scope of the service within **Package No. 1** includes, in particular:

      - Synthesis of the target molecule – the key intermediate - in 2 kg scale from the starting material (all steps must be carried out under GMP) with analysis of raw materials in accordance with specification;
      - Preparation of batch manufacturing records and cGMP report;
      - Analysis of intermediates against specifications;
      - Analysis of final product in accordance with release specification and preparation of documentation, including Certificate of Analysis (CoA)
      - Complete documentation preparation including quality review and release of the GMP batch;

- Submitting a copy of all documentation developed during the service implementation in Package No 1 in electronic systems provided by the Awarding Entity.

6) The scope of the service within **Package No. 2** includes, in particular:

- Production of 200 grams of the API (cytotoxic, high potent) with the use of the key intermediate material prepared in Package No 1; Contractor should deliver to the Awarding Entity at least 10 grams of the material produced in the non-GMP standard as a technical batch, for the purpose of in vitro studies and at least 190g of the API produced in accordance with the GMP standard (in three (3) batches) in accordance to the specification, for the clinical trial purpose,; Contractor should assess the total amount of the product taken into consideration stability and analytical studies implementation.
- 1, 3, 6 and 12-month and accelerated (0, 3 and 6-month) stability studies in solid phase and / or in solutions, in accordance with the international ICH Guidelines;
- Analytical methods validation in GLP standard for the purpose of analytical testing and stability studies;
- Qualitative analysis of the product including identification and determination of the organic impurities and residual solvents, with the preparation of the analytical report and Certificate of Analysis (CoA);
- Establishment and characterization of a reference standards (analytical standards) for the small molecular weight cytotoxic compound (reference standard of the API and its main metabolite), with the complete documentation including Certificate of Analysis (CoA);
- Primary and secondary packaging as well as labeling with complete documentation (including certificates of conformity);
- Storage of the Product in GMP compliant conditions for 12 months in accordance with specification;
- Product release by the Qualified Person for the purpose of formulation studies and clinical trials with complete documentation;
- Preparation of complete ASMF documentation, in accordance with EU GMP standards for the regulatory purposes in the right format (3.2.S module) and submitting a copy of all documentation developed during the service implementation in Package No 2 in electronic systems provided by the Awarding Entity.

NOTE: ***Packet No 2 is implemented under the condition of fully implemented tasks indicated in the Package No 1.***

7) The Ordering Party allows the preparation of documentation created as part of the service provided only in English.

8) The Ordering Party allows for submitting partial offers. Contractor may submit the bid only for one Package or for two Packages.

9) The Awarding Entity does not allow the submission of variant bids.

10) The awarding entity does not envisage awarding supplementary contracts within 3 years from the award of the basic contract.

IV. Order Delivery Date.

1. The Term for the delivery of the order shall remain valid for:

   • for Package 1 - up to 12 weeks, starting from the date of informing the Contractor by the Awarding Entity about signing the contract for project financing;

   • for Package 2 – up to 12 months, starting from the date of delivery of the key intermediate material prepared in Package No. 1, with complete documentation.

2. The object of the order will be deemed to be completed in full after the Ordering Party accepts each Package and all stages of the order carried out within the given Package, confirmed by delivery and acceptance protocols and no objections as to the manner of the contract implementation.

3. **The order will be implemented under the condition that the Awarding Entity concludes a contract for co-financing of the R&D project under the working title " *Development of an innovative drug candidate for the treatment of solid tumor metastasis to the lungs* " applying for funding in the competition "Fast track" under the Smart Growth Operational Program 2014-2020, Priority I Support for R&D by enterprises, Measure 1.1 R&D projects of enterprises, Sub-measure 1.1.1 Industrial research and development works carried out by enterprises, Competition No. 6/1.1.1/2020.**

4. A conditional agreement taking into account the essential provisions of the Request for Bids No. 01/WPD107/2020 will be concluded with the Contractor selected in this procedure, in accordance with the terms set out in Section XVI.

5. The Awarding Entity reserves the right to extend the provision of the conditional agreement template, and to sign additional working agreements with the selected contractor (if applicable).

V. Place of the order implementation.

1. The contract object will be implemented by the Contractor.
2. The contract object will be delivered by the contractor to the Awarding Entity headquarter at:

   WPD Pharmaceuticals Sp. z o.o.

   ul. Żwirki i Wigury 101

   02-089 Warszawa, Poland

VI. Contract award procedure participation terms.

1. In the contract award procedure may participate Contractors who:

   1) have the necessary knowledge and experience and have technical potential and people capable to perform the object of the order or present a written commitment of other entities to provide technical potential and persons capable to perform the object of the order, such as:

      a) for Package No 1:

      - The Awarding Entity requires the Contractor to have documented experience in the provision of services consisting on the synthesis of low-molecular weight organic compounds for the third parties, in particular experience in carrying out multi-stage (at least two-stage) synthesis of the low-molecular weight organic compounds and

optimization of the process. To confirm the above, it will be necessary for the Contractor to demonstrate duly completed at least (2) two contracts involving, in particular, a multi-stage (at least two-stage) synthesis and process optimization of the production of the low-molecular weight organic compounds;

- In terms of staff resources, the Awarding Entity requires the Contractor to have at his disposal or to engage persons with appropriate qualifications and experience for the execution of the contract, including at least (2) two persons with specialized education (pharmacy, chemistry or related fields, i.e. medicine, biological sciences), experienced in conducting organic synthesis and technologies for the production of active substances, as well as the development and validation of analytical methods and conducting analysis;
- In terms of technical potential, the Awarding Entity requires the Contractor to have appropriate technical facility dedicated to the synthesis of the low-molecular weight organic compounds in septic conditions and to have certificate of the European GMP standards for the production of the organic compounds and have other required by law documents for the production, analysis and storage of the organic compounds, such as valid authorization for manufacturing of the low-molecular weight organic compounds, issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor.

b) for Package No 2:

- The Awarding Entity requires the Contractor to have documented experience in the provision of services consisting of the synthesis of the low-molecular weight cytotoxic organic compounds (high potent API) in accordance with the GMP standard, intended for clinical trials for the third parties, in particular experience in conducting multi-stage (at least two-stage) synthesis of cytotoxic organic compounds and process optimization. To confirm the above, it will be necessary for the Contractor to demonstrate duly completed at least two (2) orders involving, in particular, multi-stage (at least two-stage) synthesis of the low-molecular weight organic cytotoxic compounds with high potency (high potent APIs) in the GMP standard, intended for clinical trials;
- The Awarding Entity requires the Contractor to have documented experience in development of documentation for active pharmaceuticals ingredients, in accordance with European GMP standards, including ASMF documentation, in particular module 3.S.2;
- In terms of staff potential, the Awarding Entity requires Contractors to have and engage to perform the contract persons with appropriate qualification and experience, including at least (2) persons with a specialized education in medicine, biotechnology, chemistry pharmacy or other related fields (e.g. biological science) having adequate knowledge and experience in the synthesis of cytotoxic organic compounds as well as in regulatory requirements and manufacturing standards for cytotoxic active pharmaceutical ingredients (including high potent APIs), and in development and validation of analytical methods and conducting analysis, as well as in preparation of registration documentation for active pharmaceutical ingredients consistent with the regulatory requirements applicable in the European Union, including EU GMP standards;
- In terms of technical potential, the Awarding Entity requires Contractor to have appropriate technical facility dedicated to the production of cytotoxic organic

compounds as API (including high potent API) in septic conditions and to have certificate of the European GMP standards for the production of the cytotoxic organic compounds and have other required by law documents for the production, analysis and storage of the cytotoxic organic compounds, such as valid authorization for manufacturing of the cytotoxic organic compounds, issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor.

2) are in financial and economic situation that will allow the contract object to be performed;

3) are not excluded from the contract award procedure.

2. Contractors, in order to confirm the fulfillment of the condition for participation in the contract award procedure, shall submit the declarations and documents indicated below:

1) The "Bid Form" completed in accordance with the specimen and signed by the Contractor, which constitutes Appendix 1 to the Request for Bids;

2) Declaration of the compliance with the requirements indicated in Section VI, point 1 of the Request for Bids, which constitutes Appendix 2 to the Request for Bids;

3) Declaration of no capital or personal links, which constitutes Appendix 3 to the Request for Bids: "Declaration of no capital or personal links;

4) List of services provided in accordance with the specimen indicated in paragraph 1, point 1) a, b, which includes:

   – Contract object (name of the service),

   – Scope and the purpose of the service (i.e. type of the compound, the amount produced, types of documents prepared),

   – Names of the entities for which the orders have been completed (or the country of origin, if providing name of the entity is not possible),

   – Order delivery date,

   which constitutes Appendix 4 to the Request for Bids: "List of the services";

5) In the scope of the possibility of involving people capable to perform the object of the order, in accordance with the requirements specified by the Awarding Entity, the Contractor shall present a list of persons together with their professional CVs, dedicated to perform the service, which constitutes Appendix 5 to the Request for Bids: "List of Persons";

6) Written declaration of a Qualified Person dedicated by the Contractor to perform the service, confirming authorization to release active pharmaceutical ingredients within the European Union, together with an indication of the possibility of confirming the data provided in the statement by means of publicly available register or data made available by relevant offices, by providing the www address of the registry website or office or other reliable source, which constitutes Appendix 6 to the Request for Bids: "Statement of a Qualified Person";

7) Documents (or certified true copies) confirming that the Contractor has an EU GMP certificate for the manufacturing of low-molecular weight cytotoxic organic compounds as API or equivalent, recognized by the European Union;

8) Other documents required by law (or certified true copies) related in particular to the production, analysis and storage of low-molecular weight cytotoxic organic compounds, including actual manufacturing authorization for the production of low-molecular weight

cytotoxic organic compounds issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor, recognized by the European Union, allowing confirmation of compliance with the requirements specified by the Awarding Entity in the description of the object of the order.

3. Submitted statements and documents should confirm that the conditions for the participation in the contract award procedure have been met for the date on the day of the deadline for the bid submission.
4. Assessment of compliance with the above conditions will be made in accordance with the formula "meets - does not meet", based on information contained in the submitted documents. The content of the submitted documents must clearly show that the abovementioned conditions are met by the Contractor.
5. Failure to complete at least one of the above conditions will result in exclusion of the Contractor from the contract award procedure.
6. The bid of the excluded Contractor shall be considered rejected. Awarding Entity shall notify the Contractor about the exclusion, stating the justification for the exclusion.
7. The Awarding Entity reserves the right to verify the proper performance of the services referred in paragraph 1 point 1) by calling the selected Contractor to present at the stage of signing the contract documents confirming the proper performance of the services indicate in the bid. As a proof that the order has been duly completed, the Awarding Entity shall consider references of other documents issued by the entity, for which the order has been completed, and in the event of objective reasons that such documents cannot be obtained, a statement of the Contractor.

VII. Grounds for exclusion from the contract award procedure.

1. Excluded from the contract award procedure shall be Contractors who:
   a) do not meet the conditions listed in Section VI;
   b) performed activities directly related to the preparation of the contract award procedure or used to prepare the bid with persons participating in these activities, unless the participation of these contractors does not hinder the fair competition;
   c) submitted false information affecting the outcome of the contract award procedure.
2. Contractors who have capital or personal links to the Awarding Entity shall also be excluded from participation in the contract award procedure; capital or personal links shall be understood as mutual ties between the Contractor and the Awarding Entity or persons authorized to incur obligations on behalf of the Awarding Entity, or persons performing any activities related to the contractor selection procedure on behalf of the Awarding Entity; such links shall in particular include:
   a) participation in the company in the capacity of a partner in a civil law company or partnership;
   b) ownership of at least 10% of shares or stock, provided that a lower threshold is not mandated under legal regulations or rules concerning the principles of implementation of the project covered by the Request for Bids,
   c) holding the function of a member of a supervisory or management body, a commercial representative or an attorney;

d) being married to or having lineal consanguinity or direct affinity, collateral consanguinity or affinity to the second degree to, or being adopted by, or being under the guard or custody of such persons,

or any other relationships which may result in the conflict of interests while awarding the contract and in the violation of the competition principle. Should any capital or personal links be revealed between the Contractor and the Awarding Entity, the contract shall not be awarded to the Contractor.

3. In order to demonstrate the absence of premises referred to in the paragraph 2, being the basis for excluding the Contractor from participation in the contract award procedure, the Contractor is obligated to submit together with the Bid Form, declaration of no capital or personal links, according to the specimen, which constitutes Appendix 3 to the Request for Bids: "Declaration of no capital or personal links".
4. Failure to submit the declaration referred to in paragraph 3 will exclude the Contractor from the contract award procedure. Excluding the Contractor from the contract award procedure means rejection of the Bid submitted by the Contractor.
5. The Awarding Entity may exclude the Contractor from the contract award procedure at any stage.

VIII. Bid evaluation criteria and method. Information on the weights assigned to particular criteria.

1. In selection the best offer the Awarding Entity shall evaluate the "Gross total price" criterion for the total gross prices of the Contract Object descripted in Section III(3) on the basis of the information supplied by the Contractor in the Bid Form.
2. The score for this criterion shall be calculated as follows:

$$\text{Score granted to the evaluated offer} = \frac{\text{Lowest bid price}}{\text{Evaluated bid price}} \times 100$$

3. The score will be expressed with the accuracy of up to two decimal places.
4. As a result of the evaluation, according to the criterion indicated in the clause 1 above, the bid may receive the score of maximum 100 points.
5. The most economic and best quality bid shall be the one which has not been excluded from the procedure and which receives the highest score during the evaluation.
6. The price shall be given in Polish zlotys (PLN) or any currency other than PLN.
7. The price must be expressed numerically with the accuracy of up to two decimal places and in words.
8. The price must include all the costs of the contract including all fees and taxes (including goods and services).
9. Any other costs which have been incurred by the Contractor while completing the order and have not been included in the bid price will not be additionally covered by the Awarding Entity.
10. Bids submitted by the foreign Contractors participating in the contract award procedure, who under other regulations are not obligated to pay VAT in Poland, contain prices without VAT (0% VAT). Tax liability in the situation of acquiring goods or services from foreign entities rests with

the Awarding Entity, in accordance with the provisions of the Value Added Tax Act. For the purpose of comparing the bids Awarding Entity will add to the bid price submitted by the foreign Contractors, the amount of VAT and custom duty (if applicable, for Contractors from outside the European Union), which are charged to the Awarding Entity for the performance of the contract.

11. For the purpose of comparing the bids the bid price in a foreign currency will be converted into PLN using the average exchange rate given by the National Bank of Poland (NBP) valid for the day of the request for bids publication in the Competitiveness Base. Average exchange rate is available at the NBP official web site: http://www.nbp.pl.
12. The price stated in the bid is not negotiable.
13. The prices stated in the bid shall remain valid throughout the entire period of its validity and shall be binding for the signed contract.
14. When the two or more bids receive the same score, the Awarding Entity will select the best offer by the criterion of positive environmental impact. Positive environmental impact may be demonstrated by, for example:
    - the use of solutions that reduce energy consumption during service performance or during the operation of the object of the contract,
    - the use of solutions that reduce or eliminate the amount of waste generated during the service performance or during the operation of the object of the contract,
    - the use of solutions that reduce the consumption of consumables during the service performance or during the operation of the object of the contract,
    - other.

    The Contractor may indicate and describe any number of solutions having a positive impact on the environment, indicating technical parameters that allow verification of the declared impact in comparison with standard solutions.

    The bid may receive (1) one point for each solution indicated regarding positive environmental impact. If no solution is indicated or solution is indicated but without technical parameters allowing verification of the declared environmental impact in comparison with standard solutions, the bid will not receive a point.
15. The Awarding Entity shall award the contract to the Contractor whose bid received the highest score during the evaluation process.

IX. Bid preparation method.

1. The bid must be prepared using the form which constitutes Appendix 1 to the Request for Bids - "Bid Form".
2. The content of the submitted bid must be consistent with the Request for Bids and it must include all of the required documents and declarations indicated in the Section VI. Contractor shall submit with the Bid:
    a) Declaration of the compliance with the requirements, which constitutes Appendix 2 to the Request for Bids;
    b) Declaration of no grounds for exclusion, according to the specimen which constitutes Appendix 3 to the Request for Bids: "Declaration of no capital or personal links",

c) List of services, according to the specimen which constitutes Appendix 4 to the Request for Bids: "List of the services",

d) List of persons, according to the specimen which constitutes Appendix 5 to the Request for Bids: "List of Persons", together with documentation confirming their qualification and experience,

e) Declaration of a Qualified Person, confirming authorization to release active pharmaceutical ingredients within the European Union, according to the specimen which constitutes Appendix 6 to the Request for Bids: "Statement of a Qualified Person",

f) Documents confirming that the Contractor has an EU GMP certificate for the manufacturing of small molecular cytotoxic organic compounds as API or equivalent, recognized by the European Union,

g) Any additional required by low documents (or certified true copies) related in particular to the production, analysis and storage of low-molecular weight cytotoxic organic compounds, including actual manufacturing authorization for the production of low-molecular weight cytotoxic organic compounds issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor, recognized by the European Union,

h) a power-of-attorney for submitting an original or certified copy of the bid, where the bid has been signed by an attorney-in-fact on behalf of the Contractor,

i) where the contractor transfers any personal data other than the data which concerns it directly and where the information obligation referred to in Article 13(4) or Article 14(5) of the 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 (General Data Protection Regulation) (OJ L 119, p. 1) is not excluded, the following declaration: "I declare that I have fulfilled the information obligation set out in Article 13 or Article 14 of the 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 (General Data Protection Regulation) (OJ L 119 of 4 May 2016, p. 1) with respect to any natural persons whose personal data I have directly or indirectly obtained in order to apply for the award of a public contract as part of this procedure".

3. The bid, including attachments, must be signed by a person authorized to represent the Contractor. The bid unsigned will be considered invalid and will be rejected.

4. The Awarding Entity accepts submission of the bid, including all appendices in the Polish or English language.

5. Before the expiry of the deadline for bid submission, the Contractor may amend or withdraw the submitted bid.

6. The Awarding Entity announces that the bids submitted in this procedure are public and may be made available from the moment of their opening, with the exception of any information which constitutes a business secret. Any elements of the bid which the Contractor would like to withhold from the public as a business secret within the meaning of Article 11(4) of the Polish Unfair Competition Act of 16 April 1993 (consolidated text: Journal of Laws of 2018, item 419) should be placed in a separate sealed envelope (or protected in a different manner, e.g. if bids are submitted electronically) with the note: "business secret", attached to the original bid. The content

of the bid should include the information that the document is confidential. The Contractor shall be obliged to demonstrate that the confidential information constitutes a business secret. Consequently, if the Contractor fails to fulfil the above obligation, the Awarding Entity will have reason to deem the classification of information as a business secret ineffective and thus it shall not treat the information as subject to protection or as a business secret within the meaning of the Polish Unfair Competition Act.

7. The Contractor shall bear all the costs related to the preparation and submission of the bid.

X. Bid submission method.

Bids must be submitted by email to the Awarding Entity's address:

oferty@wpdpharmaceuticals.com with the note "Request for Bids No. 01/WPD107/2020".

XI. Bid submission date.

1. The bid submission deadline shall expire on **08.09.2020 at 23:59 CET**.
2. The submission date shall be deemed as the date when the bid is received at the Awarding Entity's email address.
3. Bids submitted past the bid submission deadline shall not be considered.
4. The Awarding Entity reserves the right to extend the bid submission deadline. In such an event, the Awarding Entity shall each time publish a relevant notice at the site of the publication of Request for Bids No. 01/WPD107/2020, i.e. in the Competitiveness Base at https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ and on the Awarding Entity's website at: www.wpdpharmaceuticals.com.

XII. Bid validity period.

1. The bid shall be valid for 60 days starting from the date of the bid submission deadline.
2. The Contractor alone or at the request of the Awarding Entity may extend the period of being bound by the bid with the provision that the Awarding Entity may only once, at last 3 days before the expiry of the bid validity period, ask the Contractor for permission to extend this period for a designated time, but no longer than 60 days.

XIII. The manner, scope and persons authorized to communicate with Contractors.

1. Communication between the Awarding Entity and Contractors shall be carried out using electronic means of communication and messages shall be sent to the email address of the Awarding Entity specified in Section I of the Request for Bids:

   (oferty@wpdpharmaceuticals.com)

2. In order to obtain additional confidential information regarding the contract object, the Contractor is requested to sign and send to the e-mail address: oferty@wpdpharmaceuticals.com Non-Disclosure Agreement, according to the specimen, which constitutes Appendix 7 to the Request for Bids. The Awarding Entity shall immediately from the date of receipt of the partially executed NDA send to the return address or other address indicated in the correspondence additional information about the Contract Object. The Contractor shall send NDA to the Awarding Entity

within the time limit set for submission requests for clarifications or inquires to the contract award procedure. The Awarding Entity shall not be liable for any delay in submitting the bid resulting from the late receipt of the additional information about the Contract Object, resulting from the Contractor sending the NDA too late or indicating the wrong e-mail address or failure of the Contractor's electronic system or other reasons attributable to the Contractor.

3. The Contractor may request clarifications of the content of the Request for Bids from the Awarding Entity. The Awarding Entity shall reply to the questions posed by the Contractor within a time limit enabling the bid to be submitted, but not later than 6 working days prior to the bidding deadline, provided that the request for the clarifications is received by the Awarding Entity no later than by the end of the day when half of the bidding period has lapsed.
4. If the request for clarifications of the content of the Request for Bids has been received later than by the end of the day when half of the bidding period has lapsed, the Awarding Entity may provide the clarifications or leave the request unconsidered.
5. The Awarding Entity shall publish the questions and answers at the site of publication of Request for Bids No. 01/WPD107/2020, i.e. in the Competitiveness Base at: https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ and on the Awarding Entity's website at: www.wpdpharmaceuticals.com.
6. The Awarding Entity reserves the right to amend or supplement the Request for Bids at any time before the lapse of the bid submission deadline. In such an event, the Awarding Entity shall promptly publish a notice of the amendments or supplements made, providing the date of announcement of the changes and a description of such changes or supplements, at the site of the publication of Request for Bids No. 01/WPD107/2020, i.e. in the Competitiveness Base at https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ and on the Awarding Entity's website at: www.wpdpharmaceuticals.com.
7. Where the scope of the changes introduced into the Request for Bids or the clarifications provided result in the need to modify the bids, the Awarding Entity shall at the same time extend the bid submission deadline, according to the Section XI, paragraph 4.
8. In case the price indicated in the bid by the Contractor seems abnormally low and raises doubts of the Awarding Entity as to the possibility of performing the object of the contract in accordance with the requirements specified in the Request for Bids, the Awarding Entity may request the Contractor to provide explanations, including providing evidence regarding the calculation of the price.
9. The Awarding Entity reserves the right to correct obvious spelling mistakes in the bid, as well as obvious calculation errors, taking into consideration the calculation consequences of the corrections made, provided that they do not significantly alter the content of the bid. The Awarding Entity shall not correct the "Gross total price" quoted in the offer.
10. The Awarding Entity reserves the right to demand that Contractors whose bids were submitted on time but contain missing information or errors supplement or correct them or provide clarifications, while at the same time the Awarding Entity shall set an appropriate deadline and specify the scope of the necessary corrections and supplements and how they should be submitted. Corrections and supplements submitted past the deadline set by the Awarding Entity will result in the bid being rejected. Requests for correction, supplementation or clarification may only concern missing elements or errors of a formal nature. Complex changes to the submitted bids shall not be allowed.

XIV. Announcement of the selected bid and grounds for the selection.

1. The Awarding Entity shall publish the results of the procedure indicating the name and address of the selected Contractor and the bid price on the website where Request for Bids No. 01/WPD107/2020 was first published, i.e. in the Competitiveness Base on: https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ and on the Awarding Entity's website: www.wpdpharmaceuticals.com, not later than within 30 days of the expiry of the bid submission deadline.
2. The Awarding Entity is not planning to hold a public opening of the bids.

XV. Procedure cancellation conditions.

1. The Awarding Entity reserves the right to cancel or amend the contract award procedure at any stage or to declare the procedure null and void or not to select any Contractor, without stating the cause. At the same time, the Awarding Entity announces that pursuant to valid legal regulations this Request does not constitute an offer within the meaning of Article 66 of the Act of 23 April 1964 – Civil Code (Journal of Laws of 2018, item 1025, as amended), neither is it an announcement within the meaning of the Public Procurement Act (Journal of Laws of 2017, item 1579, as amended).
2. Contractors shall not assert any claims against the Awarding Entity should the Awarding Entity enforce the right referred to in clause 1 above.

XVI. Contract signing and amendment terms; deadline and manner of the contract execution.

1. Contract signing terms.

1) The Awarding Entity shall request the selected Contractor to sign the conditional agreement by sending a notice to the email address stated in the bid, indicating date of signing the contract.
2) Where a Contractor chooses not to sign the conditional agreement, the Awarding Entity may sign it with the next Contractor whose offer received the second highest score.
3) The conditional agreement will be signed based on the relevant provisions, which are indicated in the Appendix 8 to the Request for Bids.

2. Contract amendment terms.

The Awarding Entity indicated the contract amendment terms in the Appendix 8 to the Request for Bids.

3. Deadline and manner of contract execution.

1) The Awarding Entity plans to sign the conditional agreement with the selected Contractor within a maximum of 60 days from the date of the submission of the bids. This deadline may change in the event of the extension of the period of being bound by the bid.
2) The deadline for contract execution shall start:
   a) For Package No. 1 – after informing the Contractor by the Awarding Entity about signing the contract for project financing,
   b) For Package No.2 – after transfer to the Contractor by the Awarding Entity the key intermediate material produced in the Package No. 1

and expire upon final approval of the delivery and acceptance protocol for each of the Package and providing the Awarding Entity complete documentation developed as a part of the contract (including submitting to the electronic database provided by the Awarding Entity) and with no objections as to the performance of the Contract.

3) The Awarding Entity shall pay for each task package or stage of the order, confirmed by the Awarding Entity with the delivery and acceptance protocol, within 30 days from the date of receipt of the correct invoice. The value of the invoice submitted for payment will correspond to the value of the contract.

4) The invoice will be submitted after approval and signing the delivery and acceptance protocol, which confirms the correct implementation of each stage of the contract by the Awarding Entity.

XVII. Additional information.

Protection of natural persons with respect to personal data processing:

Pursuant to Article 13(1) and (2) 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 (General Data Protection Regulation) (OJ L 119 of 4 May 2016, p. 1) (henceforth "GDPR"), the Awarding Entity would like to inform you that:

– WPD Pharmaceuticals sp. z o. o. is the controller of your personal data;

– Your personal data shall be processed pursuant to Article 6(1)(c) of GDPR for purposes related to contract award procedure 01/WPD107/2020, organized in the form of a request for bids compliant with the Competitiveness Rule set out in Section 6.5.2 of the *Guidelines on the Eligibility of Expenses under the European Regional Development Fund, European Social Fund and Cohesion Fund for 2014-2020*;

– Recipients of your personal data will include persons or entities who will be granted access to the bidding procedure documentation under:

  - Regulation 1303/2013 (EU) of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347 of 20 December 2013, page 320, as amended), hereinafter referred to as "Regulation 1303/2013";

  - Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006 (OJ L 347 of 20 December 2013, p. 289);

  - Commission Regulation No 651/2014 (EU) of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty (OJ L 187 of 26 June 2014, p. 1, as amended);

  - Act of 11 July 2014 on the principles of implementation of cohesion policy programs funded in the 2014-2020 financial perspective (Journal of Laws of 2017, item 1460);

- Your personal data will be stored for the period referred to in Article 140(1) of Regulation 1303/2013 and at the same time for not less than 10 years of the date when the last aid was granted under the aid scheme, with the provision that the indicated deadline is a minimum one and may be extended by the Intermediate Body, i.e. National Centre for Research and Development with its registered seat in Warsaw, at the following address: ul. Nowogrodzka 47a.
- The obligation for you to provide your personal data results from the Guidelines on the eligibility of expenses under the ERDF, ESF and CF for 2014-2020 (Chapter 6);
- Decisions concerning your personal data will not be taken in an automated manner, pursuant to Article 22 of GDPR;
- You have:
  - The right to access your personal data, under Article 15 of GDPR;
  - The right to correct your personal data, under Article 16 of GDPR*;
  - The right to demand the restriction of the processing of your personal data from the organizer, subject to the cases referred to in Article 18(2) of GDPR**, under Article 18 of GDPR;
  - The right to lodge a complaint with the President of the Office for Personal Data Protection if you believe that the processing of your personal data violates provisions of GDPR;
- You do not have:
  - The right to have your personal data erased, in conjunction with Article 17(3)(b)(d)(e) of GDPR;
  - The right to transfer your personal data referred to in Article 20 of GDPR;
  - The right to object to personal data processing under Article 21 of GDPR, as the legal basis for the processing of your personal data is Article 6(1)(c) of GDPR,

* Explanation: The exercise of the right to correct your personal data must not lead to a change of the result of the contract award procedure or to an amendment of the provisions of the contract in a manner which is inconsistent with the request for bids and it must not violate the integrity of the best bid selection report or any attachments thereto.

** Explanation: The right to restrict processing shall not apply to the storage of data for the purpose of ensuring the use of any judicial remedies or for protecting the rights of a different natural or legal person or for important reasons of public interest of the European Union or a Member State.

XVIII. Appendices:

Appendix No. 1 - Bid form

Appendix No. 2 - Declaration of the Contractor

Appendix No. 3 - Declaration of no capital or personal links

Appendix No. 4 - List of services

Appendix No. 5 - List of persons dedicated to perform the service

Appendix No. 6 – QP Declaration

Appendix No. 7 – Non-Disclosure Agreement template

Appendix No. 8 – Important provisions of the Contract - example

Appendix No. 9 – Additional confidential information about the Contract Object