Warsaw, 23.08.2024

PRICE INQUIRY No. NUSI/76/PR71749/2024
conducted by means of market discernment

In connection with the implementation of the project entitled "Development of a universal fastresponse platform, based on RNA technology, ensuring the national drug and epidemiological safety" funded by the state budget from the Medical Research Agency, Zakłady Farmaceutyczne Polpharma S.A., are requesting bids for the provision of services for conducting analytical tests described in detail in point. III.

I. NAME AND ADDRESS OF THE ORDERING PARTY

Zakłady Farmaceutyczne Polpharma S.A.

Pelpinska St. 19, 83-20 0 Starogard Gdanski

II. MODE OF AWARDING THE CONTRACT

2.1. This order is not subject to the provisions of the Act of September 11, 2019. Public Procurement Law (i.e. Journal of Laws of 2019, item 2019)

2.2. Proceedings conducted by market discernment, in an expedient and economical manner in compliance with the rules:

2.2.1. getting the best results from given inputs;

2.2.2. optimal selection of methods and means to achieve the objectives;

2.2.3. openness, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE PRICE INQUIRY

3.1. The subject of the price inquiry is the purchase of services related to the validation of analytical methods in the field of characterization of the active substance and the finished product containing the active substance Nusinersen, as well as the performance of comparative analyses against the reference product according to the previously developed methodology and the performance of routine analyses.

3.2.CPV CODE: 73100000-9 Research and experimental development services

3.3. The order consists of three stages:

a) Perform validation of analytical methods,
b) conduct comparative studies and
c) conduct routine tests.

The purchaser reserves the right to implement the various stages in parallel and in any order depending on the progress of the R&D project.

3.4. Perform validation of developed analytical methods for the product and active substance under pharmaceutical development in terms of techniques and in terms of requirements:

- Nuclear magnetic resonance (1H NMR, 13C NMR, 31P NMR),
- Differential scanning calorimetry (DSC),
- circular dichroism (CD),
- Sedimentation velocity by ultracentrifugation (SV-AUC).

3.4.1. For the circular dichroism (CD) method:

Objective of the method:
Study of higher order structures in the product performed on a circular dichroism (CD) spectrometer
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.
Parameters of the conducted method to be included in the report:
Specificity of the analytical method (minimum of one vehiculum test, minimum of one test sample).
Repeatability of the analytical method (minimum of six test samples).

3.4.2. For the method, differential scanning calorimetry (DSC):

Objective of the method:
Study of higher-order structures in the product performed on a differential scanning calorimeter (nano DSC).
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.
Parameters of the conducted method to be included in the report:
Specificity of the analytical method (minimum of one vehiculum test, minimum of one test sample).
Repeatability of the analytical method (minimum of six test samples).

3.4.3. For the method, sedimentation velocity by ultracentrifugation (SV-AUC):

Objective of the method:
Study of higher-order structures in the product performed on an analytical ultracentrifuge (SV-AUC).
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.
Parameters of the conducted method to be included in the report:
Specificity of the analytical method (minimum of one vehiculum test, minimum of one test sample).
Repeatability of the analytical method (minimum of six test samples).
Robustness of the analytical method (stability of the test sample) (minimum of four test samples).

3.4.4. For the nuclear magnetic resonance method (1H NMR, 13C NMR, 31P NMR):

Objective of the method:
One- and two-dimensional techniques should be used to study of the structure and stereoisomers in the product performed on a nuclear magnetic resonance spectrometer (NMR 600 MHz)
Scope:
The method should be specific for structure identification and the characterization of stereoisomers and should provide an opportunity to compare products against each other.
Parameters of the conducted method to be included in the report:
Specificity of the analytical method (minimum of one vehiculum test, one test sample)
Repeatability of the analytical method (minimum of six test samples)
Detection limit of the analytical method (minimum of three test samples)

3.5. Whenever the Procuring Entity describes the Subject of the Contract by indicating trademarks, it allows solutions equivalent to those described. The Bidder who refers to equivalent solutions is obliged to demonstrate that they meet the requirements specified by the Ordering Party. The Ordering Party allows the use of equivalent instruments during validation, provided that the full costs of optimizing the method to the required conditions are covered.

Due to the uniqueness, uniqueness, strictly defined methodology of the projects, scientific research and experiments carried out, as well as the necessity to maintain continuity and repeatability of the research carried out by the Ordering Party, the Supplier offering products equivalent to those described in this request for proposal shall be obliged, at the request of the beneficiary:

- demonstrate on the basis of technical documentation/reagent data sheets/etc. and a written declaration that the equivalent products offered by it (each individually) meet the requirements allowing the Buyer's scientific research to continue without the need for additional steps (procedures), including, for example, calibration of equipment,

- demonstrate (through a written declaration) that the equivalent products offered will not result in increased costs due to the need to purchase additional products and other consumables,
- demonstrate (through a written declaration) that the equivalent products offered will not result in increased costs due to the need to purchase additional products and other consumables.

3.6. The basic order includes analytical method validations, which should be performed in accordance with ICH guideline Q2(R2). The minimum scope of validation includes specificity/selectivity (confirmed by negative samples) and reproducibility of the method.

3.7. The Ordering Party reserves the right to award additional orders in case additional samples are needed during method validation. Additional samples will be ordered by the Ordering Party after agreeing with the Contractor on the scope of testing and delivery date.

3.8. Method validation protocols (plans) (including a description of sample preparation and the number of samples to be tested) should be provided for approval by the Employer before the tests are performed.

3.9. The purchaser requires the delivery of a method validation report with the results and raw data for the test samples, after the test is performed.

3.10. The Employer requires that the Bidder propose, based on the validation performed, acceptance criteria for comparative product testing (test product vs. reference product).

3.11. The bidder is required to ensure that the validated analytical methods are conducted in a GMP-compliant quality system.

3.12.Conduct a comparative study of the test product against the reference product (sameness) using validated methods.

3.12.1. At the bidding stage, the execution of comparative studies for 6 series for each of the above-mentioned techniques (listed in items 3.4.1-3.4.4) is subject to pricing. The final number of series will be determined during the execution of the study. Criteria for acceptance of the comparative study should be agreed with the Employer.

3.12.2. The Ordering Party reserves the right to award additional orders in case additional batches need to be tested. Additional samples will be ordered by the Ordering Party after agreeing with the Contractor on the scope of the test and the delivery date.

3.12.3. The purchaser requires the delivery of a comparative test report with raw data for the samples tested, along with a description of the equipment used to perform the analyses, upon completion of the test.

3.12.4. The bidder is required to ensure that the study is conducted in a GMP-compliant quality system.

3.13. Conduct routine tests, scope of analysis:

- Nuclear magnetic resonance (1H NMR, 13C NMR, 31P NMR),
- Differential scanning calorimetry (DSC),
- circular dichroism (CD),
- Sedimentation velocity by ultracentrifugation (SV-AUC).

3.13.1. Tests will be carried out repeatedly during the term of the contract, at a minimum for one batch, and also as additional samples. The number of samples for testing will be agreed with the Contractor prior to shipment.

3.13.2. The bidder is required to ensure that the research is conducted in a GMP-compliant quality system.

3.13.3. The purchaser requires the delivery of a report with a description and parameters of the method performed, results and raw data for the samples tested, upon completion of the test.

3.13.4. The Contractor will conduct batch testing of the test product or reference product during the period of the research project - until March 31, 2027.

3.14. A detailed description of the method **Appendix No. 4** will be provided to the bidder after signing the confidentiality agreement attached as **Appendix No. 3.** The contractor should send the completed confidentiality agreement in an editable version to the email address: dominika.radzanowska@polpharma.com. Upon receipt of the confidentiality agreement, the signatures of the authorized person (or persons) in accordance with the representation rules of the respective Contractor will be collected by the DocuSign platform. The Contracting Authority will make Appendix No. 4 available no later than two business days after the date of mutual signing of the confidentiality agreement.

3.15. The purchaser will provide the product, vehiculum and necessary materials to prove specificity in the case of method validation in an amount sufficient to perform the service.

3.16. The contracting authority does not allow partial or variant bids**.**

3.17. The Contracting Authority at any stage of the service may cancel further implementation if the results of a particular stage do not meet the requirements of the Contracting Authority. The Contractor may not claim compensation for this reason.

IV. PLACE AND DATE OF EXECUTION OF THE PRICE INQUIRY

4.1. Planned contract signing date: September/October 2024

4.2. Duration of contract: from signing until March 31, 2027

4.3. The planned period of performance of the subject of the price inquiry:

4.4. No longer than 10 weeks counted from the date of delivery of all samples to the bidder's laboratory to the submission of the final report, for validation of analytical methods

4.5. not more than 4 weeks counted from the date of delivery of samples to the submission of the report in the final version, for comparative studies

4.6. No more than 4 weeks counted from the date of delivery of samples to the submission of the final report, for routine analysis.

4.7. The organization and cost of shipping samples is the responsibility of the Ordering Party.

V. REQUIREMENTS FROM CONTRACTORS

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

5.1.1. They will provide assumptions as to the method validation plan for evaluation by the Contracting Authority on the date of submission of the bid, along with the amount of material required for analysis**. (Appendix 1)**

5.1.2. Have knowledge and a minimum of 3 years of experience in conducting comparative studies of DSC, CD, SV-AUC analytical methods for oligonucleotides. (**Appendix 2)**

5.1.3. Have knowledge and a minimum of 5 years of experience in conducting comparative studies of 1H NMR, 13C NMR, 31P NMR analytical methods for oligonucleotides. **(Appendix 2)**

5.1.4. Have the knowledge and experience to validate the above analytical methods for oligonucleotides in a GMP-compliant quality system.

5.1.5. Have knowledge and a minimum of 3 years of experience in routine testing by DSC, CD, SV-AUC analytical methods.

5.1.6. Have knowledge and a minimum of 5 years of experience in routine testing with 1H NMR, 13C NMR, 31P NMR analytical methods.

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

5.1.8. Have the required personnel background of at least 1 person with at least 5 years of experience in conducting the research that is the subject of the request for proposal.

5.2. The bids of Contractors who demonstrate compliance with the required conditions will be admitted for examination and evaluation. Evaluation of the fulfillment of the conditions presented above will be carried out according to the formula: "meets - does not meet". A Contractor who fails to meet any of the conditions will be rejected in the proceedings.

How to evaluate the condition:
*The Contracting Authority will consider that the Contractor meets this condition if the Contractor submits a statement of fulfillment of the conditions for participation in the proceedings (**Appendix No. 1 and Appendix No. 2 to the Request for Proposal).***

The contracting authority reserves the right to verify the fulfillment of conditions at the bidder's premises or to call for relevant documentation.

VI. PLACE AND DEADLINE FOR SUBMITTING BIDS

6.1. Bids must be submitted by the deadline of **16.09.2024.**
- in electronic form (in the form of a scan of the signed document or electronically signed documents) to the address: dominika.radzanowska@polpharma.comowska@polpharma.com

6.2. Submission of a bid will be considered successful if a complete bid is received at the e-mail box with the above address by the deadline specified in this section.
6.3. Bids submitted after the deadline will not be considered.
6.4.The bid should be signed by persons authorized to represent the Bidder by virtue of entries in the relevant registers or by power of attorney. The power of attorney should be attached to the bid.

VII. DESCRIPTION OF PRICE CALCULATION

7.1. How to calculate the bid price: the price should be calculated net and gross.
7.2. For evaluation, bids submitted in a currency other than PLN will be converted into PLN at the average exchange rate of the National Bank of Poland (https://www.nbp.pl/) on the closing date for submission of bids.
7.3. The price should include all costs associated with the preparation and execution of the subject of the request.
7.4. The price submitted in the bid cannot be changed during the execution of the contract.

VIII. DESCRIPTION OF THE CRITERIA THAT THE CONTRACTING AUTHORITY WILL BE GUIDED BY WHEN SELECTING A BID

8.1. In evaluating bids, the Contracting Authority will be guided by the criteria listed:
- total net order price - 100%

The scoring of the bid will be done according to the formula:

$$\boldsymbol{O_P = P_C}$$ Where:

O_P - offer scoring
P_C ○ - number of points obtained in the criterion "Total net order price"

○

The number of points (P_C) in the criterion "Total net order price" will be calculated according to the formula:

$$P_C = \frac{C_N}{C_B} * 100\ pkt$$

Where:

- P_C – Number of points for the criterion "Total net order price"
- C_N – of the non-rejected bids, the lowest total net bid price
- C_B – total net price of the tested 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 on the closing date for submission of bids.

8.2. The maximum the Bidder can obtain is 100 points. Calculations will be made to two decimal places.

IX. DESCRIPTION OF BID PREPARATION

9.1. The bidder should prepare one price offer in accordance with the model form attached as Annex 1 to the request.
9.2. The bid should be signed by persons authorized to represent the Bidder by virtue of entries in the relevant registers or by power of attorney. The power of attorney should be attached to the bid.
9.3. The bidder may amend or withdraw its bid before the deadline for submission of bids.
9.4. Bidders are required to carefully review the information contained in the Price Request.
9.5. The cost of preparation and delivery of the bid shall be borne by the Contractor.
9.6. For matters related to this inquiry, please contact the Contracting Authority, e-mail: dominika.radzanowska@polpharma.com

X. METHOD OF COMMUNICATION BETWEEN THE BUYER AND THE SELLERS, PERSONS AUTHORIZED TO CONTACT THEM

10.1. In the proceedings, statements, applications, notices and information shall be submitted by the Buyer and the Seller in Polish or English
10.2. All notices, statements, requests and information transmitted in electronic form shall require, at the request of either party, immediate confirmation of receipt.
10.3. In the absence of an acknowledgment of receipt of correspondence by the Seller, the Buyer shall presume that the correspondence sent by the Buyer to the email address provided by the Seller has been delivered to the Buyer in such a way as to enable the Buyer to become acquainted with its contents.
10.4. Correspondence related to this inquiry should be addressed to the e-mail address: dominika.radzanowska@polpharma.com
10.5. In correspondence related to this inquiry**,** the Seller should use the procedure number: **NUSI/76/PR71749/2024.**
10.6. The person authorized to communicate with the Seller is **Ms. Dominika Radzanowska**.
10.7. No verbal or telephonic information, explanations or answers to inquiries addressed to the Buyer are provided.
10.8. Any questions regarding this inquiry should be submitted by email to the address indicated above no later than 3 days before the deadline for submission of bids.
10.9. Responses to questions and the detailing of the Inquiry resulting from questions from potential Sellers will be sent to the entity that sent the question.

XI. PROCEDURE FOR EVALUATION OF TENDERS AND ANNOUNCEMENT OF RESULTS

11.1. In the course of examination and evaluation of bids, the Buyer may request from the Seller supplements (if this does not violate competitiveness) and clarifications regarding the content of submitted bids. He may also request correction of obvious mistakes and calculation errors.

11.2. The Buyer reserves the right to check, in the course of evaluating the offer, the credibility of the documents, statements, lists, data and information presented by the Sellers.

11.3. If two or more Sellers obtain the same number of points, the bid with the most favorable environmental and climate impact will be selected. For this purpose, the Buyer has the right to call on the Bidders whose bids received the highest final number of points to supplement their bids by providing the information indicated by the Buyer regarding the environmental impact of the subject of the bid.

11.4. **The Procuring Entity reserves the right to negotiate bids** with all bidders whose bids meet the specifications, especially if the price offered by the Bidders exceeds the budget allocated by the Procuring Entity for the execution of the contract.

11.5. Until the deadline for submission of bids, the Procuring Entity reserves the right to amend or supplement the contents of this price inquiry.

11.6. The Procuring Entity reserves the right to terminate the proceedings without selecting a Contractor, without giving any reason. Bidders shall not be entitled to claim reimbursement of costs incurred in the preparation of the bid.

11.7. If the supplier's income earned in connection with the execution of the project is subject to withholding tax in Poland, then ZF Polpharma S.A. is required by law to withhold withholding tax from the supplier's remuneration and pay it to the Polish tax authorities **(the remuneration includes withholding tax).**

11.8. Transfer to the Ordering Party (as part of the agreed remuneration) all exclusive rights and all transferable other rights to intangible assets that will arise in connection with the performance of the subject matter of the contract (hereinafter: "Intellectual Property Rights"). Thus, all Intellectual Property Rights created in connection with the performance of the contract shall become the exclusive property of the Ordering Party. Intellectual Property Rights, shall include both "work", "inventive design" and "know-how", which shall be defined in detail in the body of the contract.

XII. AMENDMENT TO THE CONTENT OF THE AGREEMENT

12.1. The Contracting Authority reserves the **right to make significant changes to the provisions of the Agreement** for the offered services in relation to the content of the offer on the basis of which the Contractor was selected, in the following scope and situations:

12.1.1. changes in the law, to the extent affecting the implementation of the Agreement (in particular, changes in VAT rates);

12.1.2. improve the technical parameters of the subject of the Agreement, resulting from the update of solutions due to technological progress, without affecting the gross lump sum price

12.1.3. extension of the term of the Contract as a result of the need to perform additional work, the performance of which is necessary for the proper execution of the Contract, and the performance of which the Contracting Authority, acting with due diligence, could not have foreseen earlier, subject to Section XII.1.7 below;

12.1.4. extension of the deadline for execution of the Agreement as a result of force majeure, together with all the consequences occurring in connection with the extension of this deadline

12.1.5. Extend the contract completion date if, due to the testing process, there are delays in the delivery of test samples and other required materials or information

12.1.6. changes in the parameters of the subject matter of the Agreement, not leading to changes in the nature of the Agreement - technological changes, in particular: the need to implement the Agreement using other technical/technological, material solutions than those indicated in the Request for Proposal, in a situation where the use of the provided solutions would threaten non-performance or faulty performance of the Agreement, subject to item XII.1.8. below;

12.1.7. changes relate to the performance of additional supplies or services of the Contractor, not covered by the Contract, if they have become necessary and the following conditions are met together:

- change of the Contractor cannot be made for economic or technical reasons, in particular concerning interchangeability or interoperability of equipment, services or installations, ordered under the basic subject of the Contract,

- change of the Contractor would cause substantial inconvenience or a significant increase in costs for the Ordering Party,
- the value of each subsequent change does not exceed 50% of the net value of the original net subject of the Agreement;

12.1.8. the change does not lead to a change in the nature of the Agreement and the following conditions have been met together:

- the need to amend the Contract is due to circumstances that the Contracting Authority, acting with due diligence, could not foresee,
- the value of the change does not exceed 50% of the value of the original net subject of the Agreement;

12.2. The contractor is to be replaced by a new contractor:

- as a result of a merger, demerger, transformation, bankruptcy, restructuring or acquisition of the Contractor or its enterprise, provided that the new contractor meets the conditions for participation in the proceedings, there are no grounds for exclusion against it and it does not involve other material changes to the Contract,
- as a result of the Ordering Party's assumption of the Contractor's obligations to its subcontractors.

12.3. The Contracting Authority also provides for **the possibility of making non-substantive changes to the provisions of the Agreement** in relation to the content of the offer on the basis of which the Contractor was selected.

12.4. Amendments to the Agreement will be made in the form of annexes signed by both Parties, and the possibility of their introduction is subject to approval by the Ordering Party.

12.5. The Ordering Party provides for the possibility of changing the Contractor's remuneration depending on:

- changes in the laws regulating the rates of tax on goods and services and excise tax, the amount of the minimum wage and the amount of the minimum hourly rate, the rules of submission and the rates of social security or health insurance contributions, and the rules of collection and the amount of payments to employee capital plans; however, the change in remuneration will apply only to payments that have not yet been made on the date of the contract amendment,
- changes in the prices of materials or costs affecting the remuneration, the Contractor, with the method of determining the change to be made before the order/signing of the contract with the Contractor.
- The increase in remuneration may occur due to increased costs of contract execution, resulting from a possible unfavorable increase in the level of electricity prices, according to the **average annual index of consumer prices of energy carriers** announced by the President of the Central Statistical Office or, in the situation of a bidder from outside Poland, the equivalent of such a body operating in the Bidder's country.
- The valorization of the remuneration shall require the presentation of justification to the Contracting Authority with the indication of objective evidence, calculations confirming the increase in the aforementioned costs and may not be carried out more often than once a year. The valorization requires the consent of the Contracting Authority and will be implemented in the form of an annex to the Agreement/Contract. The parties will proceed to renegotiate the amount of remuneration specified in the contract, while the target change in remuneration **may not exceed 3% with respect to unit prices for individual items of the request.** The change in remuneration will require the conclusion of an annex, and the lack of agreement on this subject may be the basis for termination of the contract by the Contractor.

XIII. LIST OF ANNEXES

The following documents are attached to this Price Request:

Appendix Designation	Name of the Appendix
Appendix 1	Sample price form

Appendix 2	Model statement of compliance with the conditions set in the price inquiry
Appendix 3	Model non-disclosure agreement
Appendix 4	Detailed description of the method

Appendix No. 1 to the Price Request No. NUSI/76/PR71749/2024

BID FORM

Bidder:

Full name (company) or first and last name	
Registered office/place of residence/address of main place of business	
The e -mail address to which the Employer should send correspondence related to the price inquiry	
NIP	
REGON	
Phone	
Contact person for the Purchaser	

We offer to perform the subject of the contract for the ***provision of research services*** in accordance with the requirements of the Price Request:

STAGE NO.	Subject of the price inquiry		number of measurements	Net price PLN/EUR/USD* per one measurement	Total net value PLN / EUR / USD*	Total gross value PLN / EUR / USD*
1	**Validation of analytical methods**					
	- differential scanning calorimetry **DSC**	**1A**	validation (as a minimum validation scope)			
		1B	additional test (1 sample)			
	- CD circular dichroism	**1C**	validation (as a minimum validation scope)			
		1D	additional test (1 sample)			
	- Sedimentation velocity with **SV-AUC** ultracentrifugation	**1E**	validation (as a minimum validation scope)			
		1F	additional test (1 sample)			
	- Nuclear magnetic resonance **(1H NMR, 13C NMR, 31P NMR).**	**1G**	validation (as a minimum validation scope)			
		1H	additional test (1 sample)			
TOTAL PRICE FOR METHOD VALIDATION MINIMUM RANGE (1A+1C+1E+1G):						
TOTAL PRICE FOR VALIDATION OF ADDITIONAL TESTS (1B+1D+1F+1H):						

STAGE NO.	Subject of the price inquiry		number of measurements	Net price PLN/EUR/USD* per one measurement	Total net value PLN / EUR / USD*	Total gross value PLN / EUR / USD*
2	**Comparative study against a reference product for using orthogonal techniques:**					
	DSC *reference* and ***test product***	**2A**	1 study for 6 series (minimum range)			
		2B	1 test for 1 series (additional order)			
	CD *reference* and ***test product***	**2C**	1 test for 6 series (minimum range)			
		2D	1 test for 1 series (additional order)			
	Reference and test product sedimentation velocity by **SV-AUC** ultracentrifugation	**2E**	1 test for 6 series (minimum range)			
		2F	1 test for 1 series (additional order)			
	Reference product/active substance and ***test*** nuclear magnetic resonance **(1H NMR, 13C NMR, 31P NMR)**	**2G**	1 test for 6 series (minimum range)			
		2H	1 test for 1 series (additional order)			
TOTAL PRICE FOR COMPARATIVE TESTING OF SAMPLES MINIMUM RANGE (2A+2C+2E+2G) :						
TOTAL PRICE FOR COMPARATIVE SAMPLE TESTING ADDITIONAL TESTING (2B+2D+2F+2H) :						

STAGE NO.	Subject of the price inquiry		number of measurements	Net price PLN/EUR/USD* per one measurement	Total net value PLN / EUR / USD*	Total gross value PLN / EUR / USD*
3	**Conducting routine examinations**					
	Examination of the material sample during the project period using the **DSC** technique	**3A**	1 test for 1 series (minimum range)			
	Examination of the material sample during the project period using the DSC technique	**3B**	subsequent sample for 1 series (additional order)			
	Examination of a sample of material during the project period using the CD technique	**3C**	1 test for 1 series (minimum range)			
	Examination of a sample of material during the project period using the CD technique	**3D**	subsequent sample for 1 series (additional order)			
	Examination of the material sample during the project period using the SV-AUC technique	**3E**	1 test for 1 series (minimum range)			
	Examination of the material sample during the project period using the SV-AUC technique	**3F**	subsequent sample for 1 series (additional order)			
	Examination of the material sample during the project period using **1H NMR, 13C NMR, 31P NMR** techniques	**3G**	1 test for 1 series (minimum range)			
	Examination of the material sample during the project period using **1H NMR, 13C NMR, 31P NMR** techniques	**3H**	subsequent sample for 1 series (additional order)			
TOTAL PRICE FOR ROUTINE TESTING MINIMUM RANGE (3A+3C+3E+3G):						

STAGE NO.	Subject of the price inquiry		number of measurements	Net price PLN/EUR/USD* per one measurement	Total net value PLN / EUR / USD*	Total gross value PLN / EUR / USD*
TOTAL PRICE FOR ROUTINE TESTS ADDITIONAL ORDER (3B+3D+3F+3H):						
SUMMARY OF MINIMUM ORDER ITEMS OF ALL STAGES (1A,C,E,G+2A,C,E,G+3A,C,E,G):						
SUMMARY OF ITEMS FOR ADDITIONAL ORDERS OF ALL STAGES (1B,D,F,H+2B,D,F,H+3B,D,F,H): THE VALUE ENTERED IN THE SUMMARY WILL BE TAKEN FOR EVALUATION IN ACCORDANCE WITH POINT. VIII OF THE INVITATION						

***delete as necessary, select the correct currency.**

Invoice payment terms: .....days (minimum 30)

Quantities of materials required for analysis (to be completed by the Subcontractor):

Information table for the Purchaser, in order to properly prepare samples for testing.

Technology	**Amount of vehiculum needed for validation [ml].**	**Quantity of drug product/active substance needed for validation [ml].**	**Amount of standard substances needed for validation [ml]/[mg]**	**Additional information**
Quantities of material to be validated				
differential scanning calorimetry DSC				
CD circular dichroism				
Sedimentation velocity by ultracentrifugation (SV-AUC):				
Nuclear magnetic resonance (1H NMR, 13C NMR, 31P NMR).				
Quantities of material for comparative tests				
differential scanning calorimetry DSC				
CD circular dichroism				
Sedimentation velocity by ultracentrifugation (SV-AUC):				
Nuclear magnetic resonance (1H NMR, 13C NMR, 31P NMR).				
Quantities of material for routine testing				
differential scanning calorimetry DSC				
CD circular dichroism				
Sedimentation velocity by ultracentrifugation (SV-AUC):				
Nuclear magnetic resonance (1H NMR, 13C NMR, 31P NMR).				

Order completion date:

..... weeks (maximum 10 weeks) calculated from the date of delivery of all samples to the laboratory to the date of delivery of the validation report by the bidder for **method** validation

..... weeks (maximum 4 weeks) counted from the date of delivery of samples to the laboratory to the date of delivery of the work report for comparative tests

..... weeks (maximum 4 weeks) counted from the date of delivery of samples to the laboratory to the date of delivery of the work report for routine analyses

At the same time, we declare that:

a. we have familiarized ourselves with the Request for Quotation and its attachments and do not raise any objections, and we have acquired the necessary information to prepare our offer,

b. The price includes a lump sum remuneration for all the Seller's obligations necessary to complete the subject of the Price Request,

c. we consider ourselves bound by this bid for a period of 60 calendar days from the deadline for submission of bids ,

d. circumstances do not apply to us :

b) described in Article 7 (1) of the Law of April 13, 2022, on special solutions to prevent support for aggression against Ukraine and to protect national security;

c) described in Article 5k of Council Regulation (EU) No. 833/2014 of July 31, 2014 concerning restrictive measures in connection with Russia's destabilizing actions in Ukraine.

..... (place and date)

..... (signature of the person(s) authorized to make a statement of intent on behalf of the Bidder)

Appendix No. 2 to the Price Request No. NUSI/76/PR71749/2024

STATEMENT OF COMPLIANCE WITH THE CONDITIONS SET OUT IN THE PRICE INQUIRY

... ... (Company/Contractor) declares that it meets the terms and conditions specified in the request for proposals in accordance with the table below:

No.	Condition	Yes/No
For analytical method validation:		
1	We have knowledge and a minimum of 3 years of experience in the validation of DSC, CD, SV-AUC analytical methods. We have knowledge and a minimum of 5 years of experience in the validation of 1H NMR, 13C NMR, 31P NMR analytical methods	
2	We have the required personnel background of a minimum of 1 person with at least 5 years of experience in conducting the research that is the subject of the request for proposal.	
3	Together with the offer, we present for each method a preliminary validation plan for evaluation by the Principal.	
4	The laboratory is FDA-certified for the analytical techniques under inquiry.	
5	Upon completion of all work related to each technique, we will deliver:	
	- validation report including a description of the analytical method, sample preparation, number of test samples and sample concentration dedicated to testing the active substance/product with conclusions	
	- test results obtained during method validation.	
	- Raw data linked to the surveys conducted.	
For comparative studies:		

No.	Condition	Yes/No
1	We have knowledge and a minimum of 3 years of experience in DSC, CD, SV-AUC comparative testing. We have knowledge and a minimum of 5 years of experience in 1H 1H NMR, 13C NMR, 31P NMR comparative studies.	
2	We have the required personnel background of a minimum of 1 person with at least 5 years of experience in conducting research that is the subject of the request for proposal.	
3	Along with the offer, we present for each method a preliminary test plan for evaluation by the Principal.	
4	Upon completion of all work related to each technique, we will deliver:	
	- A report describing the analytical method dedicated to testing the active substance/product with conclusions,	
	- test results obtained during method development/sample testing,	
	- Raw data linked to the surveys conducted.	
For routine testing:		
1	We have knowledge and a minimum of 3 years of experience in DSC, CD, SV-AUC routine testing. We have knowledge and a minimum of 5 years of experience in 1H NMR, 13C NMR, 31P NMR comparative studies.	
2	We have the required personnel background of a minimum of 1 person with at least 5 years of experience in conducting research that is the subject of the request for proposal.	
3	Upon completion of all work related to each technique, we will deliver:	
	- test results obtained during method development/sample testing,	
	- Raw data linked to the surveys conducted.	

All of the above options must be fulfilled, which the Bidder confirms by filling YES. The use of the option NO in at least one item of the above table will result in rejection of the bid.

.....	.....
(place and date)	(signature)