Starogard Gdański, December 23, 2025

REQUEST FOR QUOTATION No.: NUSI_131_PR137000_2025
conducted as a market inquiry

In connection with the implementation of the project entitled "*Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety*" co-financed from the state budget by the Medical Research Agency, Pharmaceutical Works Polpharma S.A. requests the submission of quotation for **a consulting service related to risk assessment and cost estimation regarding the implementation of a Quality System compliant with US-FDA** requirements at Pharmaceutical Works Polpharma, Branch in Starogard Gdański.

I. NAME & ADDRESS OF THE BUYER

Pharmaceutical Works Polpharma S.A.
Pelplińska 19 Street, 83-200 Starogard Gdański, Poland
Tax Identification Number: 5920202822

II. PROCEDURE FOR AWARDING THE CONTRACT

II.1. The Contract is not subject to the provisions of the Public Procurement Law of September 11, 2019 (i.e. Journal of Laws of 2019, item 2019).

II.2. The procedure is conducted as a market inquiry, in a purposeful and economical manner, in accordance with the following principles:

II.2.1. achieving the best results from the resources used,

II.2.2. optimal selection of methods and means to achieve the intended objectives,

II.2.3. transparency, fair competition, and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE REQUEST FOR QUOTATION

III.1. The subject of this Request for Quotation is the risk assessment and cost estimation related to the implementation of a Quality System compliant with US-FDA requirements for the pilot manufacturing area, including:

III.1.1. defining the required scope of Quality System documentation to be reviewed,

III.1.2. reviewing the Quality System documentation and other documents provided by the Buyer (if required),

III.1.3. conducting remote interviews with key users (online meetings),

III.1.4. conducting an on-site audit at the Buyer's facility in Starogard Gdański, covering the pilot manufacturing area and operational areas affected by pilot manufacturing, no later than within **3 weeks** from the date of signing the Contract,

III.1.5. verification of systems/media supporting the pilot manufacturing area, such as: HVAC, WFI, clean steam, nitrogen, compressed air, RMS/BMS, and others,

III.1.6. verification of the pilot manufacturing area in terms of Data Integrity, including, among others, the production area (including maintenance), quality area (including product testing and release), warehousing, etc.

III.1.7. verification of compliance with **Annex 1** ("*Manufacture of sterile medicinal products*"), validation approach, validation documentation, compliance of areas, compliance of process and supporting equipment, compliance of infrastructure, environmental monitoring, contamination strategy, and others,

III.1.8. verification of Quality System documentation, including change control procedures, deviation management, supplier qualification, etc., as well as instructions and batch documentation,

III.1.9. assessment of infrastructure, including auxiliary systems, safety systems; requirements for the CCTV monitoring system,

III.1.10. defining the scope of the assessment in the R&D area as well as at the target site for product testing and release at the PAI stage,

III.1.11. verification of the Buyer's level of preparedness for a US-FDA inspection, including required documentation, employee training and preparation, inspection management, etc.
III.1.12. analysis of the possibility of extending the purpose of the pilot manufacturing area to include FDA registration,
III.1.13. identification of risks for the pilot manufacturing area in the context of FDA registration,
III.1.14. presentation of conclusions, recommendations, and suggestions to eliminate or minimize risks,
III.1.15. estimation of costs/expenditures resulting from the above recommendations and suggestions.

III.2. As part of the activities, verifications, and assessments of the situation and documentation carried out in accordance with point III.1, the Bidder (selected Contractor) shall perform the following actions based on the Framework Work Schedule constituting **EXHIBIT NO. 6**, including:
III.2.1. agree with the Buyer on the schedule of activities (plan of online meetings in accordance with point III.1.3 and the planned audit date in accordance with point III.1.4),
III.2.2. within **2 business days** from the date of conducting the interviews as per point III.1.3, provide an oral summary to the Buyer covering preliminary results regarding the subject of this Request for Quotation,
III.2.3. conduct an audit at the Buyer's Branch in Starogard Gdański within **3 weeks** from the date of signing the Contract,
III.2.4. summarize and provide the results to the Buyer in written form (hereinafter: **Report**), which will include, among other:
III.2.4.1. analysis of deficiencies in the context of US-FDA requirements and the expectations of US-FDA inspectors,
III.2.4.2. a list of necessary actions to eliminate the above deficiencies and minimize potential risks identified during the audit,
III.2.4.3. required resources and cost estimation related to addressing deficiencies, reducing risks, and maintaining a Quality System compliant with US-FDA requirements,
III.2.4.4. potential implications (impact) on the strategy and operational activities of the Buyer in the event of a decision to enter the US market with products from the pilot manufacturing area at the Buyer's facility (Starogard Gdański),
III.2.4.5. conclusions, suggestions, and recommendations regarding the advisability of registering products from the pilot manufacturing area in Starogard Gdański for the US market (including justification of whether this is the right course of action),
III.2.5. verify **the Report** with the Buyer (e.g., remove formal errors, clarify entries, provide explanations), with the Buyer obliged to submit all comments within **3 business days** from the date of receiving **the Report**,
III.2.6. provide the Buyer with the verified and, if necessary, corrected/supplemented **Report** within **7 weeks** from the date of signing the Contract,
III.2.7. present the results and discuss further actions with the Representatives of the Buyer remotely.

III.3. The Buyer does not allow the submission of partial or variant offers.

IV. PLACE AND DEADLINE FOR THE EXECUTION OF THE REQUEST FOR QUOTATION

IV.1. Deadline for submission of offers: **by January 12, 2026**
IV.2. Planned date of contract signing: **by January 26, 2026**
IV.3. Deadline for execution of the subject of the Request for Quotation: **up to 10 weeks in accord. with EXHIBIT NO. 6**
IV.4. The date of execution of the subject of the Contract is considered to be the date of presentation of **the Report** by the Bidder to the Representatives of the Buyer.
IV.5. The place for the presentation of **the Report** is TEAMS (remote meeting) organized by the Bidder.

V. REQUIREMENTS FOR BIDDERS

V.1. The evaluation of offers in terms of meeting the requirements will be carried out according to the formula: "**compliant – non-compliant**." Any Bidder who does not meet any of the conditions specified in point V.2 will be excluded from this procedure.

V.2. Bidders who meet the following conditions may apply for the Contract:

V.2.1. The Bidder is not a person or entity related to the Buyer by personal or capital ties. Personal or capital ties are understood as mutual connections between the Buyer and the Bidder or persons authorized to incur obligations on behalf of the Buyer or persons performing activities related to the preparation and conduct of the selection procedure for the Bidder (Contractor) on behalf of the Buyer.

To meet this condition, the Bidder is required to submit, together with the offer, a signed ***Statement of No Affiliation of the Bidder*** (**EXHIBIT NO. 2** to this Request for Quotation).

V.2.2. The Bidder has appropriate competencies and experience, in particular:

V.2.2.1. experience in similar tasks in the pharmaceutical/biotechnological industry or similar projects involving risk assessment and cost estimation related to the implementation of a Quality System compliant with US-FDA requirements (documented knowledge of US-FDA registration for at least three (3) similar tasks in the last three (3) years, as specified in **EXHIBIT NO. 4**),

V.2.2.2. proficiency in Polish or English (spoken and written at a communicative level),

V.2.2.3. knowledge of general requirements of EU-GMP, FDA, CA, and the Polish Ministry of Health Regulation on Good Manufacturing Practice requirements, knowledge of qualification and validation issues in accordance with Annex 11 and Annex 15 of EU-GMP, CFR requirements and guidelines applicable in the US and CA markets, knowledge of other applicable guidelines such as ISPE (PDA or WHO), GAMP, ISO, ASTM,

V.2.2.4. Knowledge of the revised **Annex 1**: *Manufacture of sterile medicinal products, knowledge of systems/media/data integrity* as referred to in points III.1.5–III.1.6,

V.2.2.5. knowledge of microbiology and supervision of production and areas with a sterile profile,

V.2.2.6. knowledge of production issues carried out during industrial operations in the area of manufacturing sterile products in an aseptic process.

To meet this condition, the Bidder is required to submit, together with the offer, a signed ***Statement of Competencies*** (**EXHIBIT NO. 3** to this Request for Quotation),

V.2.3. The Bidder shall attach to the offer, confirmed by relevant entities, positive references (copies) for at least three (3) analogous tasks (US-FDA feasibility analysis) in the last 3 years, as specified in **EXHIBIT NO. 3**,

V.2.4. The Bidder shall attach to the offer the proposed team for the execution of the subject of the Contract, along with CVs of the team members confirming their competencies and experience, as specified in **EXHIBIT NO. 4.** At least two (2) persons with a minimum of 15 years of experience in the pharmaceutical industry are required, including one person with experience in at least three (3) tasks preparing for the first US-FDA Inspection (so-called "pre-approval inspections").

V.3. Before submitting the offer, the Bidder is required to familiarize themselves with the accompanying documents in this procedure (Information Exhibits), which will be required at the Contract signing stage:

V.3.1. Nondisclosure Agreement constituting **EXHIBIT NO. 8**,

V.3.2. Provisions on the transfer of proprietary copyrights constituting **EXHIBIT NO. 9**,

V.3.3. Conditions for exemption of the Bidder from withholding tax (**WHT**) constituting **EXHIBIT NO. 10**.

EXHIBITS NO. 8÷NO. 9 are open exhibits, and their content is subject to arrangements with the Bidder selected in this procedure.

V.4. Method of evaluating requirements for Bidders:

V.4.1. Verification of compliance with the requirements for Bidders will be based on:

V.4.1.1. verification of the data, values, and rates provided in ***the Offer Form*** and the validity of signatures made by persons representing the Bidder,

V.4.1.2. verification of ***Statement of No Affiliation of the Bidder*** – correctness of completion and validity of signatures made by persons representing the Bidder,

V.4.1.3. verification of ***the Statement of Competencies*** along with copies of references – completeness of data, attachments with references,

V.4.1.4. verification of ***the List of Team Members*** for the execution of the subject of the Request for Quotation along with attached CVs of these persons,

V.4.1.5. verification of ***the Sanction Clause*** regarding the absence of ties – correctness of completion and validity of signatures made by persons representing the Bidder,

V.4.1.6. verification of confirmation of acceptance to execute ***the Framework Work Schedule*** – validity of signatures made by persons representing the Bidder,

V.4.1.7. verification of ***the Advantageous Owner Statement*** – correctness of completion and validity of signatures made by persons representing the Bidder,

V.4.1.8. verification of powers of attorney of persons signing the above documents – verification/validity of signatures of persons signing the relevant power of attorney.

VI. PLACE AND DEADLINE FOR SUBMISSION OF OFFERS

VI.1. Offers must be submitted no later than **January 12, 2026** to the following address: waldemar.ganko@polpharma.com , in the form of electronically signed documents or scanned copies of documents.

VI.2. The offer must be **signed by persons authorized to represent the Bidder**, either by entries in the relevant registers or by power of attorney. The power of attorney should be attached to the offer.

VI.3. Submission of the offer will be considered effective if the complete offer is received in the mailbox at the above address within the deadline specified in point **VI.1**.

VI.4. The date of receipt of the offer by the Buyer determines compliance with the deadline.

VI.5. Offers submitted after the deadline will not be considered.

VI.6. The Buyer **does not provide for public opening of offers**.

VI.7. The Bidder may change or withdraw their offer before the deadline for submission of offers.

VII. DESCRIPTION OF THE METHOD FOR CALCULATING PRICES

VII.1. The method for calculating the offer value: the value must be calculated as net and gross and provided in ***the Offer Form*** constituting **EXHIBIT NO. 1**.

VII.2. Offers submitted in a currency other than PLN will be converted to PLN at the average NBP exchange rate (https://www.nbp.pl/) on the date of the offer submission deadline.

VII.3. The offer value should also include all costs specified in **Table No. 1 of EXHIBIT NO. 1** related to the preparation of the offer and the execution of the subject of the Request for Quotation.

VII.4. The value of the offer selected in this procedure cannot be changed during the execution of the Contract.

VIII. DESCRIPTION OF THE CRITERIA THAT THE BUYER WILL USE WHEN SELECTING THE OFFER

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

VIII.1.1. Criterion: *Net Offer Value* (**NOV**): **weight 70%**

VIII.1.1.1. The net value of the offer must include all costs foreseen for the execution of the Contract.

VIII.1.1.2. The table presenting a breakdown of all estimated costs by individual works, services, and activities (hourly rate), as well as estimated transport and accommodation costs, is specified in **Table No. 1** in **EXIBIT NO. 1**.

VIII.1.1.3. The valuation of the subject of the Contract may be provided in a currency other than PLN, provided that the offer value is converted to PLN in accordance with the provision in point **VII.2**.

VIII.1.1.4. The maximum number of points a Bidder can obtain for the evaluated offer under the *Net Offer Value* (**NOV**) criterion is 70 points.

VIII.1.2. Criterion: *Completion Date* of the subject of the Contract: **weight 30%**

VIII.1.2.1. The Framework Work Schedule is specified in **EXHIBIT NO. 6**.

VIII.1.2.2. The evaluated deadlines are:

a) conducting the on-site audit (**ACD**) at the Buyer's facility within the deadline specified in **point III.1.4** (**weight 15%**), with a reference deadline of **3 weeks** from the date of signing the Contract,

b) submitting **the Report** (**SR**) to the Buyer within the deadline specified in **point III.2.6** (**weight 15%**), with a reference deadline of **7 weeks** from the date of signing the Contract,

VIII.1.2.3. Shorter deadlines declared by Bidders for conducting the audit (**3 weeks**) and submitting **the Report** (**7 weeks**), counted from the date of signing the Contract, will be used as reference deadlines for point calculation.

VIII.1.2.4. The maximum number of points a Bidder can obtain for the evaluated offer under the *Completion Date* criterion is 30 points, including:

a) for audit completion date (**ACD**) - up to 15 points,

b) for **the Report** submission date (**RSD**) - up to 15 points.

VIII.2. The total number of points (P_{TOT}) for the evaluated offer will be calculated according to the following formula:

$$P_{TOT} = P_{NOV} + P_{ACD} + P_{RSD}$$

when:

P_{TOT} - total number of points obtained by the offer,

P_{NOV} - number of points obtained by the offer for the criterion "*Net Offer Value*" (**NOV**)

P_{ACD} - number of points obtained by the offer for the criterion "*Audit Completion Date*"" (**ACD**)

P_{RSD} - number of points obtained by the offer for the criterion "*Report Submission Date*" (**RSD**)

The maximum number of points that a Bidder can obtain as a result of the offer evaluation is 100 points.

Item	Offer evaluation criterion	Weight	Max. number of points
1	*Net Offer Value* (**NOV**)	70 %	70 pkt
2	*Audit Completion Date* (**ACD**)	15 %	15 pkt
3	*Report Submission Date* (**RSD**)	15 %	15 pkt

VIII.3. The number of points for individual criteria will be calculated according to the formulas below, as applicable for each criterion:

For the criterion "*Net Offer Value*" (**NOV**):

$$P_{NOV} = \frac{V_{LO}}{V_{EO}} \times 70\% \times 100pts$$

when:

P_{NOV} - number of points obtained by the offer for the criterion "*Net Offer Value*" (**NOV**),

V_{LO} - net value of the lowest offer in PLN among non-rejected offers,

V_{EO} - net value of the evaluated offer in PLN,

For the criterion „*Audit Completion Date*" (**ACD**):

$$P_{ACD} = \frac{D_{REF-A}}{D_{ACD}} \times 15\% \times 100pts$$

when:

P_{ACD} - number of points obtained by the offer for the criterion "*Audit Completion Date*" (**ACD**)

D_{REF-A} - reference deadline for audit completion equal to **3 weeks** from the date of signing the Contract,

D_{ACD} - deadline declared by the Bidder (in weeks) for audit completion, counted from the date of signing the Contract; any declared deadline **shorter than 3 weeks** will be considered as D_{REF-A} for calculation purposes,

For the criterion „*Report Submission Date*" (**RSD**):

$$P_{RSD} = \frac{D_{REF-R}}{D_{RSD}} \times 15\% \times 100pkt$$

when:

P_{RSD} - number of points obtained by the offer for the criterion "*Report Submission Date*" (**RSD**)

D_{REF-R} - reference deadline for **Report** submission equal to **7 weeks** from the date of signing the Contract,

D_{RSD} - deadline declared by the Bidder (in weeks) for **Report** submission, counted from the date of signing the Contract; any declared deadline **shorter than 7 weeks** will be considered as D_{REF-R} for calculation purposes,

VIII.1. The total number of points (P_{TOT}) for the evaluated offer may amount to a maximum of 100 points.

VIII.2. Calculations will be performed with an accuracy of two decimal places.

IX. DESCRIPTION OF THE METHOD FOR PREPARING THE OFFER

IX.1. Each Bidder should prepare and submit only one offer, without variants or options, in accordance with the template provided in **EXHIBIT NO. 1** to this Request for Quotation.

IX.2. The Bidder shall complete the ***Offer Form*** (**EXHIBIT NO. 1**), providing all costs foreseen for the execution of the subject of this Request for Quotation.

IX.3. The Bidder shall attach to the offer a statement confirming that they are not subject to the ***Sanctions Clause*** (**EXHIBIT NO. 5** to this Request for Quotation).

IX.4. The Bidder shall attach a statement confirming acceptance of the Framework Work Schedule and that the subject of the Contract can be completed within the timeframe specified therein (**EXHIBIT NO. 6** to this Request for Quotation).

IX.5. A Bidder whose registered office is outside the territory of Poland shall attach a ***Advantageous Owner Statement***, as per the template in **EXHIBIT NO. 7**.

IX.6. The Bidder shall attach copies of powers of attorney for persons authorized to make declarations and submit offers on behalf of the entity they represent, if such authorizations are not listed in the relevant registers.

IX.7. The Bidder submitting an offer shall remain bound by it for a period of **60 calendar days** from the deadline for submission of offers.

IX.8. Until the deadline for submission of offers, the Buyer reserves the right to amend or supplement the content of this Request for Quotation.

IX.9. Bidders are obliged to thoroughly familiarize themselves with the information contained in the Request for Quotation.

IX.10. The costs of preparing and delivering the offer shall be borne by the Bidder.

IX.11. For matters related to this Request for Quotation, please contact Mr. Waldemar Gańko, email: waldemar.ganko@polpharma.com .

IX.12. The offer must be prepared in Polish or English.

IX.13. The minimum invoice payment term is **30 days** from the date of receipt of the invoice.

X. METHOD OF COMMUNICATION BETWEEN THE BUYER AND BIDDERS, AND CONTACT PERSONS

X.1. In this procedure, all statements, applications, notifications, information, and all correspondence between the Buyer and Bidders shall be communicated in Polish or English.

X.2. Any notifications, statements, applications, and information transmitted electronically must, upon request of either Party, be promptly confirmed as received.

X.3. If the Bidder does not confirm receipt of correspondence, it shall be deemed that the correspondence sent by the Buyer to the email address provided by the Bidder has been delivered in a manner enabling the Bidder to become acquainted with its content.

X.4. Correspondence related to this Request for Quotation should be sent to the following address e-mail: waldemar.ganko@polpharma.com

X.5. In correspondence related to this Request for Quotation, the Bidder should use the procedure number: **NUSI_131_PR137000_2025.**

X.6. The person authorized to communicate with the Bidder is Mr. Waldemar Gańko.

X.7. No oral or telephone information, explanations, or answers to questions addressed to the Buyer shall be provided.

X.8. Any questions regarding this Request for Quotation should be submitted by email to the address indicated above in section **X.4**, **no later than 3 days before the offer submission deadline**.

X.9. Answers to questions and clarifications of the Request for Quotation resulting from Bidders' inquiries will be sent to the entity that submitted the question.

XI. METHOD OF EVALUATING OFFERS AND ANNOUNCEMENT OF RESULTS

XI.1. Until the deadline for submission of offers, the Buyer reserves the right to amend or supplement the content of this Request for Quotation.

XI.2. During the examination and evaluation of offers, the Buyer may request the Bidder to provide supplements (provided this does not violate competitiveness) and explanations regarding the content of the submitted offers. The Buyer may also request corrections of obvious mistakes and calculation errors.

XI.3. The Buyer reserves the right to verify, during the evaluation process, the credibility of documents, statements, lists, data, and information provided by the Bidder.

XI.4. In the event that two or more Bidders obtain the same highest number of points, the offer with the most favorable environmental and climate impact will be selected. For this purpose, the Buyer has the right to request Bidders whose offers received the highest final score to supplement their offer by providing information specified by the Buyer regarding the environmental impact of the subject of the offer.

XI.5. The Buyer reserves the right to negotiate the offer with the Bidder whose offer meets the requirements of this specification and has obtained the highest number of points, particularly if the value of the offer exceeds the budget allocated by the Buyer for the execution of the subject of the Contract.

XI.6. The Buyer reserves the possibility of **negotiations with the selected Bidder** who obtained the highest number of points during the evaluation process. Such negotiations **shall not change** the outcome of the offer selection procedure.

XI.7. The Buyer reserves the right to cancel this procedure without providing a reason. In such a case, Bidders shall not be entitled to claim reimbursement of costs incurred in connection with preparing the offer and participating in this procedure.

XI.8. If the income of a Bidder whose registered office is outside Poland, earned in connection with the execution of the subject of the Contract, is subject to withholding tax in Poland, then ZF Polpharma S.A., as the Buyer, is legally obliged to deduct withholding tax (**WHT**) from the remuneration for the selected Bidder (the Contractor) and pay it to the Polish tax authorities. This means that the net value of the offer constituting the remuneration for the selected Bidder (Contractor) includes withholding tax. Conditions for withholding tax exemption are specified in **EXHIBIT NO. 7**.

XI.9. Transfer to the Buyer (within the agreed remuneration) of all exclusive rights and any other transferable rights to intangible assets created in connection with the execution of the subject of the Contract (hereinafter referred to as “Intellectual Property Rights”). Accordingly, all Intellectual Property Rights created in connection with the execution of the Contract shall become the exclusive property of the Buyer. Intellectual Property Rights include, among others, “work,” “inventive project,” and “know-how,” which will be defined in detail in the Contract.

XII. AMENDMENT TO THE CONTRACT TERMS

XII.1. The Buyer reserves the right to make significant amendments to the provisions of the Contract for the offered services compared to the content of the offer on the basis of which the Bidder was selected, in the following scope and situations:

XII.1.1. changes in legal regulations affecting the performance of the Contract (in particular changes in VAT tax rates),

XII.1.2. correction of technical parameters or requirements to be met by the subject of the Contract, resulting from updates due to technological progress, without affecting the gross lump-sum price,

XII.1.3. extension of the Contract performance deadline due to the necessity of carrying out additional works, the execution of which is essential for proper performance of the Contract and which the Buyer, acting with due diligence, could not have foreseen earlier, subject to item XII.1.7 below,

XII.1.4. extension of the Contract performance deadline due to Force Majeure, along with all consequences arising from such extension,

XII.1.5. The Buyer reserves the right to make significant amendments to the provisions of the Contract for the offered services compared to the content of the offer on the basis of which the Bidder was selected, in the following scope and situations:

- the Contractor cannot be changed for economic or technical reasons,

- changing the Contractor would cause significant inconvenience or substantially increase costs for the Buyer,
- the value of each subsequent change does not exceed 50% of the original net contract value,

XII.1.6. the amendment does not change the nature of the Contract, and the following conditions are jointly met:
- the need to amend the Contract is caused by circumstances that the Buyer, acting with due diligence, could not have foreseen,
- the value of the amendment does not exceed 50% of the original net Contract value;

XII.1.7. The selected Bidder (Contractor) is to be replaced by a new contractor:
- as a result of merger, division, transformation, bankruptcy, restructuring, or acquisition of the Contractor or its enterprise, provided that the new contractor meets the participation requirements, is not subject to exclusion grounds, and this does not entail other significant changes to the Contract,
- as a result of the Buyer assuming the Contractor's obligations towards its subcontractors.

IX.1.8. **t**he amendment does not change the nature of the Contract, and the total value of changes is less than EUR 215,000 and at the same time less than 10% of the original net Contract value.

XII.2. The Buyer also foresees the possibility of making non-material amendments to the provisions of the concluded Contract compared to the content of the offer on the basis of which the Contractor was selected.

XII.3. Amendments to the Contract shall be introduced in the form of annexes signed by both Parties, and their introduction is subject to acceptance by the Buyer.

XIII. OTHER INFORMATION

XIII.1 Until the deadline for submission of offers, the Buyer reserves the right to amend or supplement the content of this Request for Quotation.

XIII.2. The validity period of each submitted offer shall be at least **60 calendar days** from the deadline for submission of offers referred to in section VII.1.

XIII.3. Providing a draft Contract subject to negotiation of its provisions lies solely within the discretion of the Buyer. The draft will be presented after the Contractor is selected.

XIII.4. The Contractor shall pay contractual penalties to the Buyer:
(a) for delays in the performance of the subject of the Contract, for each commenced day of delay, provided the delay is not attributable to the Buyer,
(b) for improper performance of the Contract,
(c) for incomplete execution of the Contract.

The amount of contractual penalties will be agreed between the Buyer and the selected Bidder at the stage of signing the Contract.

XIII.5. The Bidder agrees to the deduction of contractual penalties directly from the payment of the VAT invoice related to the execution of the subject of the Contract.

XIII.6. After completing the performance of the subject of the Contract, and prior to issuing the invoice, the selected Bidder (Contractor) is obliged to sign, together with the Buyer, a Service Acceptance Protocol confirming full completion of the subject of the Contract.

XIV. LIST OF EXHIBITS TO THIS REQUEST FOR QUOTATION

The exhibits to this Request for Quotation are the following documents:

EXHIBIT LABEL		EXHIBIT Name
EXHIBIT NO 1	MANDATORY TO SUBMIT WITH THE OFFER	Offer Form
EXHIBIT NO 2	MANDATORY TO SUBMIT WITH THE OFFER	Statement of No Affiliation of the Bidder
EXHIBIT NO 3	MANDATORY TO SUBMIT WITH THE OFFER	Statement of Competence + References
EXHIBIT NO 4	MANDATORY TO SUBMIT WITH THE OFFER	List of Team Members + CVs
EXHIBIT NO 5	MANDATORY TO SUBMIT WITH THE OFFER	Sanctions Clause
EXHIBIT NO 6	MANDATORY TO SUBMIT WITH THE OFFER	Framework Work Schedule
EXHIBIT NO 7	MANDATORY TO SUBMIT WITH THE OFFER	Advantageous Owner Statement

EXHIBIT NO 8	MANDATORY TO SUBMIT WITH THE OFFER	Template: Nondisclosuer Agreement
EXHIBIT NO 9	MANDATORY TO SUBMIT WITH THE OFFER	Template: Transfer of Proprietary Copyrights
EXHIBIT NO 10	MANDATORY TO SUBMIT WITH THE OFFER	Template: Conditions for Withholding Tax Exemption (WHT)

EXHIBIT NO 1
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

OFFER FORM

The Bidder:

Full Name of the Bidder (Company/Entity Name) or First and Last Name in case of Sole Proprietorship	
Bidder's Registered Office (company or entity headquarters, as stated in registration documents)	
Email address to which the Buyer should send correspondence related to the Request for Quotation	
Tax ID of the Bidder	
REGON of the Bidder	
Bidder's Phone Number (company/entity)	
Contact Person for the Buyer	

We offer to perform the subject of the Request for Quotation in the scope of **risk assessment and cost estimation related to the implementation of a quality system compliant with US-FDA** requirements, in accordance with the provisions of this Request for Quotation, for the total amount of:

Net Offer Value		**…… currency [1)]**
Declared Date for Conducting the Audit [weeks] [2)]		**…… weeks**
Declared Date for Submission of the Report [weeks] [2)]		**…… weeks**
Applicable Value Added Tax (where applicable)	**…… %**	**…… currency [1)]**
Gross Offer Value		**…… currency [1)]**
Gross Offer Value (*in words*)		***…… currency[1)]***

1) please indicate the currency of the quotation
2) the period specified in the offer, expressed in weeks, starting from the date of Contract signing

The offered net value has been specified in **Table No. 1** below of this **EXHIBIT**.

continuation of the: EXHIBIT NO 1
to the Request for Quotation no.: NUSI_131_PR137000_2025

Table No. 1: Detailed Breakdown of Planned Costs in Currency ..... [1]:

A: Estimated cost of the work of the team defined in EXHIBIT NO. 4 (engagement of team members: remote, on-site, own work, etc..)				
Item	Full Name – Job Title	Quantity (man-hours)	Hourly Rate	Total Net Value
A.1	Person 1			
A.2	Person 2			
A.3	Person 3			
A.4	.....			
A.5	.....			
B: Estimated expenses for transport, travel, etc. (per team member)				
Item	Full Name – Job Title	Air travel	Other transportation	Total Net Value
B.1	Person 1			
B.2	Person 2			
B.3	Person 3			
B.4	.....			
B.5	.....			
C: Estimated expenses for the nights (per team member)				
Item	Full Name – Job Title	Number of nights	Cost per night	Total Net Value
C.1	Person 1			
C.2	Person 2			
C.3	Person 3			
C.4	.....			
C.5	.....			
D: Other expenses				
D.1	.....			
D.2	.....			
D.3	.....			
D.4	.....			
D.5	.....			

1) please indicate the currency of the quotation

We hereby declare that we meet the participation requirements specified by the Buyer in Request for Quotation No. NUSI_131_PR137000_2025 and:

a. we have reviewed this Request for Quotation together with its exhibits and raise no objections, and we have obtained the necessary information to prepare this offer,
b. the value includes a lump-sum remuneration for all obligations as a potential future Contractor, necessary to perform the subject of the Request for Quotation,
c. we consider ourselves bound by this offer for a period of **60 calendar days** from the deadline for submission of offers,
d. we are / are not* an affiliated entity within the meaning of Commission Regulation (EC) No. 1126/2008,
e. there are no circumstances applicable to us as described in:
   - Article 7(1) of the Act of 13 April 2022 on special solutions to counteract supporting aggression against Ukraine and to protect national security;
   - Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine.

* cross out if not applicable

..... (location and date)

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

EXHIBIT NO 2
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

STATEMENT OF NO AFFILIATION OF THE BIDDER

By submitting an offer for **performing the risk assessment and estimating the costs related to the implementation of a quality system compliant with US-FDA** requirements, I/we hereby declare as follows:

We, the undersigned, declare on behalf of:

..... *(name, address of the Bidder)* .....

that our company/entity is not an affiliated party with the Buyer, either personally or financially, and that we meet the participation requirements specified by the Buyer in **Section V.2.1** of Request for Quotation No. **NUSI_131_PR137000_2025.**

By personal or financial affiliation, we understand mutual connections between the Buyer and the Bidder or persons authorized to incur obligations on behalf of the Buyer, or persons performing activities related to the preparation and conduct of the Bidder (Contractor) selection procedure on behalf of the Buyer, consisting in particular of:

a) participation in a company as a partner in a civil law partnership or a personal partnership,
b) holding **at least 10%** of shares or stock,
c) serving as a member of a supervisory or management body, proxy, or attorney,
d) being in a marital relationship, in a direct line of kinship or affinity, in a second-degree kinship or affinity in a collateral line, or in a relationship of adoption, guardianship, or custody.

Signatures and Bidder's Seals ……. …….

Date: ……. …….

EXHIBIT NO 3
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

STATEMENT OF COMPETENCE

By submitting an offer for **performing the risk assessment and estimating the costs related to the implementation of a quality system compliant with US-FDA** requirements, I/we hereby declare as follows:

I/we declare that we meet the participation requirements specified by the Buyer in **Section V.2.2** of Request for Quotation No. **NUSI_131_PR137000_2025**. The list of completed tasks confirming our competence and experience, as detailed in points V.2.2.1 to V.2.2.6, is provided in **Table No. 1**.

REGISTER OF EXECUTED PROJECTS / TASKS DEMONSTRATING COMPETENCE AND EXPERIENCE

Table No. 1:

Item	**Name of the Completed Task / Project**	**Implementation Period of the Task / Project (from – to)** (MM/YYYY)	**Client / Beneficiary of the Task or Project** (company name, address)	**FDA Inspection Result** (Positive / Negative)
1.				
2.				
3.				
4.				
5.				
6.				

continuation of the: EXHIBIT NO 3
to the Request for Quotation no.: NUSI_131_PR137000_2025

Comment:

In this section, the Bidder may enter comments regarding the completed tasks/projects listed in Table No. 1 above.

At the same time, in accordance with the condition described in **Section V.2.3**, we attach copies of positive references, confirmed by the relevant entities, for at least three (3) similar tasks (US-FDA feasibility analysis) completed within the last five (5) years:

1. Reference 1: ……..
2. Reference 2: ……..
3. Reference 3: ……..

Signatures and Bidder's Seals …… ……

Date: …… ……

EXHIBIT NO 4
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

PROPOSED LIST OF TEAM MEMBERS FOR THE EXECUTION OF THE CONTRACT SCOPE

By submitting an offer for **performing the risk assessment and estimating the costs related to the implementation of a quality system compliant with US-FDA** requirements, we propose a team of individuals for the execution of the subject of the Contract, in accordance with the participation requirements specified by the Buyer in **Section V.2.4** of Request for Quotation No. **NUSI_131_PR137000_2025**.

Item	Name and Surname	Job Title	Years of experience in the pharmaceutical industry	CV Attached (YES / NO)
1				
2				
3				
4				
5				

Signatures and Bidder's Seal ……. …….

Date: ……. …….

EXHIBIT NO 5
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

SANCTIONS CLAUSE

By submitting an offer for **performing the risk assessment and estimating the costs related to the implementation of a quality system compliant with US-FDA** requirements, I/we hereby declare as follows:

I/we declare that we meet the participation requirements specified by the Buyer in **Section V.2.5** of Request for Quotation No. **NUSI_131_PR137000_2025**.

1. We hereby declare that on the date of submission of this offer,

   .....(enter Bidder name, registered office address, National Court Register (KRS), Tax ID, Statistical Number (REGON).....

   nor its subsidiaries or any other entities personally, financially, or organizationally affiliated, members of governing bodies, or (to the best of its knowledge) any employee of the Bidder, are subject to sanctions imposed by the European Union, the Republic of Poland, the United States of America, or the United Kingdom

2. Additionally, we declare that during the tender procedure and throughout the term of the Contract:
   a) we conduct and will conduct our business in compliance with applicable sanction regulations,
   b) we do not violate and will not violate applicable sanction regulations,
   c) no proceedings have been initiated against us in connection with a breach of sanctions,
   d) we have not been involved in any practice aimed at circumventing or evading sanctions,
   e) we will actively monitor entities subject to sanctions (listed on the relevant sanction lists), and we will not make financial resources or economic assets available, directly or indirectly, to sanctioned entities or for their benefit, and that such resources and assets will not be used to benefit such entities to the extent that such activity is prohibited under applicable sanction regulations.

   n the event of any change in the situation referred to in points 1–2, we undertake to immediately inform the Buyer.

3. At the same time, ……(name of the Bidder's company)..... we accept the full right of the Buyer to terminate the Contract with immediate effect, without incurring any financial consequences, if it is determined that our company is subject to sanctions or if there is a justified risk of being considered subject to such sanctions.
4. We also accept the right of the Buyer not to perform or to temporarily refrain from performing certain or all provisions of the Contract if, due to changes in applicable sanction regulations, the performance of such obligations would result in a breach of those regulations. In such a case, the Buyer shall not be liable for any damages arising from non-performance or temporary suspension of the Contract.

Signatures and Bidder's Seal ……. …….

Date: ……. …….

EXHIBIT NO 6
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER
REGARDING COMPLIANCE WITH THE PARTICIPATION CONDITIONS IN THE TENDER

FRAMEWORK WORK SCHEDULE

By submitting an offer for **performing the risk assessment and estimating the costs related to the implementation of a quality system compliant with US-FDA** requirements, I/we hereby declare as follows:

I/we declare that we accept the Framework Work Schedule and the participation requirements specified by the Buyer in **Section V.2.6** of Request for Quotation No. **NUSI_131_PR137000_2025**.

Offer submission deadline	**Scheduled date for carrying out the formalities**	**Tasks for the On-Site Audit, including conducting the Audit**	**Work on the Report**	**Presentation of the Report**
January 12. 2026	Podpisanie umów	week 1 / week 2 / week 3	week 4 / week 5 / week 6 / week 7	week 8 / week 9 / week 10
Mo	Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo	Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo	Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo	Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo Tu We Thu FR Sa Su Mo
Bidder Selection	Scheduled execution of the Confidentiality Agreement and the Contract for the subject matter of the Request for Quotation	1. Establishing the action schedule 2. Verbal summary of online discussions 3. Conducting the on-site audit	1. **Report** preparation 2. **Report** verification 3. Subbission of the verified **Report**	Presentation of the **Report**
Section .XI.		Section: III.2.1. , III.2.2 , III.2.3	Section: III.2.4. , III.2.5 , III.2.6	Section: III.2.7.
Offer Evaluation and Result Announcement Procedure		Planned deadline for completing the work, including the on-site audit	Preliminary preparation of the **Report** by the Bidder (Contractor) including conclusions and recommendations, as well as verification of its accuracy and submission to the Representative of the Buyer	Online presentation via Teams (Bidder and Buyer representatives)

EXHIBIT NO 7
to the Request for Quotation no.: NUSI_131_PR137000_2025

MANDATORY EXHIBIT TO THE OFFER

ADVANTEGOUES OWNER STATEMENT

I (We), the undersigned:

……,

……,

[names and surnames of the duly authorized representatives of the foreign entity and the position in the entity]

acting on behalf of and being duly authorized to represent

……,

[full name of the foreign entity]

seated at:

……,

[registered seat of the foreign entity – address, city, country]

registered in the commercial register at:

……,

[city, country of the commercial register]

using, for the tax identification purposes, the number

……,

[the tax identification number in the country of the residence]

hereinafter referred to as "**The Service Provider**"

hereby declare that the Service Provider is a beneficial owner of any payments made by Zakłady Farmaceutyczne Polpharma S.A. ("**the Service Recipient**") for the services, i.e. that meets jointly all the following conditions:

CONDITIONS/*WARUNKI*	**YES/NO**
1. receives the payment for its own benefit, in particular, decides about this payment's destiny by itself and bears the economic risk of loss for all or part of this payment,	
2. is not an intermediary, representative, trustee or other entity obliged by law or fact to transfer all or part of the payment to another entity,	
3. conducts a real economic activity in the country of tax residence, if the payment is connected with business activity i.e.:	
a) actually performs activities constituting an economic activity, including in particular possession of the premises, qualified personnel and the equipment used in business operations	
b) does not create a structure operating in isolation from its economic reasons;	

	c) there is a commensurability between the scope and actually owned premises, personnel or equipment;	
	d) the agreements concluded by the Service Provider are in line with economic reality, have economic justification and are not obviously contrary to the general economic interests of the Service Provider;	
	e) the Service Provider performs its basic economic functions by itself, using its own resources, including managing persons present at premises.	
4.	is an entity whose income is subject to corporate income tax in the country of its residence irrespective of the source of the incomes. (country which issued its certificate of residence presented to the Service Recipient)	
5.	does not carry on business in the territory of the Republic of Poland through a permanent establishment situated therein according to the Double Taxation Treaty signed between Poland and _____ or the income paid by the Service Recipient is not related with such permanent establishment.	

_____

Signature and Company's Seal

_____

Name and surname of the person(s) representing the Service Provider

_____

Date

EXHIBIT NO 8
to the Request for Quotation no.: NUSI_131_PR137000_2025

INFORMATION EXHIBIT
REQUIRED AT THE CONTRACT SIGNING STAGE

TEMPLATE
NON-DISCLOSURE AGREEMEN

Date from which the Agreement enters into force: .....

PARTIES:

PARTY	POLPHARMA	COUNTERPARTY
Company's name:	**ZAKŁADY FARMACEUTYCZNE "POLPHARMA" SPÓŁKA AKCYJNA**	
Address:	Pelplińska Street 19, 83-200 Starogard Gdański	
A: Please complete only part A, if the Counterparty is a company registered in a company register		
Name of the court or relevant register:	**District Court for Gdańsk Północ in Gdańsk, 7th Commercial Division of the National Court Register**	
Register number:	**0000127044**	
Tax identification number:	**5920202822**	
Statistical identification number:	**190929369**	
Share capital* *if applicable	**100 207 830,00 zlotys, paid in full**	
Represented by*: *name, surname and function	**Waldemar Gańko - Pełnomocnik**	
Contact persons:	Waldemar Gańko Waldemar.ganko@polpharma.com +48-665-615-026	
B: Please complete part B if the Counterparty is a natural person or a sole entrepreneur		
Name and surname / Name of the enterprise:	----------	
Address:	----------	
Personal identity number:	----------	
Tax identification number:	----------	
Statistical identification number:	----------	
Represented by*: *name, surname and function	----------	
Contact persons:	----------	

1. PURPOSE

In connection with _____ (the "**Purpose**"), the Parties will share **Confidential Information** with each other.

2. CONFIDENTIAL INFORMATION

2.1. "**Confidential Information**" shall mean any information disclosed by, or on behalf of, one **Party** (the "**Discloser**") to another **Party** (the "**Receiver**") in connection with the performance of the **Purpose**. **Confidential Information** is in particular information:

2.1.1. regarding the **Purpose**, conclusion of the **Agreement** and its content,
2.1.2. regarding the **Party's** enterprise or business activity, in particular, constituting its Trade Secret,
2.1.3. of an economic, financial, commercial, marketing, scientific, technical, technological, administrative, organizational, know-how, personal (including contact information: email addresses, phone numbers, etc.), planning or strategic nature.

"**Trade secret**" is defined by the Law on Combating Unfair Competition of April 16, 1993. According to Article 11 (2), a business secret is:

- technical, technological, organizational information of the enterprise or other information of economic value,
- which, either as a whole or in a particular compilation and collection of their elements, are not generally known to, or not readily available to, persons normally dealing with this type of information,
- as long as the person entitled to use or dispose of the information has taken steps, with due diligence, to keep it confidential.

The law and its definition may change - the current definition always applies.

2.2. The form in which the **Confidential Information** will be disclosed is irrelevant to its confidential nature.

2.3. **Access to Confidential Information** may be granted only to:

2.3.1. employees and associates of the **Parties**,
2.3.2. Affiliates of the **Parties**,
2.3.3. advisors/consultants, lawyers and tax advisors,

to whom disclosure of **Confidential Information** is necessary in connection with the implementation of the **Purpose** and who are obliged to maintain confidentiality to the same extent as specified for the **Parties** in the **Agreement**.

"Affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with a Party. For these purposes, "control" refers to: (i) the possession, directly or indirectly, of the power to manage the management or policies of the entity, whether through ownership of voting shares, by contract or otherwise, or (ii) the possession, directly or indirectly, of thirty percent or more of the voting shares.

2.4. The **Receiver** shall be liable for the acts and omissions of the entities listed in Section 2.3 as for its own acts and omissions.

2.5. If the **Receiver** is required to disclose **Confidential Information** in accordance with applicable regulations, the **Receiver** shall promptly notify the **Discloser** and shall disclose the **Confidential Information** only to the extent necessary. It shall also use its best efforts to minimize the damage that the **Discloser** may suffer as a result of the disclosure.

2.6. **Confidential Information** shall not be information that **without breach of the Agreement**:

2.6.1. are publicly available,
2.6.2. the **Receiver** has lawfully obtained independently of the **Discloser**.

3. DUTIES

3.1. The **Parties** shall:
- **3.1.1.** use **Confidential Information** solely for the realization of the **Purpose**,
- **3.1.2.** not publish, share or disclose the **Confidential Information** without the prior consent of the **Discloser** (in which the **Discloser** may reserve the terms of disclosure),
- **3.1.3.** exercise due diligence to safeguard **Confidential Information** from disclosure,
- **3.1.4.** immediately inform each other of violations of the **Agreement**.

3.2. If the **Parties** decide not to pursue the realization of the **Purpose**, the **Receiver** shall immediately cease using the **Confidential Information**. In such event, the **Receiver** shall return to the **Discloser** or, at the **Discloser's** request, destroy the **Confidential Information**. The **Receiver** may retain appropriately secured **Confidential Information** if its retention is necessary:
- **3.2.1.** for technical and archival reasons (e.g. backups and e-mail archives),
- **3.2.2.** to secure the interests of the **Parties** (performance of legal and regulatory obligations, audit, court proceedings, pursuing claims from the other **Party**).

4. PERSONAL DATA

4.1. In connection with the conclusion of the **Agreement**, the **Parties**, as controllers of personal data, will make personal data of the following persons available to each other:
- **4.1.1.** representatives signing the **Agreement**,
- **4.1.2.** employees or associates of the **Parties** involved in the performance of the **Agreement**.

4.2. When fulfilling the information obligation, the **Parties** shall communicate to each other the content of information clauses, undertake to inform the above-mentioned persons of the processing of their personal data and to communicate to them the content of the information clause of the other **Party**. Polpharma's information clause is included in **Appendix No. 1** to the **Agreement**. The **Counterparty's** information clause is included in ……..

4.3. If, in order to perform the **Agreement**, it is necessary to entrust the processing of personal data, the **Parties** shall conclude an appropriate agreement in this regard, which will constitute an appendix to this **Agreement**.

5. TERM OF THE AGREEMENT

5.1. The **Agreement:**
- **5.1.1.** is valid for 5 (five) years from the date of its entry into force or 5 (five) years from the achievement of the **Purpose** or termination of legal relations between the **Parties** as a result of the achievement of the **Purpose** - whichever is later,
- **5.1.2.** may be terminated before the end of the term only by agreement of the **Parties**.

6. EXCLUSIVITY OF RIGHTS

6.1. **Confidential Information** and the materials that are their carriers remain the property of the **Discloser** and, at its request, the **Recipient** is obliged to return them.

6.2. Disclosure of **Confidential Information** will not be considered as granting any intellectual property rights. Especially:
- **6.2.1.** shall not be treated as granting a license or authorization to exercise derivative rights to the **Works**;
- **6.2.2.** shall not be equivalent to granting rights to any **Inventive Projects**, as well as any rights to patents relating thereto.

> "**Work**" is defined by the Act on Copyright and Related Rights of February 4, 1994. Pursuant to Art. 1 sec. 1, the subject of copyright is any manifestation of creative activity of an individual nature, established in any form, regardless of the value, purpose and manner of expression.
>
> The "**Inventive project**" is defined by the Industrial Property Law of June 30, 2000. Pursuant to Art. 3 sec. 1 point 6, when referring to Inventive Projects, it means inventions, utility models, industrial designs, topographies of integrated circuits and rationalization projects.
>
> The laws and the definition may change - the current definition always applies.

7. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

7.1. This **Agreement** shall be exclusively governed by and construed in accordance with the substantive laws of **Poland**, excluding its conflict of laws principles and excluding the UN Convention on Contracts for the International Sale of Goods.

7.2. Any dispute arising out of or in relation to this Agreement, including regarding the validity, breach, or termination thereof, shall be resolved by arbitration in accordance with the **Swiss Rules of International Arbitration of the Swiss Arbitration Centre** in force on the date on which the Notice of Arbitration is submitted in accordance with those Rules.

7.3. The number of arbitrators shall be 1 (one) where the amount in dispute does not exceed 1 000 000 (*one million*) euro. Where the amount in dispute exceeds 1 000 000 (*one million*) euro the number of arbitrators shall be 3 (three). The amount in dispute includes the claims made in the Request for Arbitration and any counterclaims made in the Answer to the Request for Arbitration.

7.4. The language of jurisdiction (including documents) will be English.

7.5. The decision of the Arbitral Tribunal shall be final, and the Parties waive all challenge of the award in accordance with Art. 192 Private International Law Statute.

7.6. The Place of arbitration will be Zurich, Switzerland.

8. SANCTIONS

8.1. The **Parties** declare that as of the date of entering into the **Agreement**, the **Parties**, members of their bodies, and (to the best of their knowledge) employees of the **Parties** are not subject to sanctions imposed by the European Union, the Republic of Poland, the United States of America, or the United Kingdom.

9. FINAL PROVISIONS

9.1. For ongoing communication related to the execution of the **Agreement**, contact persons are indicated in the table with the description of the **Parties**.

9.2. Each **Party** may transfer the rights and obligations under this **Agreement** to a third party only with the prior consent of the other **Party**.

9.3. Notifications and consents required under the **Agreement** as well as amendments to the **Agreement** may be made by the **Parties** only:

9.3.1. electronically - using qualified electronic signatures or electronic signatures submitted online, using a tool selected by both **Parties** (e.g. DocuSign) or

9.3.2. in writing - using handwritten signatures.

Notices, consents and amendments made in any form other than those indicated above will be null and void.

9.4. If the **Agreement** is signed by hand, it will be drawn up in the number of copies corresponding to the number of **Parties**. If electronic signatures are used, each copy of the **Agreement** will be its original.

/ signatures of the Parties /

Appendix No. 1 to the Agreement - POLPHARMA Information Clause

Information on the processing of your personal data by Polpharma:

1. Your personal data controller is Zakłady Farmaceutyczne Polpharma S.A. with its registered office in Starogard Gdański, at Pelplińska Street 19, 83-200 Starogard Gdański, entered in the Register of Entrepreneurs kept by the District Court for Gdańsk-Północ in Gdańsk, 7th Commercial Division of the National Court Register, KRS No.: 0000127044, Tax ID No. (NIP): 5920202822 ("Polpharma").

2. Your personal data will be processed for the following purposes:

   - performance of the agreement;
   - making tax settlements and keeping accounting records;
   - defending, establishing or asserting any potential claims between us and you;
   - creation of anonymised statistical data for the purposes of the Transparency Report;

3. You have the right to:

   - access your personal data,
   - request their rectification,
   - request their removal,
   - request restriction or objection to their processing,
   - request data portability,
   - lodge a complaint against unlawful processing of personal data with the President of the Personal Data Protection Office.

4. You can obtain full information on the processing of personal data at: https://polpharma.pl/en/clauses/ , by scanning the following QR code, by calling: +48 22 309 51 56, or it can be provided to you for inspection by Polpharma Commercial Representative.

Appendix no. 1 – Counterparty Information Clause

Information on the processing of your personal data by Counterparty:
…….. to *be completed by the selected Bidder* ……..

EXHIBIT NO 9

to the Request for Quotation no.: NUSI_131_PR137000_2025

INFORMATION EXHIBIT
REQUIRED AT THE CONTRACT SIGNING STAGE

TEMPLATE
TRANSFER OF PROPRIETARY COPYRIGHTS

1. The Contractor (selected Bidder) declares that all documentation, studies, concepts, expert opinions, and other documents, in particular the Report, in whole and in part, as well as any other works created in the course of performing the subject of the Agreement, are the result of its own creative work of an individual nature (hereinafter: **Works**), do not infringe any third-party economic or moral copyrights, and are protected in accordance with the provisions of the Act of 4 February 1994 on Copyright and Related Rights (Journal of Laws 2000 No. 80, item 904, as amended).
2. As part of the agreed contractual remuneration, the Contractor (selected Bidder), together with the delivery of the **Works**, transfers to the Buyer all economic copyrights to these **Works** in the fields of exploitation specified in section 6 below, along with the exclusive right to further authorize the exercise of derivative copyrights (disposal and use of adaptations and granting further rights to dispose and use adaptations), as well as transferring ownership of all copies of the **Works** prepared and delivered to the Buyer under the performance of the Agreement.
3. The date of transfer of rights to the **Work** shall be deemed the date of delivery of the **Work** to the Buyer (date of acceptance of the **Report** or its part).
4. The Contractor (selected Bidder) does not consent to any changes, alterations, or other modifications of the **Works** and confirms that all rights to such changes, alterations, and modifications shall belong exclusively to the Contractor.
5. Upon the transfer of economic copyrights, the Buyer acquires full and unlimited rights, territorially and for the entire duration of the rights, to exclusively dispose of and use the **Works** in whole or in part, in any manner and at any time, including the right to make the **Works** available to other entities.
6. The transfer of economic copyrights to the **Works** shall cover the following fields of exploitation:
   a) in terms of fixation and reproduction: producing copies of the **Works** by any technique, in particular by photosensitive, magnetic, and digital recording – on any type of medium, in an unlimited number of copies, in any format, as well as by introducing them into computer or server memory and permanently or temporarily fixing or reproducing such records, including making copies and freely using and disposing of such copies,
   b) in terms of trading copies on which the **Works** have been fixed: placing on the market, lending, leasing, or renting copies of media containing the **Works** on any type of medium and in an unlimited number of copies,
   c) transferring the **Works** to other entities (e.g., design offices or contractors).
7. The Contractor (selected Bidder) warrants that:
   a) data, information, drawings, processes, concepts, proposed solutions, and everything delivered as part of the contractual work or in connection with such work will be free from any infringement of patent rights, copyrights, trademarks, trade names, trade secrets, or any other intellectual property rights (such rights are collectively referred to as “Intellectual Property”),
   b) at its own expense, it will secure, defend, and indemnify the Buyer against any claims, lawsuits, proceedings, costs, and losses arising from any infringement of Intellectual Property or demands related to the Agreement or associated with it.
8. Under the declarations made in points 1 and 7, the Contractor (selected Bidder) assumes warranty liability towards the Buyer that no third party will raise claims against the Buyer. In particular, the Contractor (selected Bidder) undertakes to cover any claims directed at the Buyer or satisfied by it from third parties. In the event of litigation, the Contractor (selected Bidder) undertakes to join the proceedings on the side of the Buyer and act in its interest within the limits provided by law. In the event of an attempt to settle the dispute out of court by the Contractor (selected Bidder), the Contractor shall ensure the Buyer’s right to participate in all actions taken in connection with such settlement.
9. The Contractor (selected Bidder) undertakes that if any economic or moral copyrights or derivative rights belong to third parties, including in particular employees and subcontractors, the Contractor shall ensure that all such third parties immediately and without additional remuneration transfer their economic copyrights and derivative rights to the Buyer as described above, and grant the Buyer, immediately and without additional remuneration, all authorizations and

permissions to use and disseminate economic copyrights as well as moral and derivative rights, to an extent no less than that specified in the Agreement.

10. The Contractor warrants that persons who created the **Works** produced during the performance of the subject of the Agreement and who hold economic and moral copyrights or any rights to derivative works will not raise any claims against the Buyer for infringement of their rights.

EXHIBIT NO 10
to the Request for Quotation no.: NUSI_131_PR137000_2025

INFORMATION EXHIBIT
REQUIRED AT THE CONTRACT SIGNING STAGE

TEMPLATE
CONDITIONS FOR WITHHOLDING TAX EXEMPTION (WHT)

1. The Contractor (selected Bidder) shall understand the Contractor's Remuneration due under the Contract as the gross amount, i.e., the amount including withholding tax payable in Poland (hereinafter: **WHT**).
   If:
   a. the Remuneration is subject to VAT in Poland, and/or
   b. the Remuneration is subject to deduction or withholding of **WHT**,
   then the Remuneration shall be reduced by the amount of **WHT**, and the amount payable shall be decreased by the tax withheld in Poland (if applicable).
2. Together with the first invoice, the Contractor (selected Bidder) is obliged to provide the Buyer with a valid and correct Tax Residency Certificate (**TRC**) issued for the Contractor by the competent tax authority in its country of tax residence. This document should confirm that at the time of payment of the invoice, the Contractor is a resident of that country within the meaning of the applicable Double Taxation Treaty (**DTT**) between Poland and that country.
3. Annually, if the task extends to subsequent years, together with the first invoice in a given year, the Contractor must provide the Buyer with the original Tax Residency Certificate valid for that year. Furthermore, the Contractor is obliged to immediately inform the Buyer of any changes that may affect its tax residency status.
4. Each year, if the task extends to subsequent years, together with the first invoice in a given year, the Contractor must submit to the Buyer a ***Advantageous Owner Statement*** in the form specified in **EXHIBIT NO. 7**, confirming that the Contractor is the recipient of the remuneration (the beneficial owner of payments from the Buyer). Additionally, the Contractor is obliged to immediately inform the Buyer of any changes that may affect the factual circumstances stated in this declaration.
5. The Contractor confirms awareness that Polish income tax law treats payments for license fees/intangible and legal services as income subject to **20% WHT** in Poland. This withholding may be reduced under the provisions of the relevant **DTT**. However, to apply the **DTT** with a given country, the Contractor must provide:
   a. the original valid and correct Tax Residency Certificate issued by the tax authorities of that country,
   b. the declaration referred to in point 4, signed by duly authorized representatives of the Contractor,
   c. any supplementary documents confirming the factual circumstances stated in the ***Advantageous Owner Statement*** described in point 4, upon request of Polish tax authorities.
6. The Contractor acknowledges that if:
   a. for any reason, the Contractor cannot provide the Buyer with the Tax Residency Certificate within the deadlines specified in points 2 and 3,
   b. for any reason, the Contractor cannot submit the declaration described in point 4 within the deadlines specified therein,
   then the Buyer will withhold **20%** of the Remuneration from payments invoiced under the payment terms specified in the Agreement, as **WHT**, and remit the withheld amount to the Polish tax office.
7. By the end of the third month following the tax year or upon the Contractor's request within **14 days** of such request, the Buyer will provide the Contractor with information on income earned in Poland as a non-resident individual/legal entity and the amount of tax withheld (if applicable).