

Wrocław, 09.09.2019 r.

OFFER INQUIRY No. 3/BIOTTS/2019

Title of the REQUEST: Research service to be provided: In *in vivo* study on mini-pigs to assess skin absorption and irritation of the developed medicinal product, under of the project BIOTTS, the development of transdermal preparations used to treat hard to heal wounds and local anesthetics'. The programme is co-financed by the European Union under Measure 1.3.1 of the Operational Programme Intelligent Development 2014-2020.

I. ORDERING:

Biotts S.A.

Street: Krakowska 141-155, Zip code: 50-428 Wrocław, Poland

email: lab@biotts.com

KRS: 0000738948, VAT ID: 899 284 73 81, REGON: 369429734

II. COMMON PROCUREMENT VOCABULARY (CPV):

CPV code: 73111000-3 (Laboratory testing services)

III. ORDERING MODE:

1. This order is not subject to the provisions of the Act of 29 January 2004. Public Procurement Law (i.e. Journal of Laws of 2013, item 907 as amended) according to Polish law.
2. This procurement shall be conducted in accordance with the principles of competition, transparency, publicity, transparency and equal access.
3. The Ordering Party reserves the right to cancel the procedure at any stage without giving reasons.
4. The Ordering Party reserves the right to make inquiries regarding additional information, documents or explanations.
5. In justified cases, at any time before the deadline for submission of tenders, the Ordering Party may modify or supplement the content of the invitation to tender. The Ordering Party shall post information about changes on its website or inform by e-mail all potential Bidders to whom an invitation to submit offers has been sent.
6. This invitation to tender does not oblige the Ordering Party to conclude a contract.
7. Within this invitation to tender, the Ordering Party shall not allow partial tenders to be submitted.

IV. Place and method of submission of tenders:

1. The Ordering Party shall permit tenders to be submitted in writing to the address:

Biotts S.A.
street: Krakowska 141-155,
zip code: 50-428
Wrocław, Poland

with the note "Offer on request for quotation No. 3/BIOTTS/2019".

or

in electronic form (scan of the signed offer) to the address: lab@biotts.com

Contact person for the advertisement:

Konrad Krajewski

e-mail: k.krajewski@biotts.com

Project "BIOTTS, development of transdermal preparations used for treatment of difficult difficult to to heal wounds and local anaesthetics" co-financed by the European Union within Measure 1.3.1 of the Intelligent Development Operational Programme 2014-2020.

2. Tenders shall be valid for at least 30 days, with the possibility of an extension. The offer must be submitted on the Offer Form attached as Appendix 1 to this offer enquiry.
3. **Time limit for receipt of tenders: 24th of September 2019 at 11:59 p.m. Central European Time.**

PURPOSE OF THE CONTRACT

This procedure is carried out for the purpose of selecting the Service Providers to perform the following research service: In *in vivo* study on mini-pigs to assess skin absorption and irritation of the developed medicinal product, under of the project BIOTTS, the development of transdermal preparations used to treat hard to heal wounds and local anaesthetics'. The programme is co-financed by the European Union under Measure 1.3.1 of the Operational Programme Intelligent Development 2014-2020.

V. DESCRIPTION OF THE SUBJECT MATTER OF THE REQUEST:

The subject of the request is to conduct an *in vivo* study in the mini-pig (non-naïve animals), which aims to:

1. determine the systemic exposure to active substances included in the preparation developed by Biotts SA
2. determine the level of active substances accumulated at the site of application,
3. determine pharmacokinetic parameters of the tested substances: AUC (AUC_{last}, AUC_{inf}), C_{max}, T_{max} i T_{1/2}
4. assess skin irritation (erythema and edema) at the site of product application (Draize skale)

A detailed description of the subject of the request, including the study design and test articles specifications (Appendix No. 3), will be made available to Service Providers who express their interest in filing a pricing proposal and sign a confidentiality agreement. The template of the confidentiality agreement is provided in Appendix No. 2 to this document. A scan of the signed confidentiality agreement should be sent to the following email address: lab@biotts.com.

Additional information will be made available to interested Parties no later than 24 hours after receipt of a scan of the signed confidentiality agreement.

Detailed description of the subject of the request

The description is available as a separate file- "Detailed description of the subject of the contract" (Appendix No. 3).

VI. TIMETABLE FOR THE COMPLETION OF THE CONTRACT

Planned order completion date:

The deadline for the performance of the contract shall be from October 2019 to December 2019

VII. CONDITIONS OF PARTICIPATION:

The Awarding Entity expects the Service Providers to jointly meet the following conditions for participation in the proceedings:

1. KNOWLEDGE AND EXPERIENCE:

Project "BIOTTS, development of transdermal preparations used for treatment of difficult difficult to to heal wounds and local anaesthetics" co-financed by the European Union within Measure 1.3.1 of the Intelligent Development Operational Programme 2014-2020.

The Request for offers relates to potential Service Providers whose scope of business activity is in full compliance with the subject of this Request.

1. The offer may be issued by parties who:
 - a) have the necessary qualifications to execute the project,
 - b) are licensed to carry out the activity in question,
 - c) have the appropriate technical capabilities and qualified human resources to execute the order,
 - d) are in a good economic and financial standing, which assures proper execution of the order in the declared time,
 - e) will sign a confidentiality agreement which is available as an Appendix 2 to this Request.
2. Regarding knowledge and experience, the Ordering Party requires the Service Provider:
 - a) to have at least three years of experience in providing the preclinical services and the bioanalytical services involving the determination of the level of low molecular weight organic compounds in biological matrix.

2. Lack of capital and personal links with the Contracting Authority

Capital or personal relationships shall be understood as mutual relations between the Ordering Party or persons authorised to incur liabilities on behalf of the Ordering Party or persons performing activities on behalf of the Ordering Party related to the preparation and conduct of the Service Provider selection procedure, and the Service Provider, consisting in particular in:

- a) participation in a partnership as a partner in a civil partnership or a partnership;
- b) holding at least 10% of the shares;
- c) performing the function of a member of the supervisory or management or a proxy;
- d) being married, in a relationship of kinship or affinity in a direct line, in a relationship of kinship or affinity in a collateral line up to the second degree or in a relationship of adoption, custody or guardianship.
- e) leave in such a legal or factual relationship that it may raise reasonable doubts as to the impartiality of these persons.

VIII. CONDITIONS FOR AMENDING THE CONTRACT:

1. As a result of the tender procedure, a contract will be concluded with the selected Service Provider.
2. The Ordering Party shall allow for the possibility of amending the contract to the extent and under the conditions set out below:
 - a) The Ordering Party allows for changes to be made to the deadline for the performance of the subject of the contract in the event of circumstances beyond the control of the Service Provider and with due diligence or circumstances beyond the control of the Contracting Authority, resulting in the inability to meet the deadline for the performance of the subject of the contract, in particular, such as force majeure and change to the research plan. In the event of a change in the date of implementation of the subject of the agreement in question, this date may be extended, no longer, however, than by the duration of these circumstances,
 - b) Changes in the VAT rate (the Ordering Party foresees the possibility of changing the salary by an amount equal to the difference in the amount of VAT).
 - c) There is a change in the generally applicable legal regulations in the scope affecting the performance of the subject matter of the contract.

- d) The necessity to introduce changes results from changes introduced in contracts between the Ordering Party and a party other than the Service Provider, including institutions supervising the implementation of the Project within which the order is executed,
- e) The necessity to introduce changes results from changes in the guidelines for the Operational Programme Intelligent Development 2014-2020.
- f) Any discrepancies or ambiguities in the agreement occur, which cannot be removed in any other way, and the amendment will make it possible to remove the discrepancies and clarify the agreement in order for the parties to interpret its provisions unequivocally,
- g) The necessity to introduce changes in the subject matter of the contract, including limiting its subject matter as a result of circumstances which the Ordering Party could not objectively foresee at the time of concluding the contract.
- h) Change of the Service Provider 's remuneration related to non-performance of part of tasks and/or research works, the performance of which will not be necessary or will be pointless, in the case of circumstances which could not have been foreseen at the time of conclusion of the contract;
- i) Extraordinary circumstances which are not "force majeure", threatening the Ordering Party or the Service Provider with a gross loss, which were not foreseen by the Parties at the time of concluding the contract, occur.
- j) Provision of security or amendment of the provisions concerning contractual penalties in case of threat to the interest of the Ordering Party.
- k) Making other significant changes if their introduction proves necessary for the proper performance of the contract or for the protection of the interests of the Ordering Party.
- l) Any immaterial changes are permissible if they are understood in such a way that knowledge of their introduction at the stage of the procurement procedure would not affect the limitation of entities applying for the contract or the outcome of the procedure. Such changes are changes of administrative and organizational nature of the contract, e.g. change of bank account number, concerning the name, head office of the Service Provider or its organizational and legal form during the term of the contract, other identification data, changes leading to the elimination of obvious errors in writing and accounting in the content of the contract,
- m) A change in the provisions of the concluded agreement may take place with the consent of both parties expressed in writing under pain of nullity.
- n) The Ordering Party shall allow the possibility of awarding supplementary contracts, selected in accordance with the competition rules, in the amount not exceeding 50% of the value of this contract.

XI. TERMS OF SETTLEMENT:

1. Form of settlement:

The Ordering Party provides for settlement on the basis of an invoice form of payment: bank transfer.

2. **Payment deadline:**

The payment deadline is 30 days after the delivery of a correctly issued invoice. The Ordering Party shall allow the invoice to be delivered by e-mail to the address indicated in the contract. The basis for the Service Provider to issue an invoice shall be a report on the tests performed, accepted by the Ordering Party.

XI. **LIST OF DOCUMENTS/STATEMENTS REQUIRED FROM THE Service Provider**

Offer prepared on the attached form (Attachment 1).

XII. **EVALUATION OF THE OFFER/EVALUATION CRITERIA**

Criteria for evaluation of tenders

1. Price – weight: of the criterion: 70% (70 points)

In this criterion, points will be awarded (to two decimal places) according to the formula below:

$$P_c = C_{\min}/C_{\text{evaluated}} \times 70\%$$

where:

P_c – points awarded in “Price” criterion

C_{\min} – the lowest Net price (among all received pricing proposals)

$C_{\text{evaluated}}$ – Net price of the offer being evaluated

The bid price should be determined to two decimal places. In the case of quoting the bid amount in foreign currencies, the Ordering Party, in order to evaluate the bids, converts the amounts into PLN at the average exchange rate of the National Bank of Poland valid on the day of the deadline for submission of bids set by the Ordering Party.

To ensure equal treatment of domestic and foreign bidders, the price to be evaluated as a criterion for evaluating the bid will be the total net price (excluding VAT) specified in the offer expressed in PLN

2. The study initiation date – weight: 20% (20points)

In this criterion, points will be awarded according to the following rules:

- a) 20 points - when the study is initiated in 2 weeks from the date of signing the contract,
- b) 15 points - when the study is initiated in 4 weeks from the date of signing the contract,
- c) 10 points - when the study is initiated in 6 weeks or more than 6 weeks from the date of signing the contract.

The following assumption shall be made: The Ordering Party intends to sign the contract with a selected Service Provider before the end of September 2019.

3. Project execution time - weight: 10% (10 pts.)

The project execution time is defined as time form the date of signing the contract to the date of receiving the final study reports.

In this criteria, points will be awarded according to the following rules:

- a) 10 points – when the project is executed in up to 60 days from the date of signing the contract.
- b) 5 points – when the project is executed in more than 60 days and less than 90 days form the date of signing the contract.
- c) 0 points – when the project is executed in more than 90 days and less than 120 days or even 120 days from the date of signing the contract.

1. Knowledge and experience:

The Request for offers relates to potential Service Providers whose scope of business activity is in full compliance with the subject of this Request.

1. The offer may be issued by parties who:
 - a. have the necessary qualifications to execute the project,
 - b. are licensed to carry out the activity in question,
 - c. have the appropriate technical capabilities and qualified human resources to execute the order,
 - d. are in a good economic and financial standing, which assures proper execution of the order in the declared time,
 - e. will sign a confidentiality agreement which is available as an Appendix 2 to this Request.
2. Regarding knowledge and experience, the Ordering Party requires the Service Provider:
 - a. to have at least three years of experience in providing the preclinical services and the bioanalytical services involving the determination of the level of low molecular weight organic compounds in biological matrix.

The fulfillment of the above conditions will be evaluated on the basis of a statement of the Service Provider, a model statement is attached as Appendix 1 to the Request for the Offer.

The Ordering Party may select the next most advantageous offer in the event that the Service Provider whose offer obtained the highest number of points refused to sign the contract or if signing the contract with such Service Provider becomes impossible due to other reasons.

2. Exclusions:

Entities with personal and capital ties to the Ordering Party are excluded from participation in the procedure. Capital or personal relationships are understood as mutual relations between the beneficiary or persons authorised to incur liabilities on behalf of the beneficiary or persons performing on behalf of the beneficiary activities related to the selection procedure of the Service Provider and the Service Provider, consisting in particular in:

- a) participation in a partnership as a partner in a civil partnership or a partnership,
- b) holding at least 10% of shares or stocks, unless a lower threshold results from legal regulations,
- c) performing the function of a member of the supervisory or management body or a proxy.
- d) being married, in a relationship of kinship or affinity in a direct line, kinship or affinity in a collateral line up to the second degree or related by adoption, custody or guardianship with the Service Provider.
- e) leave in such a legal or factual relationship that it may raise reasonable doubts as to the impartiality of these persons.

Description of verification of compliance with the condition: based on the declaration of no links in the content of the offer form. Service Providers who are related to the above will be excluded from the procedure.

Additional information:

1. Ordering Party shall provide the Service Provider with the tested product, reference product and contained in the test product

2. The Ordering Party declares its readiness to start the service and provide samples of the tested product, reference product, and active substances described in this inquiry in 10 days from the date of signing the contract.
3. The date and method of delivery of the samples shall be agreed with the Service Provider after the contract is signed.
4. Service research standard: OECD 428
5. The Service Provider shall bear all costs related to the Service described in this regard, including the following costs: supply/maintenance of animals, reagents and consumables required for the performance of research procedures, operation of its own laboratory equipment, making research equipment available from third parties, costs of euthanasia/utilization of animals after the completion of the research service.
6. The test documentation and results obtained should be provided in English.
7. The detailed scope of the research project together with the description of individual studies will be made available to the Service Provider after signing the confidentiality agreement.

XI. ADDITIONAL INFORMATION:

1. Offers submitted after the deadline for submission of offers will not be considered.
2. The procedure does not provide for an appeal.
3. After receiving the offers, the Ordering Party reserves the right to cancel the procedure without giving any reason.
4. The Service Provider must submit a bid for the entire subject of the inquiry. The Ordering Party does not allow for partial or variant bids.
5. The Service Provider shall specify in the offer the total net and gross price for the whole object. The price shall be calculated as the price including all costs necessary for the performance of the contract under this procedure.
6. In case of quoting the bid amount in foreign currencies, the Ordering Party, in order to evaluate the bids, shall convert the amounts into PLN at the average exchange rate of the National Bank of Poland valid on the day of the deadline for submission of bids set by the Ordering Party.
7. The Ordering Party shall accept offers prepared in Polish and English.
8. The Ordering Party shall not reimburse the Service Provider for the costs of participation in the proceedings caused by a request for proposal.
9. The Ordering Party reserves the right to terminate (close) the procurement procedure without selecting any of the submitted bids, without prior notice to the Service Provider and without giving reasons for such termination.
10. In the event that the selected Service Provider withdraws from signing the Contract with the Ordering Party, it is possible to sign a contract with the next Service Provider, who obtained the highest number of points in the proceedings.
11. The Ordering Party is entitled to correct obvious errors in the text of the offer, immediately notifying the Service Provider thereof. In case of discrepancies in the amount of the offer, the price of the offer shall be the amount written in words.
12. The Ordering Party reserves the right to negotiate the price with the Service Provider who submits the most advantageous offer, if the value of the offer exceeds the amount of funds earmarked for the order.
13. The Ordering Party shall allow the possibility of awarding supplementary contracts, selected in accordance with the competition rules, in the amount not exceeding 50% of the value of this contract.
14. The Ordering Party shall have the right to request explanations or to submit additional documents from Service Provider whose contents raise any doubts within the time limit specified by the Ordering Party. If the Service Provider fails to submit explanations or documents or if the submitted explanations do not fully explain the doubts of the Ordering Party, the Ordering Party reserves the

- right to consider the offer whose contents raise doubts as not meeting the requirements for participation in the procedure.
15. During the proceedings, the Service Provider shall submit documents in the original or in a copy certified to be in conformity with the original by the Service Provider.
 16. The Service Provider is obliged to sign a confidentiality agreement according to the specimen of the Ordering Party.
 17. The Ordering Party reserves the right to change the content of this offer request. If the changes might have a significant impact on the bids submitted in the course of the procedure, the Ordering Party shall extend the deadline for the submission of bids. The information about the changes will be placed on the website as well as the announcement: <https://biotts.com/en/przetargi-2-copy/>
 18. In case of questions concerning the subject of the order or the method of preparation of the offer, they should be submitted in writing to the following address: lab@biotts.com. The Ordering Party shall provide an answer within 24 hours from the date of receipt (on working days). The question should be marked with a tender enquiry number, writing it in the title: "Question for Quotation Request No. 3/Biotts/2019".
 19. The order is fulfilled within the framework of the project "BIOTTS, development of transdermal preparations used for treatment of difficult-to-heal wounds and local anaesthetics" co-financed by the European Union within the framework of Measure 1.3.1 of the Operational Programme Intelligent Development 2014-2020.
 20. Attachments to the inquiry form:
 - a) Offer form – Appendix 1
 - b) NDA - Appendix 2
 - c) A detailed description of the subject of the contract - Appendix 3. The Appendix will be made available to Contractors who express their interest in participating in the procedure and sign a confidentiality agreement in accordance with the model (Appendix 2).