

Krakow, 07.12.2022

BS BIOTECHNA S. A.

Szlak 77 / 222,

31-153 Krakow

NIP (Tax Identification Number): 945-222-64-86

REQUEST FOR PROPOSAL No. 1/12/2022

In connection with the project *“BS2020 - Research and development of a new medicinal product to be used in the treatment of cancer”*, implemented as part of the Smart Growth Operational Programme 2014-2020, Measure: Corporate R&D Projects; Submeasure: Industrial research and development works conducted by enterprises, BS BIOTECHNA S. A. announces the request for proposal procedure in accordance with the rule of competitiveness.

1. Object of contract: GMP - Drug production

Order description:

Scaling and technology transfer to manufacturing, including:

- preparation and production of the test product in GMP quality, including: test batch and GLP batch for phase I clinical trial, in the form of a liposomal nanoparticle containing a combination of two small molecules, in a liquid form for intravenous administration,
- realization of 6-month stability tests,
- preparation of documentation of the investigational medicinal product dossier for the purposes of clinical trial.

Estimated amount of test product produced: up to 5l for test batch and up to 15l for clinical batch (it is possible to produce smaller volumes, which in total adds on to expected total amounts)

Into account will be taken offers including production with and without microfluidic technology.

If the contractor is able to use microflow technology, the contractor will supervise the transfer of the microfluid technology from BS Biotechna. In the event, when the contractor is unable to use microfluidics or the use of microfluidic technology will not be appropriate for the tested medicinal product, the Contractor must perform GMP quality in a different way, in accordance with the developed BS Biotechna's synthesis protocols.

The cost of the substances of which nanoparticle is composed is covered by BS Biotechna and should not be part of the offer.

Common Procurement Vocabulary (CPV):

85000000-9 Health and welfare services

33600000-6 Pharmaceutical products

2. Planned execution date:

- by 01st Nov 2023.

Correct implementation is understood as the production and delivery of 1 test batch of the tested product and 1 batch for the phase I of clinical trial.

3. Eligibility conditions:

- Being authorised to perform a specific activity or action if such an authorisation is required by the law.
- Ability to produce the test product batch in the amount up to 5l and up to 15l for clinical batch
- Economic and financial standing that guarantees contract performance within the specified deadline.
- Having the required knowledge and experience or providing subcontractors who have the knowledge and experience required to perform the contract.
- Having adequate technical capabilities or providing subcontractors who have adequate technical capabilities to perform the contract.
- Having personnel who is capable of performing the contract or providing subcontractors who have personnel capable of performing the contract.
- Having a GMP certificate or commitment to get GMP certificate in the period of conduct of this service
- Possibility to manufacture the investigational medicinal product in accordance with GMP guidelines in the EU, such as Regulation No. 1252/2014 and Directive 2003/94 / EC, applicable to active substances and medicines for human use; Directive 91/412 / EEC applicable to medicines for veterinary use. In addition, Directives 2001/83 / EC and 2001/82 / EC establish related provisions and their possible updates, allowing the use of an investigational medicinal product for toxicological and clinical studies.
- Fully scalable in standard and production in GMP quality, also: packaging and labeling.
- Ensuring in accordance with GMP requirements of: equipment, personnel, buildings and facilities, reagents, manufacturing process, documentation, labeling and control.
- Submitting a statement in the proposal on the lack of any ties.
 - There are no grounds for exclusion under art. 5k of 833/2014 regulation and art. 7 paragraph 1 of the Act on special solutions in the field of counteracting supporting aggression against Ukraine and serving the protection of national security.

In order to confirm the fulfilment of the above conditions, the following documents must be submitted:

1) A proposal specifying:

- The business name, address and Tax Identification Number (NIP) of the contractor
- The proposal issue date
- Details that will enable the evaluation of the proposal and the award of scores for the criteria fulfilment

- The proposal validity date

2) Submission of the following statements in the proposal and presentation of the required lists of information:

- The Contractor represents that the Contractor is aware of, and accepts, the contract execution terms and conditions defined in the request for proposal, and makes no objections or comments in that respect.
- The Contractor represents that the Contractor is authorised to perform a specific activity or action if such an authorisation is required by the law.
- The Contractor declares that he has the ability to produce the tested product in total amount up to 5l for test batch and up to 15l for clinical batch
- The Contractor represents that the Contractor's economic and financial standing guarantees contract performance within the specified deadline.
- The Contractor represents that the Contractor has the required knowledge and experience or will provide subcontractors who have the knowledge and experience required to perform the contract.
- The Contractor represents that the Contractor has adequate technical capabilities or will provide subcontractors who have adequate technical capabilities to perform the contract.
- The Contractor represents that the Contractor has personnel who is capable of performing the contract or will provide subcontractors who have personnel capable of performing the contract.
- The contractor declares that he has a GMP certificate or commits to get GMP certificate in the period of conduct of this service.
- The Contractor declares that it has the ability to manufacture the investigational medicinal product in accordance with the GMP guidelines in the EU, such as Regulation No. 1252/2014 and Directive 2003/94 / EC, applicable to active substances and medicines for human use; Directive 91/412 / EEC applicable to medicines for veterinary use. In addition, Directives 2001/83 / EC and 2001/82 / EC establish related provisions and their possible updates, allowing the use of an investigational medicinal product for toxicological and clinical studies.
- The contractor declares that he has the possibility of full scaling in the standard and production in GMP quality, as well as packaging and labeling.
- The Contractor declares that he will provide in accordance with the requirements of GMP: equipment, personnel, buildings and facilities, reagents, production process, documentation, labeling and control.
- The Contractor represents that the Contractor has no personal or capital ties with the Awarding Entity. Personal or capital ties are understood as mutual ties between the Awarding Entity or persons authorised to assume obligations on behalf of the Awarding Entity or persons who perform activities related to the Contractor selection procedure preparation and conduct on behalf of the Awarding Entity and the Contractor, including but not limited to:
 - a) participation in a civil law partnership or a partnership as a partner;
 - b) holding at least 10% of shares;

- c) performing the function of a member of the supervisory body or of the managing body, a commercial representative, or a holder of the power of attorney;
 - d) being married, related by blood or by marriage in the direct line, related by blood or marriage in the collateral line up to the second degree, or related by reason of adoption, custody or guardianship.
- The Contractor declares that:
 - a) is not subject to exclusion from the procedure pursuant to Art. 5k of the Council Regulation (EU) No. 833/2014 of 31 July 2014 on restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Journal of Laws EU No. L 229 of 31.7.2014, p. 1; hereinafter: the Regulation 833/2014), 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 (Journal of Laws EU No. L 111 of 8.4.2022, p. 1; hereinafter: Regulation 2022/576);
 - b) there are no grounds for excluding him from the procedure pursuant to Art. 7 sec. 1 of the Act of April 13, 2022 on special solutions in the field of counteracting supporting aggression against Ukraine and serving the protection of national security (Journal of Laws, item 835).
 - c) all information provided in the above statements is up-to-date and truthful and has been presented with full awareness of the consequences of misleading the Ordering Party when presenting the information. At the same time, it undertakes to immediately provide the Ordering Party with an update of the above statements in the event of any changes in this respect.

4. Description of proposal preparation:

The proposal must be submitted on the proposal form (Appendix No. 1 hereto). The proposal should be prepared in Polish or English, in a legible manner. Each proposal must contain the business name and the address of the tenderer. It must be signed by the tenderer and the signature must be legible or accompanied by a name stamp. In the proposal, the tenderer should state the price for the end-to-end execution of the object of contract on terms and conditions set out in the request for proposal; furthermore, the tenderer should enclose with the proposal all documents listed in the request for proposal. As part of the submissions, the tenderer should also indicate the fulfilment of the above-mentioned terms and conditions of participation in the proceedings. The price proposed should cover all works and activities to be performed as part of the contract; it should cover all costs related to the execution of the contract, to be provided during the period and on terms and conditions set out in the tenderer's proposal and in the Request for Proposal. The price should be expressed in monetary units.

The Awarding Entity does not permit submission of partial proposals; only proposals that cover the entire scope of the object of contract will be reviewed.

Proposals that do not fulfil the conditions for participation in the procedure and/or that do not cover the entire scope of the object of contract will be rejected.

Proposal submission methods (select one):

- Via e-mail at: info@bsbiotechna.com

- In person, at the company's registered office: ul. Szlak 77 / 222, 31-153 Krakow
- By mail, registered letter, courier dispatch to the company's address: ul. Szlak 77 / 222, 31-153 Krakow – **the date of the proposal receipt is decisive**
- Directly via the Baza Konkurencyjności portal.

The deadline for the proposal submission will expire on 09.01.2023.

Contact person in relation to the request for proposal:

Marcin Olczak will provide you with information on the object of contract by e-mail at:
marcin.olczak@bsbiotechna.com

Proposal validity date: at least 90 days from the expiry of the proposal submission date.

5. Proposal evaluation criteria:

Proposals will be evaluated by the Awarding Entity based on the following criteria:

proposal evaluation criteria	Weight	maximum score
a) net price in PLN/foreign currency*	70%	70
b) Time of production and delivery of the test batch by 15/06/2023	30%	30

* where the proposal is stated in a foreign currency, the average foreign exchange rate of the National Bank of Poland (NBP) effective on the working day preceding the day on which the proposal selection report was made by the Awarding Entity will be applied for conversion.

Award of scoring for the fulfilment of a given criterion as part of the proposal evaluation:

- Scores as part of the criterion *net price in PLN/ foreign currency* will be awarded according to the following formula:

$$A_n = C_{min} / C_r \times 70$$

C_{min} – minimum price in the set

C_r – price of the proposal being reviewed

A_n – the scoring awarded to the proposal

b) Points under the criterion of Production and delivery of the test series by 15/06/2023 will be awarded according to the following formula:

- Production and delivery of the test series by 15/06/2023 inclusive - 30 points
- Production and delivery of the test series later than 15/06/2023 - 0 points

The points from the evaluation of the criteria will be summed up and the final score (the sum of points scored) will be decisive. An offer for the execution of the contract may receive a maximum of 100 points

6. Information regarding the selection of the most advantageous proposal:

- The Awarding Entity will award the contract to the tenderer whose proposal meets all of the above-listed requirements and receives the highest scoring based on the proposal evaluation criteria stated above. The procedure will end with the selection of one contractor.
- When concluding the proposal evaluation procedure, the Awarding Party will decide on the selection of the most advantageous proposal and announce the results in the Baza Konkurencyjności portal.
- Should the tenderer whose proposal is selected avoid the signing of the agreement, the Awarding Entity reserves the right to propose a conclusion of the agreement to a tenderer whose proposal is the most advantageous one from among the remaining proposals that have been submitted.

7. Information regarding disqualification from contract performance.

Entities that are excluded from the possibility of fulfilling the order:

- have personal or capital ties to BS BIOTECHNA S. A. Personal or capital ties are understood as mutual ties between BS BIOTECHNA S. A. or persons authorised to assume obligations on behalf of BS BIOTECHNA S. A. or persons who perform activities related to the contractor selection procedure preparation and conduct on behalf of BS BIOTECHNA S. A. and the Contractor, including but not limited to:
 - a) participation in a civil law partnership or a partnership as a partner;
 - b) holding at least 10% of shares;
 - c) performing the function of a member of the supervisory body or of the managing body, a commercial representative, or a holder of the power of attorney;
 - d) being married, related by blood or by marriage in the direct line, related by blood or marriage in the collateral line up to the second degree, or related by reason of adoption, custody or guardianship.

Excluded are entities, that:

1. are subject to exclusion from the procedure pursuant to Art. 5k of the Council Regulation (EU) No. 833/2014 of 31 July 2014 on restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Journal of Laws EU No. L 229 of 31.7.2014, p. 1; hereinafter: **the Regulation 833/2014**), 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 (Journal of Laws EU No. L 111 of 8.4 .2022, p. 1; hereinafter: **Regulation 2022/576**);¹
2. there are grounds for exclusion from the procedure pursuant to Art. 7 sec. 1 of the Act of April 13, 2022 on special solutions in the field of counteracting supporting aggression

¹Pursuant to Art. 5k paragraph. 1 of Regulation 833/2014 as amended by Regulation 2022/576, it is prohibited to award or continue to perform any public procurement or concession falling within the scope of the Public Procurement Directives, as well as the scope of Art. 10 sec. 1, 3, sec. 6 lit. a) -e), sec. 8, 9 and 10, art. 11, 12, 13 and 14 of Directive 2014/23 / EU, Art. 7 and 8, art. 10 lit. b) to f) and lit. h) to j) of Directive 2014/24 / EU, Art. 18, art. 21 lit. b) to e) and lit. g) -i), Art. 29 and 30 of Directive 2014/25 / EU and Art. 13 lit. a) to d), lit. f) to h) and lit. (j) Directive 2009/81 / EC for or with the participation of:

- a) Russian citizens or natural or legal persons, entities or bodies based in Russia;
- b) legal persons, entities or bodies whose ownership rights directly or indirectly belong to the entity referred to in point (a) in more than 50%; a) of this paragraph; or
- c) natural or legal persons, entities or bodies acting on behalf or at the direction of the entity referred to in point (a). a) or b) of this paragraph, including subcontractors, suppliers or entities reliant on capacities within the meaning of the Public Procurement Directives where they account for more than 10% of the contract value.

against Ukraine and serving the protection of national security (Journal of Laws, item 835).²

8. Terms and conditions of agreement amendment:

The Awarding Entity reserves the right to amend the agreement concluded as a result of the Request for Proposal procedure in the following cases:

- a) as a result of reasons beyond the control of the Ordering Party and the Contractor (with due diligence) resulting in the impossibility or significant delays in the performance of the contract, in particular the temporary lack of availability on the market of resources needed to perform the subject of the contract,
- b) “force majeure” means external, unforeseeable and unexpected event, beyond the control of the Parties, occurring after signing the Agreement and resulting in the inability to perform the Agreement,
- c) in the event of changes in the project implementation schedule, in particular in the event of the need to extend / postpone the deadlines for the implementation of individual tasks and stages, caused by objective factors, independent of the Employer and the Contractor, preventing the performance of the contract within the originally specified dates, affecting the quality of the contract subject,
- d) in the event of circumstances beyond the control of the Contractor, at his justified request, provided that this change results from circumstances that the Contractor could not foresee at the stage of submitting the offer and is not his fault,
- e) if it is necessary to introduce changes that the Ordering Party could not foresee at the time of concluding the contract, for the time necessary to introduce these changes,
- f) changes in universally applicable laws insofar as they affect the agreement execution,
- g) the occurrence of discrepancies or uncertainty regarding the understanding of terms used in the agreement that cannot be removed otherwise, and an amendment will make it possible to eliminate the discrepancies and specify the language of the agreement so that the parties are able to interpret its provisions in an unequivocal manner without changing the nature of the agreement;
- h) the amendment does not result in changing the nature of the agreement, and the total value of amendments is lower than the amounts defined in the regulations issued pursuant to Article

² Pursuant to Art. 7 sec. 1 of the Act of April 13, 2022 on special solutions in the field of counteracting aggression against Ukraine and serving the protection of national security, the following are excluded from the procedure for awarding a public contract or a competition conducted on the basis of the Act - Public Procurement Law the following are excluded:

- 1) the contractor and participant of the competition listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered into the list on the basis of a decision on entry in the list determining the application of the measure referred to in Art. 1 point 3 of the act;
- 2) the contractor and participant of the competition, whose real beneficiary within the meaning of the Act of 1 March 2018 on counteracting money laundering and financing terrorism (Journal of Laws of 2022, items 593 and 655) is a person listed in the lists specified in the regulation 765/2006 and Regulation 269/2014 or entered into the list or being such a real beneficiary from February 24, 2022, provided that it was entered in the list on the basis of a decision on entry in the list determining the application of the measure referred to in article 1. 1 point 3 of the act;
- 3) the contractor and participant of the competition, whose parent entity within the meaning of Art. 3 sec. 1 point 37 of the Accounting Act of September 29, 1994 (Journal of Laws of 2021, items 217, 2105 and 2106), is an entity listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered on the list or being such a parent entity from February 24, 2022, provided that it was entered on the list on the basis of a decision on entry in the list determining the application of the measure referred to in Art. 1 point 3 of the Act.

3, Journal of Laws of 2019, item 2019, and it is lower than 10% of the contract value initially defined in the agreement;

- i) the amendment does not result in changing the nature of the agreement and all of the following conditions have been met:
 - amendments to the agreement are necessary due to circumstances that could not have been predicted by the Awarding Entity acting with due diligence,
 - the value of the change is under 50% of the contract value initially set out in the agreement,
- j) the Contractor who was awarded the contract by the Awarding Entity is to be replaced by a new Contractor:
 - pursuant to the contractual provisions, as referred to in the items above,
 - as a result of a business combination, division, transformation, bankruptcy, restructuring or acquisition of the existing Contractor or the Contractor's enterprise, provided the new Contractor meets the eligibility criteria for the procedure, there are no reasons to exclude the new Contractor and the replacement does not entail any other material amendments to the agreement,
 - as a result of the Awarding Entity's taking over the Contractor's obligations towards the Contractor's subcontractors.

9. Reservations:

- The Awarding Entity reserves that the agreement to be concluded with the selected contractor will provide for contractual penalties for delay in order fulfillment in the amount of 0.01% of the gross order value for each day of delay, however not more than 10% of the gross contract value.
- The tenderer will pay all of its own costs related to the preparation and submission of the proposal, regardless of the procedure outcome.
- The Awarding Entity reserves the right to amend the request for proposal and the proposal form in case of mistakes in the request for proposal; should it be necessary to make such amendments, the Awarding Entity will:
 - give notice of the amendment made to the agreement in a manner used for the publication of this request for proposal,
 - give notice of the amendment made to the agreement to all tenderers who have already submitted their proposals;
 - prolong the deadline for the proposal submission to account for the time required to amend the tenderers' proposals.
- During the proposal evaluation process, the Awarding Entity may call on the tenderers to give explanations regarding their proposals or supplement them.
- When concluding the proposal evaluation procedure, the Awarding Party will decide on the selection of the most advantageous proposal.
- Submitting a proposal as part of the Request for Proposal procedure is tantamount to accepting the rules set out in the request for proposal.
- The Awarding Entity has the right to cancel the request for proposal procedure, in whole or in part, at any time during the procedure in justified cases.

10. Personal data protection:

Notice presented in accordance with Article 13 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 95/48/EC (General Data Protection Regulation) [GDPR] (OJ L 2016.119.1):

1. BS Biotechna S. A. is the controller of your personal data (the Data Controller);
2. Your personal data will be processed in relation to the procedure for the award of this contract, the conclusion and performance of an agreement, the establishment, pursuit or defence of claims, if any, and for archiving purposes – pursuant to Article 6(1)(b) and (c) of the GDPR;
3. only entities authorised to obtain personal data or entities participating in the agreement performance, including in particular persons or entities to which the procedure documentation will be disclosed, will receive your personal data;
4. Your personal data will be retained until the expiry of the mutual claims and for the duration of the archiving period arising from the secretarial instruction;
5. you have the right to demand access to personal data from the Data Controller, the right to rectify the data and restrict their processing, as well as the right to erase them, subject to Article 17(1) and (3) of the GDPR;
6. your obligation to provide personal data which directly concern you is a statutory requirement related to participation in the procurement procedure.

11. Appendices:

- **Appendix No. 1 – Proposal form**