Warsaw, 28.04.2023

PRICE INQUIRY NO. NUSI/31/PR13783/2023

In connection with 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, WZF Polfa S.A., you are kindly requested to submit a bid **for the offers for the analytical research services described in detail in point III.**

I. NAME AND ADDRESS OF THE BUYER

Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna

22/24 Karolkowa Street

01-207 Warszawa

II. PRICE INQUIRY PROCEDURE

1. This price inquiry is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019)

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 PRICE INQUIRY

3.1. The subject of the inquiry is the purchase of a service related to the feasibility study of the analytical methods characterizing the active substance nusinersen and the finished product.

3.2. CPV code: 73100000-9.

3.3. The scope of the price inquiry:

3.3.1. Developing the feasibility of analytical methods to demonstrate the similarity of the product being the subject of pharmaceutical development (in other words, testing) to the reference product for the active substance using the following techniques:
- nuclear magnetic resonance (NMR)
- differential scanning calorimetry (DSC)
- circular dichroism (CD)
- sedimentation velocity analytical ultracentrifugation (SV-AUC)

The designed scope of the method development should demonstrate that the proposed analytical methods are appropriate in terms of demonstrating the discriminatory nature and appropriate in terms of sensitivity and resolution, with particular emphasis on tests such as specificity and repeatability.

3.3.2. Testing of the test product (finished product and/or active substance) against the reference product using developed methods, testing using one batch of the product.

3.3.3. Preparation of the test protocol for approval by the Buyer before testing.

3.3.4. Providing a method development report with the results and raw data for the samples tested.

3.3.5. Providing final descriptions of the developed methods.

3.3.6. Ensuring that the developed analytical methods are carried out in a quality system compliant with GMP rules.

3.3.7. The Buyer will provide the materials necessary to develop the methods in an amount that allows to demonstrate the suitability of the developed methods.

3.4. The Buyer does not allow the submission of partial or variant offers.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

The planned period of execution of the subject of the price inquiry: no longer than 8 weeks, from the date of delivery by the Buyer of all samples to the Bidder's laboratory. The organization and cost of sending samples is the responsibility of the Buyer.

V. GENERAL REQUIREMENTS

5.1. Bidders who meet the following conditions may apply for the award of the contract:

5.1.1. They will present the assumptions regarding the method development plan and the scope of the planned tests to be assessed by the Buyer on the day of submitting the offer, along with the amount of material necessary to develop the methods and the expected amount of material necessary for the final comparative analysis of the test product against the reference product.

5.1.2. They have knowledge and experience in conducting research for oligonucleotides.

5.1.3. They have knowledge and experience in the development of the above-mentioned analytical methods for oligonucleotides in GMP quality. The laboratory has FDA certification in the scope of analytical techniques that are the subject of the inquiry.

5.1.4. Offers of Bidders who demonstrate compliance with the required conditions will be admitted for examination and evaluation. The assessment of the fulfilment of the above conditions will be made according to the formula: "meets - does not meet". A contractor who fails to meet any of the conditions will be rejected in the procedure.

<u>How to evaluate the condition:</u>
The Buyer will consider that the Bidder meets this condition if the Bidder submits a Declaration of meeting the conditions for participation in the procedure (Appendix 2 to the Request for Proposal).

The Buyer reserves the right to verify the fulfilment of the conditions at the Bidder's company office or to request the submission of the relevant documentation.

VI. PLACE AND DATE OF OFFERS' SUBMISSION

6.1. The final deadline for submitting bids is 12.05.2023.
- bids can be sent in electronic format as scanned documents to the following address: pawel.brzezinski@polpharma.com.

6.2. The date and the time when the bid is received by the Buyer determines whether the submission deadline has been complied with.

6.3. No bids submitted past the submission deadline will be considered.

6.4. The Buyer is not planning to hold a public opening of the bids.

6.5. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

VII. METHOD OF PRICE CALCULATION

7.1. Bid price calculation: the price should be calculated as a net amount.

7.2. Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland (https://www.nbp.pl/) on the end date of the time limit for the submission of bids.

7.3. The price should include all the costs related to the preparation and performance of the subject of the Price Inquiry.

7.4. The price given in the bid cannot change during contract performance.

VIII. CONTRACT AWARD CRITERIA

8.1. When evaluating the offers, the Buyer will use the following categories:
- total net order price - 60%,
- service delivery time - 20%,
- the amount of material needed to develop the methods - 20%.

8.2. The point evaluation of the offer will be calculated in accordance with the following formula:

$$\boldsymbol{O_P = P_C + P_M + P_A}$$

where:

O_P - point evaluation of the offer
P_C - number of points obtained in the category "Total net order price"
P_M - number of points obtained in the category "Service delivery time"
P_A - number of points obtained in the category „Amount of material needed to develop the methods”

8.3. The number of points (P_C) in the category „Total net order price” will be calculated using the following formula:

$$P_C = \frac{C_N}{C_B} * 60\ pkt$$

where:

P_C - number of points obtained in the category "Total net order price"
C_N - among the offers not rejected, the lowest total net price of the offer
C_B - total net price of the examined offer

Offers submitted in a currency other than PLN will be converted into PLN at the average exchange rate of the National Bank of Poland for the last day of the submission of offers.

8.4. The number of points (P_M) in the category „Service delivery time” will be calculated using the following formula:

$$P_M = \frac{M_N}{M_B} * 20\ pkt$$

where:

P_M - number of points obtained in the category „ Service delivery time”
M_N - among the offers not rejected, the shortest lead time for the subject of the offer price inquiry (*number of weeks counted from the date of receipt of all samples by the bidder's laboratory*)

M_B - time of completion of the subject of the price inquiry declared in the offer (*number of weeks counted from the date of receipt of all samples by the bidder's laboratory*)

The time of execution of the subject of the price inquiry should be given in weeks.
An Offer with a lead time longer than 8 weeks from the date of receipt of all samples to the Bidder's laboratory will be rejected.

8.5. The number of points (P_A) in the category „Amount of material needed to develop the methods" will be calculated using the following formula:

$$P_A = \frac{A_N}{A_B} * 20\ pkt$$

where:

P_A - number of points obtained in the category „Amount of material needed to develop the methods"

A_N - among the offers not rejected, the smallest amount of material needed to develop methods (*the sum of the amount of material needed to develop methods*)

A_B - the amount of material needed to develop the methods declared in the offer (*the sum of the amount of material needed to develop the methods*)

8.6. The Bidder may obtain a maximum of 100 points. Calculations will be made with an accuracy of two decimal places.

IX. PREPARATION OF BIDS

9.1. The Bidder must draw up a single price bid using the form attached as Appendix 1 hereto. Submitting more than one bid for a particular part will result in all bids submitted by the Bidder being rejected.
9.2. Bid must be prepared in the Polish or English language version,
9.3. Bidders are required to carefully read the information contained in the Price Inquiry.
9.4. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.
9.5. Until the end of the time limit for the submission of bids, the Customer reserves the right to amend or add new information to this Price Inquiry.
9.6. The submitted bids will remain valid and binding for 60 calendar days from the end date of the time limit for the submission of bids.

X. COMMUNICATIONS BETWEEN THE BUYER AND BIDDERS, PERSONS AUTHORISED FOR CONTACT

10.1. During the tender procedure the Buyer and the Bidder submit all declarations, requests, notices and information in Polish.
10.2. The receipt of any notices, declarations, requests and information submitted electronically must be immediately confirmed at the request of each of the Parties.
10.3. If the Bidder has not confirmed the receipt of the correspondence, the Buyer will assume that the correspondence sent by the Buyer to the e-mail address provided by the Bidder has been delivered in a way that enables the Bidder to read it.

10.4. Any correspondence about this Price Inquiry should be sent to e-mail: pawel.brzezinski@polpharma.com

10.5. In any correspondence related to this Price Inquiry, the Bidder should use the procedure number: Price Inquiry No. NUSI/31/ PR13783/2023

10.6. Paweł Brzeziński is the person authorised to communicate with the Bidder .

10.7. No information, clarifications or replies to any queries submitted to the Buyer will be provided orally or by phone.

10.8. Any questions about this Price Inquiry should be sent by e-mail to the address provided above, not later than 3 days before the end of the time limit for the submission of bids.

10.9. Replies to the answers and adding more detailed information to the Price Inquiry following from questions from prospective Bidders will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

11.1. During the examination and evaluation of the submitted bids, the Buyer may request the Bidder to provide additional information (if it does not infringe competition) and clarifications related to the submitted bids. The Buyer may also ask the Bidder to correct evident mistakes and calculation errors.

11.2. The Buyer reserves the right to verify, during the bid evaluation, the documents, statements, lists, data and information provided by the Bidders.

11.3. If two or more Bidders have the same score, the bid which is best in terms of the environmental and climate impact will be selected. For this purpose, the Buyer has the right to request the Bidders with the highest final score to supplement the bid with more information requested by the Buyer with respect to the environmental impact of the subject of the bid.

XII. ADDITIONAL INFORMATION

12.1. The bidder bears all costs related to the preparation and submission of the bid.

12.2. Until the deadline for submission of bids, the Buyer reserves the right to change or add the content of this price inquiry.

XIII. LIST OF APPENDICES

The following appendices are attached to this Price Inquiry:

Appendix number	Appendix title
Appendix 1	Bid Form
Appendix 2	Bidder’s declaration of meeting the conditions for participation in the procedure

Appendix 1 to the Price Inquiry No. NUSI/31/ **PR13783***/2023*

BID FORM

Bidder:

Name / Company	
Registered office/home address/address of the principal place of business	
E-mail address for the Buyer to send information related to the Price Inquiry	
NIP [Taxpayer ID Number]	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Buyer	

We offer the delivery of the subject of the order for the ***analytical research services*** in accordance with the terms of the Price Inquiry for the following **price:**

Total net value: …… PLN/EUR

VAT: ……%, VAT amount: …… PLN/EUR

The gross amount: …… **PLN/EUR**

Terms of payment: ……..days

Time of delivery: …….. weeks counted from the date of receipt of all samples by the bidder's laboratory.

The sum of the amount of material needed to develop the methods ……. (mg).

Method development plan as follow:

We also declare as follows:

a. We have read the Price Inquiry and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our bid.

b. Our bid price includes a lump sum that covers all the obligations of the future Seller as necessary to deliver the subject of this Price Inquiry.

c. Our bid will remain valid and binding for 60 calendar days from the end date of the time limit for the submission of bids,

……	……
(place and date)	(signature(s) of person(s) authorised to submit statements of will on behalf of the Bidder)

Appendix 2 to the Price Inquiry *nr NUSI/31/ PR13783/2023*

BIDDER'S DECLARATION OF MEETING THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

…… *(Bidder's name)* declares, that they meet the conditions set out in the inquiry in the following scope:

i. We present the assumptions regarding the method development plan and the scope of the planned tests to be assessed by the Buyer on the day of submitting the offer, together with the amount of material necessary to develop the methods and the expected amount of material necessary for the final comparative analysis of the test product against the reference product.
ii. We have knowledge and experience in conducting research for oligonucleotides.
iii. We have knowledge and experience in the development of the above-mentioned analytical methods for oligonucleotides in GMP quality. The laboratory has FDA certification in the scope of analytical techniques that are the subject of the inquiry.

…… (place and date)

…… (signature(s) of person(s) authorised to submit statements of will on behalf of the Bidder)