

Warsaw, 27.05.2022

REQUEST FOR QUOTATIONS No. 4
being conducted as a market assessment study

Pertaining to the implementation of the project titled “Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety”, funded from the state budget by the Medical Research Agency, WZA Polfa Warszawa S.A., you are kindly requested to submit a quotation for services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA.

I. NAME AND ADDRESS OF THE CONTRACTING PARTY

Warszawskie Zakłady Farmaceutyczne Polfa S.A.
ul. Karolkowa 22/24
01-207 Warszawa

II. CONTRACT AWARD PROCEDURE

- II.1.** This contract is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019)
- II.2.** The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
- 1) achieving the best possible outcomes using the available measures;
 - 2) choosing the best possible means and methods to meet the pre-defined objectives;
 - 3) ensuring transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE CONTRACT

- III.1.** This request for quotations relates to *the provision of services involving:*
Development, manufacture and delivery of an active substance in the form of a modified oligonucleotide – an 18-mer RNA (nusinersen).
- III.2.** The subject of the contract is as follows:
- (1) development of the method for oligonucleotide synthesis and purification,
 - (2) development of analytical methods,
 - (3) transfer of analytical methods and
 - (4) manufacture of 10 g of active substance under non-GMP conditions
 - (5) manufacture of 36 of active substance under GMP conditions.
- III.3.** This request for quotations includes as follows:
- *Development of specifications for the active substance as per ICH Q6 guidelines*
 - *Development and transfer of analytical methods*
 - *Manufacture of the material under non-GMP (3 different batches) and GMP (3 different batches) conditions in quantities specified in Section III.2*
 - *Delivery of certified standard*
 - *Preparation of registration dossier for the active substance*

– *Demonstration of sameness to the reference product Spinraza based on draft FDA guideline PSG_209531*

III.4. The Contracting Party reserves exclusive rights to sell the nusinersen drug in the following markets: PL, DE, DK, FI, NO, SE

III.5. No partial or variant proposals will be accepted. The Contracting Party reserves the right to change the quantity of substances to be manufactured and delivered.

IV. CONTRACT DELIVERY SITE AND DATE

IV.1. The contract delivery period will be up to 90 days from the date when a partial production order is submitted.

IV.2. Planned delivery schedule will be as follows:

– *Supply of about 0.5 g of the compound by the end of 2022, about 9.5 g in 2023 (under non-GMP conditions) and about 36 g in 2024-25 (material manufactured under GMP conditions).*

IV.3. Terms of delivery: CIP Warsaw (Incoterms® 2020)

V. REQUIREMENTS FROM CONTRACTORS

V.1. The procedure is open to any Contractors who meet the following conditions:

- *have infrastructure that enables the manufacture of active substances under quality system conditions;*
- *have/intend to acquire facilities for the synthesis, purification and freeze-drying of oligonucleotides;*
- *have access to analytical equipment that enables the determination of the quality of the active substance to be manufactured;*
- *have experience in preparing registration dossiers for active substances;*
- *have staff with experience in the synthesis of active substances and, in particular, in the synthesis of oligonucleotides.*

Assessment procedure

The Contracting Party will consider Contractor as meeting this condition if Contractor submits a declaration of compliance with the conditions for participation in the procedure (Appendix 2 to the Request for Quotations).

The Contracting Party reserves the right to verify the fulfilment of the conditions at the Bidder's site.

V.2. Quotations submitted by Contractors who demonstrate that they meet the specified conditions will be taken forward to the quotation evaluation stage. The compliance with the above conditions will be assessed based on a 'meet – does not meet' basis. Quotations submitted by Contractors who fail to meet any of the above conditions will be rejected.

VI. CONTRACT AWARD CRITERIA

VI.1. The quotations will be evaluated based on the following criteria:

- net contract price – 75%,
- quality system conforming to GMP requirements – 25%.

VI.2. The quotation score will be calculated according to the following formula:

$$O_P = P_C + P_G$$

where:

- O_P the quotation score
- P_C – score for the criterion “net contract price”
- P_G score for “a quality system conforming to GMP requirements”

VI.3. The score (P_C) for “Total Net Price” will be calculated according to the following formula:

$$P_C = \frac{C_N}{C_B} * 75 \text{ points}$$

where:

- P_C - score for the “net price”
- C_N - the lowest net price from among non-rejected quotations
- C_B - net price of the quotation under assessment

Quotation offering prices in currencies other than PLN will be converted to PLN using the exchange rate published by the National Bank of Poland (NBP) as at the final date for submitting quotations.

VI.4. The score (P_G) for having in place “a quality system conforming to GMP requirements” will be calculated as follows:

$$P_G = T * 25 \text{ points}$$

where:

- P_G - score for “a quality system conforming to GMP requirements”
- T - score awarded: “0” if the Bidder does not have a quality system conforming to GMP requirements “1” if the Contractor has a quality system conforming to GMP requirements

VI.5. The maximum score that can be awarded is 100 points. Calculations will be made to two decimal places.

VII. PLACE AND CLOSING DATE FOR SUBMISSION OF QUOTATIONS

VII.1. The final deadline for submitting quotations is **08.06.2022 by 11:59 p.m.**

– quotations can be sent in electronic format (in the form of a scan of the signed document) to the following address: **katarzyna.rusin@polpharma.com**

VII.2. A quotation will be considered to have been properly submitted if a complete quotation is delivered to the above e-mail address within the time limit stipulated in this section.

VII.3. No quotations submitted past the submission deadline will be taken into consideration.

VIII. PREPARATION OF QUOTATIONS

VIII.1. The Bidder should draw up one quotation using the template attached as Appendix 1 hereto.

VIII.2. Quotations may be modified or withdrawn prior to the end of the time limit for the submission of quotations.

VIII.3. Bidders are required to carefully read the information contained in the Request for Quotations.

VIII.4. The costs of preparing and delivering quotations will be borne by the respective Bidder.

VIII.5. For any matters related to this Request for Quotations, please contact the Contracting Party, e-mail: katarzyna.rusin@polpharma.com.

XII. AMENDMENTS TO THE CONTRACT

IX.1. The Contracting Party reserves the right to make material amendments to the concluded Contract in relation to the quotation on the basis of which the Contractor was selected to the following extent and in the following situations:

IX.1.1. changes to the European Union or national law that affect the performance of the Contract (in particular changes of the VAT rate);

IX.1.2. improving technical standards of the subject of the contract resulting from new solutions brought about by technological progress, without any impact on the gross flat rate;

IX.1.3. extending the deadline for the performance of the Contract due to additional work which must be completed for the proper performance of the Contract and which the Contracting Party, acting with due diligence, could not have foreseen earlier, subject to subsection IX.1.6 below;

IX.1.4. extending the deadline for the performance of the Contract due to force majeure, with all the consequences of such extension;

IX.1.5. changing the parameters of the subject of the Contract which does not lead to a change in the nature of the Contract – technological changes, in particular: the need to perform the Contract using technical/technological or material-related solutions other than as specified in the Request for Quotations if the application of the planned solutions could lead to a failure to perform or to improper performance of the Contract, subject to subsection IX.1.7. below;

IX.1.6. changes relate to additional supplies or services from the Contractor which are not covered by the Contract, as long as they are necessary and all of the following conditions are met:
– the Contractor cannot be changed due to economic or technical reasons, in particular relating to the interchangeability or interoperability of the equipment, services or installation ordered in connection with the original subject of the Contract,
– the change of the Contractor would cause significant inconvenience or a considerable increase of costs for the Contracting Party,

– the value of each subsequent change does not exceed 50% of the value of the original subject of the Contract (net amount);

IX.1.7. the change does not lead to a change in the nature of the Contract and all of the following conditions are met:

– the Contract must be changed due to the circumstances which the Contracting Party, acting with due diligence, could not have foreseen,

– the value of the change does not exceed 50% of the value of the original subject matter of the Contract (net amount);

IX.1.8. The Contractor may be replaced with a new contractor:

– as a result of merger, division, transformation, bankruptcy, restructuring or purchase of the Contractor or its enterprise as long as the new contractor meets the conditions for participating in the tender procedure, there are no grounds for exclusion and the change does not entail other material changes to the Contract,

– as a result of the Contracting Party taking over the Contractor's obligations towards his subcontractors;

- IX.1.9.** the amendment to the Contract does not lead to a change in the nature of the Contract and the total value of the amendments is less than EUR 215,000 and at the same time is lower than 10% of the value of the original subject of the Contract (net amount).
- IX.2.** The Contracting Party also allows for making non-material amendments to the concluded Contract in relation to the bid on the basis of which the Contractor was selected.
- IX.3.** Amendments to the Contract will be made in the form of an annex signed by both parties and they are subject to the Contracting Party's approval.

X. ADDITIONAL INFORMATION

- X.1.** Until the end of the time limit for the submission of quotations, the Contracting Party reserves the right to amend or add new information to this Request for Quotations.
- X.2.** Submitted quotations will remain valid and binding for 60 days from the final date for submitting quotations.

XI. LIST OF APPENDICES

The following documents are appendices to the Request for Quotations:

Appendix number	Appendix title
Appendix 1	Quotation form
Appendix 2	Declaration of compliance with the eligibility criteria for the participation in the procedure

QUOTATION FORM**Bidder:**

Name / Company	
Registered office/home address/address of the principal place of business	
E-mail address for the Contracting Party to send information related to the Request for Quotations	
NIP [Taxpayer ID Number]	
REGON [Business ID Number]	
Phone number	
Contact person for the Contracting Party	

We offer to perform the contract for the provision of services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA as per the requirements of the Request for Quotations for the total price of:

net amount: PLN/EUR*

applicable VAT at%: PLN/EUR*

gross amount: PLN/EUR*

(say:)

Net price per gram of substance manufactured under non-GMP conditions: PLN/EUR*

Net price per gram of substance manufactured under GMP conditions: PLN/EUR*

The contract will be completed within up to (0–90) days of the date when a partial order is submitted.

We have a quality system conforming to GMP requirements: (please say YES or NO)

We also declare as follows:

- a.** We have read the Request for Quotations and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our quotation.
- b.** Our bid price includes a lump sum that covers for all the obligations of the future Contractor as necessary to deliver the subject of the contract referred to hereunder.
- c.** Our quotation will remain valid and binding for 60 days from the final date for submitting quotations.

.....
(place and date)

.....
(signature(s) of person(s) authorized to submit
statements of will on behalf of the Bidder)

Contracting Party:

WZF Polfa S.A.

ul. Karolkowa 22/24

01-207 Warszawa

Contractor's Declaration**OF COMPLIANCE WITH THE ELIGIBILITY CRITERIA FOR THE PARTICIPATION IN THE
PROCEDURE**

By submitting this quotation for: **the provision services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA**, funded from the state budget by the Medical Research Agency, I hereby declare as follows:

INFORMATION ON THE CONTRACTOR:

I represent that we meet the conditions for participation in the tender procedure as specified by the Customer in part V of the Request for Quotations and relating to:

- we have infrastructure that enables the manufacture of active substances while using a quality system;
- we have or intend to acquire facilities for the synthesis, purification and freeze-drying of oligonucleotides;
- we have access to analytical equipment that enables the determination of the quality of the active substance to be manufactured;
- we have experience in preparing the registration dossier for active substances;
- we have staff with experience in the synthesis of active substances and, in particular, in the synthesis of oligonucleotides.

.....
(place and date)

.....
(signature of the Contractor's representative)