*Lodz, 11 September 2020 r.*

**Request for offer No. 1 /PMT/ 2020**

The purchase will be carried out under the Project No. PMT / 0934 / 6N / 2019 under the Smart Growth Operational Programme 2014-2020, priority axis III "Support for innovation in enterprises", Measure 3.3 "Support for the promotion and internationalization of innovative enterprises", Sub-measure 3.3.1 "Polish Technological Bridges " (European Regional Development Fund).

**NAME AND ADDRESS OF THE ORDERING PARTY:**

Pixel Technology Ltd

Ul. Piękna 1

93-558 Lodz, Poland

VAT number: PL 7271010965

**MODE OF REQUEST:**

In accordance with the principle of competitiveness set out in the Guidelines of 22 August 2019 on the eligibility of expenditures under the European Regional Development Fund, the European Social Fund and the Cohesion Fund for the years 2014-2020.

**Date of announcement of the request for offer:**

11.09.2020

**Deadline for submitting offers:**

18.09.2020, till the hour: 23:59 (Polish time - CEST)

**CPV CODE AND NAME:**

73210000-7 - consultancy services in the field of research

**SUBJECT OF THE ORDER, ITS DESCRIPTION:**

The subject of the request for offer is the purchase of advisory services related to the preparation of the Ordering Party for FDA (Food and Drug Administration) certification, the final effect of which will be the development of an FDA application for the Integrated Medical System ,,AlleRad” under the Premarket Notification 510 (k) procedure. As part of this service, the following activities will be carried out:

1. The Contractor will provide any help and knowledge necessary to fulfil FDA clearance.
2. The Contractor will represent Ordering Party before FDA.
3. Classification of the Integrated Medical System ,,AlleRad” from the point of view of trading.
4. Elaboration of a detailed list of source documents required for the preparation of documentation. Analysis of source documentation and its adaptation to the purposes of the FDA application.
5. Identification and analysis of FDA guidelines and international standards.
6. Review and analysis of the FDA database for the selection of a medical device that may constitute the so-called "Predicate devices". Selection and recommendation of the most appropriate predicate in terms of applications and technological specification.
7. Comparative analysis of potential predicates of the Integrated Medical System ,,AlleRad”, in particular based on the basis of provided source documents. Recommendations of examinations and tests necessary for the demonstration of substantial equivalence. Identification of differences and their meaning.
8. Recommendations for additional examinations and tests necessary to be carried out by the Ordering Party in order to effectively prove substantial equivalence.
9. Supplementing of the comparative analysis with the results of additional recommended studies and tests, provided that they are known before the termination of the advisory service.
10. Advisory on the development of product marking in accordance with FDA regulations and requirements.
11. Elaboration of 510 (k) application, including all required forms, medical device description, application.
12. The cooperation with the Contractor related to FDA will end when Ordering Party will receive FDA clearance and Contractor will support Ordering Party till this time in any action.

**EXPIRATION OF THE CONTRACT:**

The subject of the contract should be completed by no later than **25/01/2021**.

**SCOPE OF EXCLUSION OF BIDDERS FROM THE PROCEDURE:**

1. In order to avoid conflicts of interest, public procurement, with the exception of sectoral procurement, awarded by a beneficiary who is not an entity obliged to apply the Public Procurement Law in accordance with passage 3 of the Law, may not be granted to entities connected to it in terms of capital or personal connections. Capital or personal connections are understood as interrelationships between the beneficiary or persons authorized to incur liabilities on behalf of the beneficiary or persons performing activities on behalf of the beneficiary, related to the selection procedure of the contractor, and the contractor, in particular consisting of:

* participation in the company as a partner in a civil law partnership or partnership,
* owning at least 10% of shares or stocks, unless the lower threshold results from legal regulations or has not been determined by the Managing Authority of the Operational Programme Smart Growth 2014-2020,
* performing the function of a member of the supervisory or management body, proxy or plenipotentiary,
* being married, in relationship or affinity in a straight line, relationship of the second degree or affinity of the second degree in the collateral line or in the relationship of adoption, care or guardianship.

2. Neither liquidation nor bankruptcy has been initiated against the Contractor.

3. The bidder must not be in arrears with the payment of taxes, fees or social or health insurance contributions.

4. A bidder who has not been legally convicted of an offense committed in connection with the contract award procedure, bribery, offense against economic turnover or other offense committed for financial gain may participate in the proceedings; and a partner in a general partnership, partner or member of the management board of a partnership; general partner of a limited partnership and a limited joint-stock partnership; a member of the management body of a legal person has not been legally convicted of an offense committed in connection with the contract award procedure, bribery, offense against economic turnover or other offense committed for financial gain.

Verification of compliance with the conditions for exclusion from the procedure described above will be based on the submission by the Bidder of a signed declaration on the absence of personal / capital connections with the Ordering Party (referring to the point 1 above) and regarding situations excluding from the procedure described in the points 2, 3 and 4 above (a template of this declaration has been attached to this request for offer - annex no 2).

**CONDITIONS OF PARTICIPATION IN THE PROCEDURE:**

Bidders who can participate in the procedure:

1. have the authority to perform specific activities or activities if the law imposes an obligation to have them
2. have the knowledge and experience necessary to carry out the order
3. have the appropriate technical potential and personnel capable of carrying out the order
4. have proven experience in providing in the last 10 years before the deadline for submission of offers advisory services related to FDA
5. are in an economic and financial situation ensuring the implementation of the public order

Verification of the aforementioned conditions will be based on the declaration of compliance with the conditions above (Annex no 1 to this request for offer). In addition to this, bidders are asked to submit scans of documents confirming proper performance of 3 advisory services, as a proof of compliance with condition no 4 above.

**CONDITIONS FOR OFFERS:**

1. Offers must be submitted in writing, with the use of the offer form (Annex no 3 to the request for offer).
2. Time of binding the offer - until the end of its validity period specified in the request for offer (offer should be valid at least till 30.09.2020)
3. The offer should be signed by people authorized to sign the offer in accordance with current registration documents or power of attorney granted. Incorrect confirmation of the offer results in rejection and leaving the offer without consideration.
4. Offers must be submitted with the total net price in Polish zlotys or in another currency. If an offer is submitted in another currency than Polish zlotys, the average exchange rate of the National Bank of Poland for foreign currency/Polish zlotys from the day of opening of offers will be used for price conversion.
5. The offer should contain the following elements:
* Declaration of compliance with the conditions (Annex no 1 to the request for offer)
* Declaration on the lack of personal and capital connections with the Ordering Party and related to other situations excluding the Bidder from the procedure (Annex no 2 to the request for offer)
* Offer form (annex no. 3 to the request for offer) together with full identification of the Bidder (name, address, VAT number, registration number, e.g. [National Court Register](https://pl.bab.la/slownik/angielski-polski/national-court-register)) as well as the date of preparation and validity of the offer (the offer should be valid at least until 30 September 2020)
* Scans of documents confirming proper performance of the contract (as a confirmation of meeting the 4th condition for participation in the procedure).

**COMPLETION DATE OF THE ORDER:**

The contractor should complete the subject of the order by **25 January 2021.**

**EVALUATION CRITERIA OF THE OFFER AND INFORMATION ON POINT WEIGHTS ASSIGNED TO INDIVIDUAL OFFER EVALUATION CRITERIA:**

The selection of the best offer will be based on the following criterion:

● price - 100%

**DESCRIPTION OF THE MODE OF AWARDING POINTS FOR MEETING A GIVEN OFFER EVALUATION CRITERION:**

The maximum number of points for meeting the criterion indicated in the point VIII is 100 points.

The number of points in the ,,price" criterion will be awarded in accordance with the following formula:

LC = CMIN/CO \*100 points\* 100%

Where:

LC – number of points for the price criterion

CO - net price of the offer

CMIN - the lowest net price of the offer that was submitted in response to the request for offer

The offer should refer to the evaluation criterion mentioned above. If the Bidder fails to provide information enabling the evaluation of this criterion, its offer may be considered invalid or it will be awarded 0 points.

After assessing submitted offers, the Ordering Party will propose the conclusion of the Agreement for the implementation of the subject of the order to the Bidder that has obtained the highest number of points (template of the Agreement is annex no 4 to this request for offer).

The Ordering Party, after evaluating the submitted offers, will propose to the Bidder who obtained the highest number of points, concluding a contract for the performance of the subject of the contract (the contract template is Annex 4 to this request for offer).

**CONDITIONS FOR CHANGING THE CONTRACT CONCLUDED AS A RESULT OF THE PROCEDURE FOR GRANTING A PUBLIC ORDER:**

The Ordering Party reserves the right to change the scope of the contract concluded with the entity selected as a result of the public procurement procedure for the following reasons:

● justified changes in the content-related and financial schedule of the Project within which the purchase will be carried out

● justified changes in the way of carrying out the subject of the order

● discrepancies or ambiguities in the understanding of the terms used in the contract arise and they cannot be removed in another way and the change will allow to remove the discrepancies and clarification of the contract for clear interpretation of their provisions by the Parties

● circumstances of force majeure

● changes in legal regulations in force on the day of signing the Contract. These changes must have a direct impact on the implementation of the subject of the Contract and may lead to modification of only those provisions of the contract which they refer to

● receiving a decision of the institution financing the project related to changes in the scope of tasks, deadlines or establishing additional provisions which the Ordering Party will be required to.

**POSSIBILITY TO CANCEL THE PROCEDURE:**

The Ordering Party reserves the right to cancel the bidding procedure at any stage of its duration without giving reasons.

**POSSIBILITY OF SUBMITTING PARTIAL AND VARIANT OFFERS:**

The Ordering Party does not allow for submission of partial offers.

The Ordering Party does not allow for submission of variant offers.

**DATE AND WAY OF SUBMISSION OF OFFERS:**

Electronically (scan) to the following e-mail address: **unia@pixel.com.pl**

The deadline for submission of offers: **18 September 2020, till the hour 23:59 (Polish time, CEST)**

Offers submitted after the deadline indicated in this request for offer will not be taken into consideration.

Any additional questions regarding this request for offer should be sent to the following e-mail address: **r.zdrajkowski@pixel.com.pl**

**Annex no 1 to the request for offer no. 1/PMT/2020 of 11.09.2020**

..............., ........................

Place Date

Bidder/Stamp:

**Declaration of compliance with conditions**

In response to the request for offerno 1/PMT/2020 of 11.09.2020, I/we declare that I/we meet the conditions for participating in the procedure listed below:

1. I/we have the authority to perform specific activities or activities if the law imposes an obligation to have them
2. I/we have the knowledge and experience necessary to carry out the order
3. I/we have the appropriate technical potential
4. I/we have personnel capable of carrying out the order
5. I am/we are in an economic and financial situation ensuring the implementation of the public order.

 ……….……………………..………………………..

` (Signature of the authorized representative of the Bidder)

**Annex no 2 to the request for offer no. no. 1/PMT/2020 of 11.09.2020**

..............., ........................

Place Date

Bidder/Stamp:

**Declaration on the absence of personal / capital connections with the Ordering Party and regarding situations excluding from the procedure**

In response to the request for offer no. 1/PMT/2020 of 11.09.2020 we declare that we are not connected to the Ordering Party in terms of capital or personal connections.

Capital or personal connections are understood as interrelationships between the beneficiary or persons authorized to incur liabilities on behalf of the beneficiary or persons performing activities on behalf of the beneficiary, related to the selection procedure of the contractor, and the contractor, in particular consisting of:

* participation in the company as a partner in a civil law partnership or partnership,
* owning at least 10% of shares or stocks, unless the lower threshold results from legal regulations or has not been determined by the Managing Authority of the Operational Programme Smart Growth 2014-2020,
* performing the function of a member of the supervisory or management body, proxy or plenipotentiary,
* being married, in relationship or affinity in a straight line, relationship of the second degree or affinity of the second degree in the collateral line or in the relationship of adoption, care or guardianship.

In addition to this, we declare that situations excluding from the procedure described in points 2, 3 and 4 of the part SCOPE OF EXCLUSION OF BIDDERS FROM THE PROCEDURE of the request for offer, do not apply to us.

 ……….……………………..………………………..

` (Date and signature of the authorized representative of the Bidder)

**Annex no 3 to the request for offer no. 1/PMT/2020 of 11.09.2020**

**OFFER FORM**

Bidder's full name: .............................................. .........................................................

Registration No (e.g. [National Court Register](https://pl.bab.la/slownik/angielski-polski/national-court-register)): ....................................................................

Address:…………………………………………………………………………………………

E-mail address:……............................................ ...........................................................

Phone number: …………………………………………………………...............................

In response to the request for offer no. 1/PMT/2020 of 11.09.2020, we present our offer:

Total net price: …………………………………… ..

(If an offer is submitted in a another currency than Polish zlotys, the average exchange rate of the National Bank of Poland for foreign currency/Polish zlotys from the day of opening of offers will be used for price conversion)

Date of preparation of the offer: ...........................................................................

Offer validity date: ...........................................................................

..................................................................

(signature of the person authorized to represent the Bidder)

................................................................

(Bidder's stamp)

**Annex no 4 to the request for offer no. 1/PMT/2020 of 11.09.2020**

**Agreement with the contractor (template)**

Concluded in Lodz on ........................... between:

This Agreement (“Agreement”) is between Pixel Technology Ltd (the "Company”), located at ul. Piękna 1, 93-558 Lodz, Poland, VAT identification number: PL7271010965, and…………..(the “Consultant”), located at…….

1. The Consultant has a background and extensive experience in U.S. and international regulations and laws regarding medical devices, including FDA requirements and the conduct of clinical trials, and is willing to provide services to the Company based on this background.
2. The Company desires to have services provided by the Consultant.

Therefore, in consideration of the above recitals, the terms and conditions set forth herein, the parties agree as follows:

1. General provisions
2. The subject of the Agreement are advisory services related to the FDA certification, described in details in the request for offer no 1/PMT/2020 of 11.09.2020.
3. The subject of the contract will be financed under the Project No. PMT/0934/ 6N/2019 under the Smart Growth Operational Programme 2014-2020, priority axis III "Support for innovation in enterprises", Measure 3.3 "Support for the promotion and internationalization of innovative enterprises", Sub-measure 3.3.1 "Polish Technological Bridges " (European Regional Development Fund).
4. The Consultant declares that he has the knowledge, experience and qualifications necessary for the proper performance of the subject of the Agreement and there are no actual obstacles preventing him from performing the subject of the Agreement.
5. The Company and the Consultant agree that confirmation of performance of the subject of the Agreement will be made in writing by drawing up and signing the Acceptance Protocol without reservations, after completion of the subject of the Agreement.

 2. Description of Services

With conclusion of this Agreement the Consultant will provide services (collectively, “Services”) as requested by the Company. Specifically, those services will consist of FDA regulatory, clinical, software development and compliance related work.

 3. Performance of Services

The Consultant will perform those services that are requested by the Company as described above. The manner in which the Services are performed shall be determined by the Consultant and the Company.

 4. Payment to Consultant

1. For the implementation of this contract, the Company shall pay the Consultant a remuneration in the amount of ................................. net (in words: .................), increased by the amount of ....% VAT, which collectively represents value of.............................. gross (in words: ........................................).
2. The remuneration indicated in the point a, will be payable in 100% by January 25th, 2021, based on a VAT invoice issued by the Consultant.
3. Payment will be due within 30 days of the Company’s receipt of an invoice, no later than by January 25th, 2021. A charge of 1,5% per month will be charged for payments not received by the Consultant within 30 days.
4. VAT invoice should be issued for Pixel Technology Ltd with headquarters in Lodz ul. Piękna 1, 93-558 Lodz, Poland, VAT identification number: PL 7271010965.
5. Upon termination of this Agreement, payments under this paragraph shall cease; provided, however, that the Consultant shall be entitled to payments for periods or partial periods that occurred prior to the date of termination and for which the Consultant has not yet been paid.

5. Expenses

The Consultant shall be entitled to reimbursement from the Company for all “out-of-pocket” expenses upon receipt of a list of expenditures. Supporting receipts to the extent required by applicable income tax regulations will be kept on file at the premises of the Consultant. These expenses cannot exceed 10 % of the total remuneration of the Consultant related to this Agreement indicated in the point 4.

6. Termination

The Consultant will complete the subject of the Agreement till January 25th, 2021.

This agreement may be terminated at any time by either Party with thirty (30) days written notice to the other Party.

7. Relationship of the Parties

It is understood by the Parties that the Consultant is an independent contractor with respect to the Company and not an employee of the Company.

8. Indemnification

The Company agrees to indemnify and hold Consultant and its officers, directors, employees and agents (collectively “Indemnitees”) harmless from and against any and all liabilities, losses, damages, costs and expenses (including reasonable attorney’s fees) initiated by third parties (collectively “Claims”), and incurred or sustained by an Indemnitee because of the performance of Services for the Company, except where such Claim arises as a result of the Indemnitee’s negligence, gross negligence or willful misconduct.

Any and all amounts due for indemnity hereunder shall be paid promptly as indemnifiable damages or losses incurred and in any event within 30 days after written demand therefore. Payments shall be made in accordance with the Indemnitee’s reasonable instructions at the time.

9. Disclosure

The Consultant is required to disclose any outside activities or interests, including any ownership or participation in projects that conflict or may conflict with the best interests of the Company. Prompt disclosure is required under this paragraph if the activity or interest is related, directly or indirectly to any activity that the Consultant may be involved with on behalf of the Company.

10. Confidentiality

The Consultant recognizes that the Company has and will have products, prices, business affairs, future plans, trade secrets, process information, customer lists, technical information, product design information, and other proprietary information (collectively, “Information”) which are valuable, special and unique assets of the Company. The Consultant agrees that the Consultant will not at any time or in any manner, either directly or indirectly, use any Information for the Consultant’s own benefit, or divulge, disclose or communicate in any manner any information without the prior written consent of the Company. The Consultant will protect the information and treat it as strictly confidential.

A violation of this paragraph shall be a material violation of this Agreement.

1. Unauthorized Disclosure of Information

If it appears that the Consultant has disclosed (or has threatened to disclose) Information in violation of this Agreement, the Company shall be entitled to an injunction to restrain the Consultant from disclosing, in whole or in part, such Information, or from providing any services to any party to whom such information has been disclosed or may be disclosed. The Company shall not be prohibited by this provision from pursuing other remedies, including a claim for losses and damages.

1. Services by Consultant to Third Parties

The Parties recognize that the Consultant may provide consulting services to third parties. However, the Consultant is bound by the confidentiality provisions of this Agreement, and the Consultant may not use the Information directly or indirectly, for the benefit of third parties.

11. Notices

All notices required or permitted under this Agreement shall be in writing and shall be deemed delivered when delivered with proof of delivery addressed as follows:

Company:

ATTN:

ADDRESS:

Telephone:

Email:

Consultant:

ATTN:

ADDRESS:

Telephone:

Email:

Such addresses may be changed from time to time by either party by providing written notice in the manner set forth above.

12. Amendment

This Agreement may be modified or amended, if the amendment is made in writing and is signed by both Parties.

13. Severability

If any provision of this Agreement shall be held to be invalid or unenforceable for any reason, the remaining provisions shall continue to be valid and enforceable. If a court finds that any provision of this Agreement is invalid or unenforceable, but that by limiting such provision it would become valid and enforceable, then such provision shall be deemed to be written, construed, and enforced as so limited.

14.

1. The Agreement is binding for the Parties from the date of signature.
2. It is prohibited to sell debts related to this Agreement to third parties.
3. Any disputes arising from this Agreement shall be settled by the court competent for the headquarters of the Prosecuting Party.
4. The Agreement was made in two identical copies, one for each Party.

AGREED AND ACCEPTED BY THE PARTIES BELOW:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date