

Starogard Gdansk, 18.04.2025r.

PRICE INQUIRY no NUSI/111/PR98053/2025
conducted by means of market discernment

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, Zakłady Farmaceutyczne Polpharma S.A., you are kindly requested to submit a bid **for the provision of services for conducting analytical tests described in detail in point. III.**

I. NAME AND ADDRESS OF THE BUYER

Zakłady Farmaceutyczne Polpharma S.A.
ul. Pielplińska 19
83-200 Starogard Gdański

II. PRICE INQUIRY PROCEDURE

- II.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)
- 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 PRICE INQUIRY

- III.1.** The subject of the price inquiry is a research service.
- III.2.** CPV CODE: 73100000-9 Research and experimental development services
- III.3.** Scope of the price inquiry:

Conducting non-GMP analyses in the scope of characterization of the active substance, Nusinersen sodium, according to the Contractor's methodology.

The order consists of two stages:

- a) conducting **preliminary tests** to confirm the suitability of the methods (feasibility),
- b) conducting **routine tests**.

III.4. Detailed scope of the inquiry

III.4.1 The Contractor perform method feasibility to confirm the suitability of all methods (listed later in the price inquiry) in 1-2 runs using 1 batch of API provided by the Buyer. If any additional optimization will be needed, this will first be discussed in detail with the Buyer.

III.4.2 The Contractor will conduct the following non-GMP tests according to in-house methodology to confirm the structure of the sodium Nusinersen samples:

- nuclear magnetic resonance (¹H-NMR, ³¹P-NMR),
- ultraviolet spectroscopy (UV),
- infrared spectroscopy (IR),
- molecular mass confirmation,
- elemental composition,
- differential scanning calorimetry (DSC),
- circular dichroism (CD).

The Contractor undertakes to perform the above tests in one laboratory.

III.4.2.1 Nuclear magnetic resonance

Objective of the method:
Study of the structure and stereoisomers in the active substance performed on a nuclear magnetic resonance spectrometer (NMR 600 MHz).
Scope:
The method should be specific in terms of characterization of stereoisomers and should provide an opportunity to compare products against each other.
Information to include in the report:
¹ H-NMR spectrum, which provides an opportunity to compare products against each other. Description of the spectrum.
³¹ P-NMR spectrum. Description of the spectrum including the calculated S/R isomer ratio.

III.4.2.2 Ultraviolet spectroscopy (UV)

Objective of the method:
Recording of UV spectrum for the active substance.
Scope:
The method should provide an opportunity to compare products against each other.
Information to include in the report:
UV spectrum with its description.

III.4.2.3 Infrared spectroscopy (IR)

Objective of the method:
Recording of IR spectrum for the active substance.
Scope:
The method should provide an opportunity to compare products against each other.
Information to include in the report:
IR spectrum with its description.

III.4.2.4 Molecular mass confirmation

Objective of the method:
Confirmation of the molecular mass of the tested active substance.
Scope:
The method should clearly indicate the molecular mass of the tested substance.
Information to include in the report:
Molecular mass of the tested substance.

III.4.2.5 Elemental composition

Objective of the method:
Confirmation of the elemental composition of the tested substance.
Scope:
The method should clearly indicate the composition of the tested substance.
Information to include in the report:
The elemental composition of the tested substance.

III.4.2.6 Differential scanning calorimetry (DSC)

Objective of the method:
Study of higher-order structures in the tested substance.
Scope:
The method should be specific in terms of the presence of higher-order structures and should give the opportunity to compare products against each other.
Information to include in the report:
Graphs obtained during the experiment and their description.

III.4.2.7 Circular dichroism (CD)

Objective of the method:
Study of higher-order structures in the tested substance.
Scope:
The method should be specific in terms of the presence of higher-order structures and should give the opportunity to compare products against each other.
Information to include in the report:
CD spectrum with its description.

III.4.3 Due to the development nature of the project, the Buyer reserves the right to place additional orders. Additional tests will be ordered by the Buyer after agreeing with the Contractor on the scope of the test and the delivery date.

III.4.4 The Buyer requires the Contractor to provide a report on the preliminary tests (method feasibility) to confirm the suitability of each of the methods.

III.4.5 The Buyer requires the Contractor to provide reports containing a description and parameters of the used method, the results and raw data for each sample provided as part of routine tests - after the tests are completed.

III.4.6 For each sample provided by the Buyer, the set of tests is the same - described in point III.4.2 unless the Buyer indicate otherwise.

III.4.7 The Contractor is obliged to ensure that its analytical laboratory operates in a quality system compliant with GMP.

III.4.8 Samples for testing will be delivered in parts depending on the Buyer's needs. **The Buyer foresees the total number of samples as 9, but reserves the possibility of increasing their number during the development of the project.**

III.4.9 Deadlines:

Subject of the order	Deadline*
Feasibility	maximum 6 weeks
Routine tests	maximum 5 weeks

* counted from the date of material delivery for testing

III.4.10 Offers with deadlines exceeding the time specified in point III.4.9. will be rejected.

III.4.11 The costs of delivering samples are the responsibility of the Buyer.

III.4.12 The costs related to performing analyses are the responsibility of the Contractor.

III.5. The Buyer does not allow for partial or variant offers.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

IV.1 Planned date of signing the contract: **May-June 2025.**

IV.2 The planned duration of the contract is set at **18 months** from the date of signing the contract.

IV.3 The deadline for performing feasibility of the Contractor's in-house methods is no longer than 6 weeks from the date of sample delivery by the Buyer.

IV.4 The deadline for performing of routine tests is no longer than 5 weeks from the date of delivery of the sample by the Buyer.

IV.5 The organization and cost of sending the samples is the responsibility of the Buyer.

IV.6 The Buyer allows partial payments for the implementation of individual orders.

V. REQUIREMENTS FROM CONTRACTORS

V.1. Contractors who meet the following conditions may apply for the award of the contract:

V.1.1. Have knowledge and a minimum of 3 years of experience in conducting structural studies of MS, CD, DSC analytical methods for oligonucleotides.

V.1.2. Have knowledge and a minimum of 5 years of experience in conducting structural studies of ¹H-NMR, ³¹P-NMR analytical methods for oligonucleotides.

V.1.3. The laboratory is FDA-certified for the analytical techniques under inquiry.

V.1.4. The analytical laboratory operates in a GMP-compliant quality system.

V.2. Bids submitted by Contractors who demonstrate that they meet the specified requirements from point V.1. will be taken forward to the bid examination and assessment stage. The compliance

with the above requirements will be assessed based on a 'meet – does not meet' basis. Contractor, who fails to meet any of the conditions indicated in point V.1, will be rejected in the proceedings.

V.3. Contractors shall indicate in their offer the maximum amount of material that will be evaluated under the criteria, in accordance with the provisions of point VIII.

V.4. Entities for which the following circumstances occur are also excluded from the tender:

V.4.1. as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;

V.4.2. as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning.

VI. PLACE AND DATES FOR SUBMITTING BIDS

VI.1. The final **deadline for submitting bids is 30.04.2025r.**

- bids can be sent in electronic format as scanned documents or electronically signed documents to the following address: andrzej.kasperowicz@polpharma.com

VI.2. The date and the time when the bid is received by the Buyer determines whether the submission deadline has been complied with.

VI.3. No bids submitted past the submission deadline will be considered.

VI.4. The bid must be signed by persons authorised to represent the Contractor in accordance with the representation resulting from the relevant register or pursuant to a power of attorney granted. The power of attorney must be attached to the bid.

How to evaluate the condition:

*The Buyer will consider the Contractor as meeting the above conditions if the Contractor submits a declaration of compliance with the conditions for participation in the procedure (**Attachment no 2 to the Price Inquiry**).*

The Buyer reserves the right to verify the fulfilment of the conditions at the Contractor's premises or to call for relevant documentation to be submitted.

VII. METHOD OF PRICE CALCULATION

VII.1. Bid price calculation: the price should be calculated as a net and a gross amount.

VII.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/>) as at the final date for the submission of bids.

VII.3. The price should include all the costs related to the preparation and performance of the Subject of Inquiry.

VII.4. The price included in the submitted bid cannot change during the performance of such an agreement, with the exception of the situations described in point XII.

VIII. DESCRIPTION OF THE CRITERIA THAT THE CONTRACTOR USE IN SELECTING THE OFFER

VIII.1. When evaluating the offers, the Buyer will use the following categories:

- total net order price - 70%,
- the amount of material needed to develop the methods - 30%.

VIII.2. The scoring of the bid will be calculated according to the following formula:

$$O_P = P_C + P_A$$

where:

- O_P - the bid score
- P_C - number of points obtained in the category "Total net order price"
- P_A - number of points obtained in the category „Amount of material needed to develop the methods”

VIII.3. The number of points (P_C) in the category „Total net order price” will be calculated using the following formula:

$$P_C = \frac{C_N}{C_B} * 70 \text{ points}$$

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

Bids 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.

VIII.4. The number of points (P_A) in the category „Amount of material needed to develop the methods” will be calculated using the following formula:

$$P_A = \frac{A_N}{A_B} * 30 \text{ pkt}$$

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 maximum amount of material needed to develop methods, indicated in Attachment 1*)
- A_B - the amount of material needed to develop the methods declared in the offer (*the maximum amount of material needed to develop the methods, indicated in Attachment 1*)

VIII.5. The bid with the highest score out of all the non-rejected bids will be considered the best bid. The maximum score to be awarded to the Contractor is 100 points. Calculations will be made to two decimal places.

IX. PREPARATION OF BIDS

IX.1. The Contractor must draw up a single price bid using the form attached as Attachment No 1 hereto.

IX.2. Bid must be prepared in the Polish or English language version,

- IX.3.** The submitted bids will remain valid and binding for 90 calendar days from the end date of the time limit for the submission of bids.
- IX.4.** Until the end of the time limit for the submission of bids, the Contractor reserves the right to modify or withdraw their bid.
- IX.5.** Contractors are required to carefully read the information contained in the Price Inquiry
- IX.6.** Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Contractors.
- IX.7.** For matters related to this inquiry, please contact the Buyer at the following email: andrzej.kasperowicz@polpharma.com

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

- X.1.** During the tender procedure the Buyer and the Contractors submit all declarations, requests, notices and information in Polish or English.
- X.2.** The receipt of any notices, declarations, requests and information submitted electronically must be immediately confirmed at the request of each of the Parties.
- X.3.** If the Contractor 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 Seller has been delivered in a way that enables the Contractor to read it.
- X.4.** Any correspondence about this Price Inquiry should be sent to e-mail: andrzej.kasperowicz@polpharma.com
- X.5.** In any correspondence related to this Price Inquiry, the Seller should use the procedure number: Price Inquiry No. **NUSI/111/ PR98053/2025**.
- X.6.** Andrzej Kasperowicz is the person authorised to communicate with the Contractor.
- X.7.** No information, clarifications or replies to any queries submitted to the Buyer will be provided orally or by phone.
- X.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.
- X.9.** Replies to the answers and adding more detailed information to the Price Inquiry following from questions from prospective Contractors will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

- XI.1.** During the examination and evaluation of the submitted bids, the Buyer may request the Contractor to provide additional information (if it does not infringe competition) and clarifications related to the submitted bids. The Buyer may also ask the Contractor to correct evident mistakes and calculation errors.
- XI.2.** The Buyer reserves the right to verify, during the bid evaluation, the documents, statements, lists, data and information provided by the Contractors.
- XI.3.** If two or more Contractors 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 Contractors 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.
- XI.4.** **The Buyer reserves the right to negotiate** with the selected Contractor who obtained the highest number of points during the examination of the bids, especially in cases where the price offered by the Contractor exceeds the budget allocated by the Buyer for the execution of the order.

XII. AMENDMENTS TO THE CONTRACT

XII.1. The Buyer reserves the **right to make material changes to the provision of the Contract**, as compared to the bid based on which the Buyer was awarded the contract, to the following extent and in the following situations:

XII.1.1. to reflect changes in law that affect the delivery of the services covered by the Contract (in particular changes in VAT rates);

XII.1.2. to improve technical parameters of the Contract in line with new solutions brought about by technological advancements, without any effects on the gross flat rate;

XII.1.3. to extend the deadline for the delivery of the services covered by the Contract due to additional works which need to be carried out to ensure proper delivery of the services covered by the Contract and which the Buyer, while exercising due diligence, could not have foreseen beforehand, subject to point XII.1.6 below;

XII.1.4. to extend the deadline for the delivery of the services covered by the Contract due to force majeure event(s), with any consequences of such an extension;

XII.1.5. To change the parameters of the services covered by the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to deliver the services covered by the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-delivery or improper delivery of the services covered by the Contract, subject to point XII.1.7. below;

XII.1.6. to make changes with respect to additional deliveries or services to be provided by Contractor, which are not covered by the Contract, as long as they are necessary and when all of the following requirements are met:

- Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted under the original Contract,
- Contractor replacement could cause significant inconvenience or a material increase in costs for the Buyer,
- each subsequent change does not exceed 50% net of the original Contract net amount;

XII.1.7. to make changes without altering the nature of the Contract, when all of the following requirements are met:

- the Contract needs to be changed due to circumstances which could not have been foreseen by the Buyer while exercising due diligence,
- the change does not exceed 50% of the original Contract net amount;

XII.1.8. to replace the Contractor with a new contractor:

- as a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participation in the procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
- as a result of the Buyer taking over Contractor's obligations towards its subcontractors;

XII.2. The Buyer can also make non-material amendments to the Contract as compared to the bid based on which Contractor was awarded the Contract.

XII.3. Any amendments to the Contract will be made in the form of an annex signed by both parties and will require approval from the Buyer.

XIII. ADDITIONAL INFORMATION

XIII.1. The Contractor shall bear all costs associated with the preparation and submission of the Bid.

XIII.2. Until the end of the time limit for the submission of bids, the Buyer reserves the right to amend or add new information to this Price Inquiry.

XIII.3. PERSONAL DATA PROTECTION.

As far as personal data contained in bids are concerned, the Buyer – as soon as the bid is submitted – will become the Data Controller as defined under Article 4(7) 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 (“GDPR”). The Buyer will process the data for the purposes of bid evaluation, concluding an agreement with the awarded contractor and implementing the concluded agreement, i.e. under Article 6(1)(b) of the GDPR.

The Buyer will transfer the personal data contained in the submitted bids, under relevant regulations, to authorised bodies and institutions entitled to audit projects co-financed from the funds of the Medical Research Agency. For more information on the processing of personal data by competent institutions, visit: <https://abm.gov.pl/pl/wolnytekst/198,Polityka-dotyczaca-cookies.html>

The Buyer will process the personal data throughout the period during which it is required, under relevant regulations, to store the whole documentation related to projects co-financed from the funds of the Medical Research Agency.

XIV. LIST OF ATTACHMENTS

The following attachments are attached to this Price Inquiry:

Attachments number	Attachments title
Attachment No 1	Bid form
Attachment No 2	Declaration of meeting the conditions for participation in the procedure

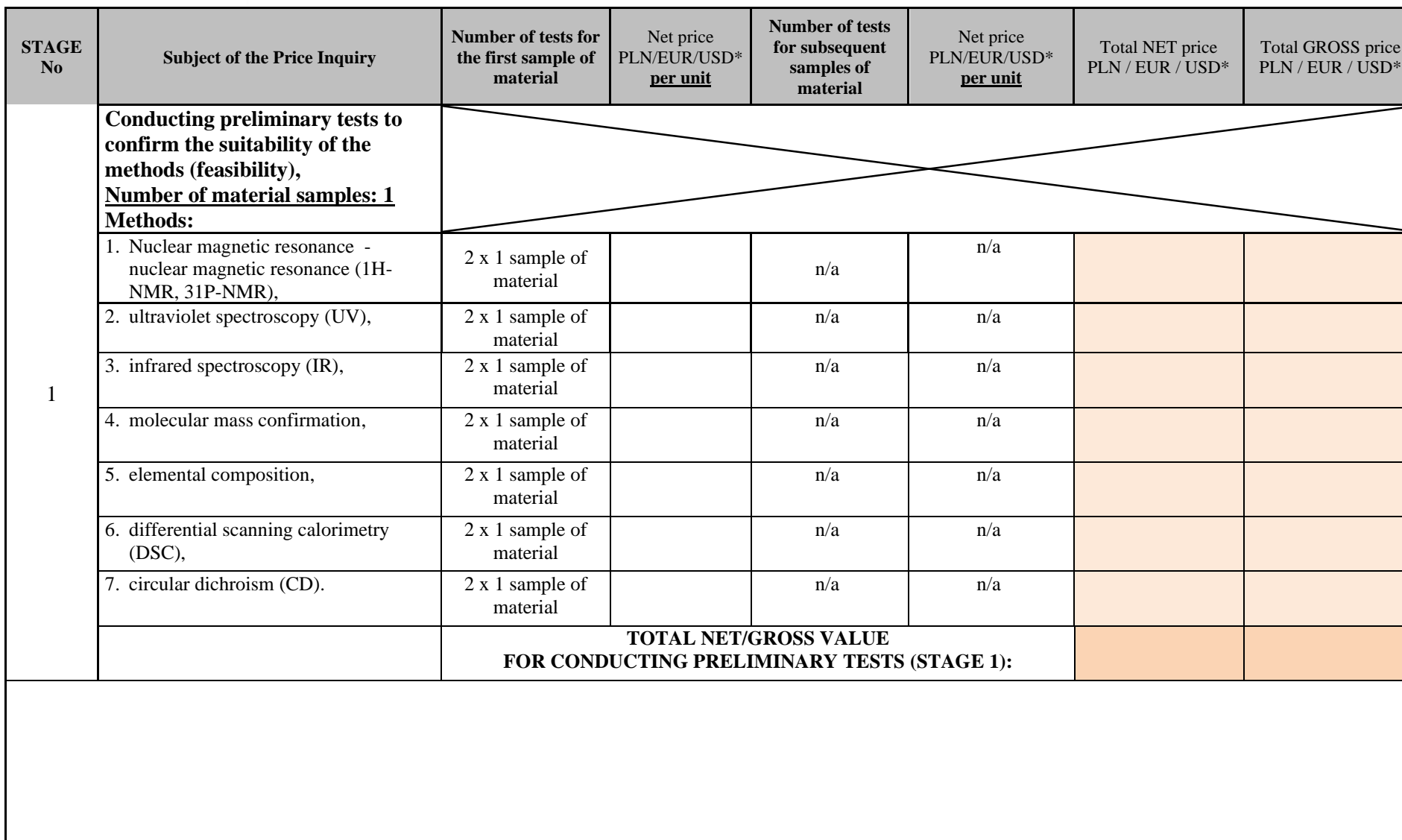
Attachment 1 to the Price Inquiry No. NUSI/111/ PR98053/2025

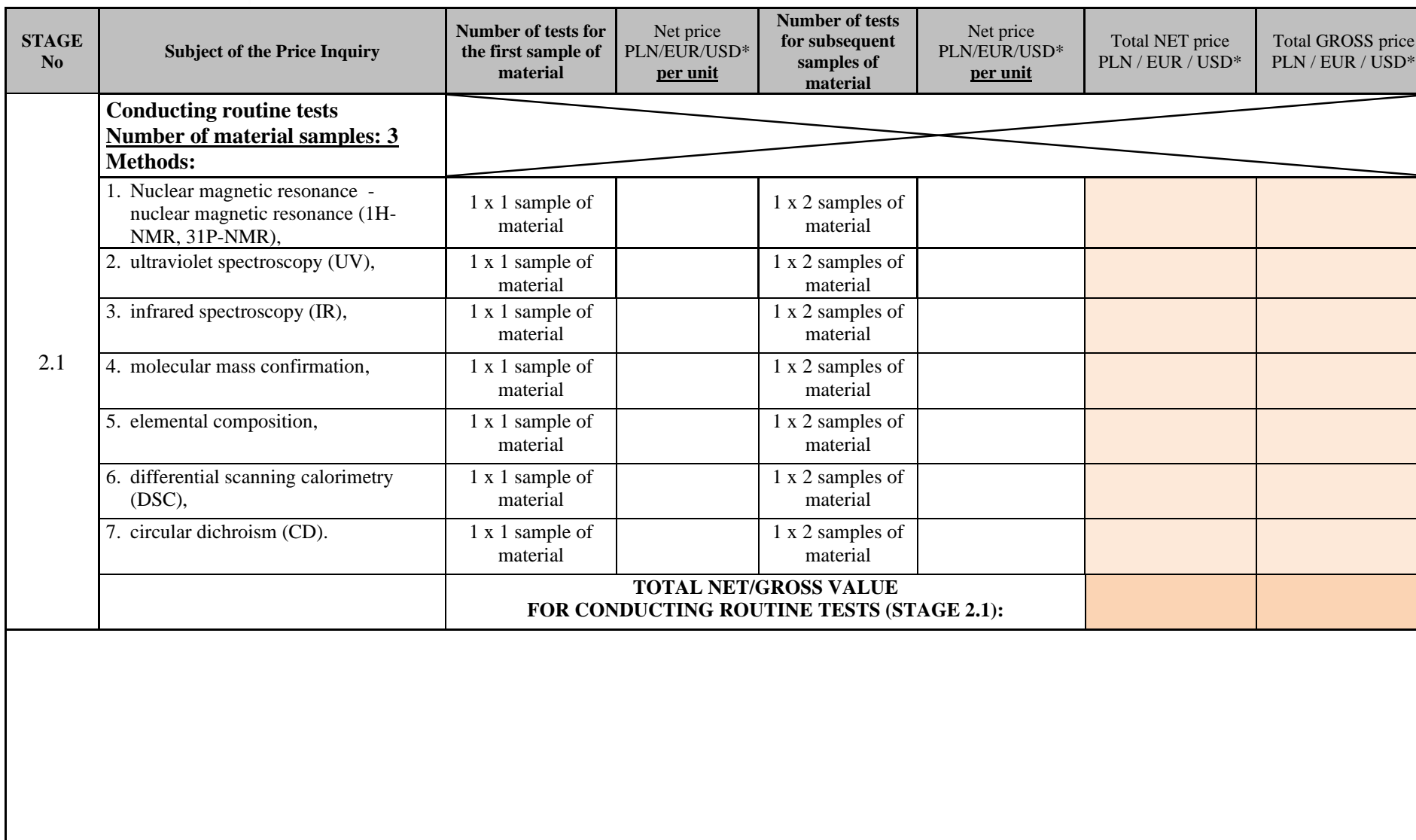
BID FORM

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:**







STAGE No	Subject of the Price Inquiry	Number of tests for the first sample of material	Net price PLN/EUR/USD* <u>per unit</u>	Number of tests for subsequent samples of material	Net price PLN/EUR/USD* <u>per unit</u>	Total NET price PLN / EUR / USD*	Total GROSS price PLN / EUR / USD*
2.2	Conducting routine tests <u>Number of material samples: 6</u> Methods:						
	1. Nuclear magnetic resonance - nuclear magnetic resonance (1H- NMR, 31P-NMR),	1 x 1 sample of material		1 x 5 samples of material			
	2. ultraviolet spectroscopy (UV),	1 x 1 sample of material		1 x 5 samples of material			
	3. infrared spectroscopy (IR),	1 x 1 sample of material		1 x 5 samples of material			
	4. molecular mass confirmation,	1 x 1 sample of material		1 x 5 samples of material			
	5. elemental composition,	1 x 1 sample of material		1 x 5 samples of material			
	6. differential scanning calorimetry (DSC),	1 x 1 sample of material		1 x 5 samples of material			
	7. circular dichroism (CD).	1 x 1 sample of material		1 x 5 samples of material			
		TOTAL NET/GROSS VALUE FOR CONDUCTING ROUTINE TESTS (STAGE 2.2):					
		TOTAL NET/GROSS PRICE ** FOR CONDUCTING PRELIMINARY TESTS (STAGE 1) AND ROUTINE TESTS (STAGES 2.1 & 2.2) **)THE TOTAL NET PRICE WILL BE CONSIDERED FOR THE EVALUATION OF OFFERS IN ACCORDANCE WITH POINTS VIII.1; VIII.2; VIII.3					

*) delete as appropriate, select the correct currency

Time of delivery:

- a. **Preliminary tests: weeks** counted from the date of receipt of all samples by the contractor's laboratory
- b. **Routine tests: weeks** counted from the date of receipt of all samples by the contractor's laboratory

Maximum amount of material needed to develop the full range of methods (preliminary tests: 2 tests/method and routine tests: 9 tests/method) specified in the Price Inquiry
..... (mg).

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 Contractor as necessary to deliver the subject of this Price Inquiry.
- c. By submitting this offer, we declare that we meet the participation conditions specified in point V of the Price Inquiry
- d. The following circumstances do not occur with respect to us:
 - a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;
 - b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

.....
(place and date)

.....
(signature)

Attachment 2 to the Price Inquiry nr NUSI/111/ PR98053/2025

**DECLARATION OF MEETING THE CONDITIONS FOR PARTICIPATION IN THE
PROCEDURE**

..... (Contractor's name)

declares, that they meet the conditions set out in the inquiry in the following scope:

- i. We have knowledge and a minimum of 3 years of experience in conducting structural studies of MS, CD, DSC analytical methods for oligonucleotides.
- ii. We have knowledge and a minimum of 5 years of experience in conducting structural studies of ¹H-NMR, ³¹P-NMR analytical methods for oligonucleotides.
- iii. The laboratory is FDA-certified for the analytical techniques under the inquiry.
- iv. The analytical laboratory operates in a GMP-compliant quality system.

.....
(place and date)

.....
(signature)