**Connecting Innovation**

**High Impact Project Advert Template**

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| **Company Name** | Paxman Coolers Ltd |
| **Company Address** | International House  Penistone Road  Fenay Bridge  Huddersfield, HD8 0LE |
| **Company Contact** | Emma Thornhill & Pat Burke  [emma@paxmanscalpcooling.com](mailto:emma@paxmanscalpcooling.com)  [patrick@paxmanscalpcooling.com](mailto:patrick@paxmanscalpcooling.com)  01484 349444 |
| **Description of Company Activity** | Paxman is a medical technology company with an established leadership position in the Scalp  Cooling sector. The Paxman Scalp Cooling System (PSCS) minimizes hair loss in connection with chemotherapy treatment. The product is distributed to over 60 markets internationally, including: France, Germany, The Netherlands, Switzerland, Sweden, Russia, Brazil, Mexico, Australia, and the U.S. Scalp cooling is an important treatment, which has a strong clinical support and is a fully established therapy in many countries throughout the world.  Chemotherapy-induced alopecia is the most feared side effect of treatment in >75% of patients. Often patients feel this is the most traumatic side effect of their cancer treatment and not only can it lead to social isolation, but hair loss can affect self-image more than breast surgery. Eight percent of patients refuse chemotherapy or request a less efficacious treatment due to the prospect of hair loss.  The company has extensive global experience - since 2003, more than 65 clinical studies have been conducted in more than 17 countries and includes the first-ever randomized clinical trial to evaluate modern scalp cooling, which took place at several Cancer Centers in the United States as part of the FDA (Food and Drug Administration) clearance process. |
| **Objective of the proposed project (Please explain what is required in the project) (max 250 words)** | As part of Paxman’s investment in biological research, it has been discovered that chemotherapy drugs induce oxidative stress inside cells of the hair follicles which causes cell toxicity (and ultimately hair loss).  Therefore, a novel patented combinatorial approach was designed to reduce cell toxicity at “sub-optimal” cooling temperatures and has the potential to dramatically enhance the efficacy of the Paxman scalp cooling device.  This intervention combines cooling with treatment with a reactive oxygen species (ROS) inhibitor (antioxidant compound) delivered into cells to reduce oxidative stress (and these findings have been confirmed using whole follicles mini-organ cultures).  Using in vitro models, the company have now established a panel of antioxidant compounds which has shown extremely good efficacy in minimising or preventing cytotoxicity in combination with cooling.  Paxman now need the expertise to be able to target these antioxidant compounds to human hair follicles of the scalp. This will require expertise in pharmaceutics in order to prepare topical agents with appropriate formulations for delivery of these antioxidants to the hair follicles.  The identified third-party organisation must have both the cell biology/skin research as well as pharmaceutics expertise and research capabilities in order to be in position to deliver the proposed project. |
| **Tenders are Invited from suppliers who can provide the necessary skills and expertise to deliver the specification**  **Successful applicants should be aware that this project is part-funded by the England European Regional Development Fund as part of the European Structural and Investment Funds Growth Programme 2014-2020 and the Local Growth Fund.**  **Successful applicants should be aware that award of the contract is reliant on the successful issue of a grant funding agreement following the close of the tender process.** | This proposal aims to develop topical application products, comprising nanoparticulate formulations of ROS inhibitors (antioxidants). These formulations need to able to deliver therapeutically relevant concentrations of antioxidants to hair follicles of the scalp.  The project will involve the appropriate pharmaceutical formulation of the panel of five antioxidants recently characterised by Paxman’s research for targeted delivery to the skin. It is anticipated that successful targeting of these ROS inhibitors (which are already approved for use in humans) to hair follicles, combined with scalp cooling, would result in an additive or potentially synergistic effect in protection from chemotherapy-induced toxicity and thus alopecia.  The work will require utilisation of nanocarrier-based delivery systems, as nanoparticles are a promising approach to increase the percutaneous absorption of topically applied substances. Several nanocarrier-based platforms will need to be investigated, in order to develop a range of topical formulations to deliver these ROS inhibitors encapsulated in nanocarriers for optimized follicular drug delivery.  The approach will be to develop formulations of antioxidant (AO) compounds in lipid-based vesicles of a size suitable to target the hair follicles. Five AO actives with a range of physicochemical properties will be tested; although a platform technology will be the preferred approach, this may require modifications to ensure efficient encapsulation of the actives in each case.  Physicochemical characterization of nano-formulations will require particle size analysis and zeta potential. Analytical methods, typically high-performance liquid chromatography (HPLC), to quantify the encapsulation efficiency (and deposition in the skin) will need to be developed for each AO.  In order to determine the effects of short- and long-term storage on these formulations, they will need to be subjected to accelerated stability testing to provide evidence on how the quality of the pharmaceutical active as well as the structural consistency of the nanocarrier within the formulation varies with time under the influence of a variety of environmental factors (e.g., temperature and humidity). This will inform the robustness of the pharmaceutical formulations for eventual patient use.  Once developed, the formulations will require testing using an in vitro transdermal model system composed of Franz diffusion cells fitted with skin membranes to determine rates of drug diffusion and selective targeting of follicular sites. The ROS inhibitors in the nano-carrier based systems, dispersed in a gel, lotion or spray, will be assessed using this vitro model of transdermal drug delivery, with capacity to differentiate drug in the different compartments, including skin appendages such as the hair follicles.  The work will permit the selection of the best optimised drug/nanocarrier/base formulations with optimal characteristics and thus provide the groundwork for future studies that will involve preclinical testing of these formulations in combination with cooling.  Applicants are expected to have expertise in the area of nano-formulation and should have developed at least two products to date. |
| **Required project timescales** | July 2022 to 28 Feb 2023 (up to 9 months) |
| **Total Anticipated Project Value** | £87,500 |
| **Required response date** | 25 July 2022 |
| **How to apply?** | The advertisement is available on Contracts Finder  For any further questions around the procurement opportunity please contact Liza Hirst via the email address below  Liza@paxmanscalpcooling.com |
| **Criteria for decision making** | |  |  | | --- | --- | | Criteria | % | | Price | 20 | | Expertise in nano formulation with experience of developing at least 2 products | 50 | | Ability to meet deadlines | 30 | | Total | 100 | |
| **Scoring** | **Price**  The lowest priced tender will score full marks and other tender scores will be calculated on the basis of their deviation from the lowest. For every 1% a price is higher than the lowest, 1% of the score will be deducted from that tenderer’s score. The minimum score will be 0. For example:   |  |  |  |  | | --- | --- | --- | --- | | Lowest gets full marks - all others 1% off the score for every 1% higher than lowest | | | | | Tenderer | Price | Score | % difference | | Tender A | £50,000 | 30 | - | | Tender B | £58,000 | 25 | 16 | | Tender C | £75,000 | 15 | 50 | | Tender D | £82,000 | 11 | 64 | | Tender E | £100,000 | 0 | 100 |   **Quality**  Quality related criteria will be scored on the basis of the following scale:   |  |  | | --- | --- | | 100% | In respect of each element of the Services identified in the question, the proposals fully explain how the relevant element will be delivered to the standards required, throughout the term.  The proposals are clear, precise and robust.  The explanation is sufficient to give a high degree of confidence that all of the relevant aspects of the specification will be delivered. | | 80% | In respect of each element of the Services identified in the question, the proposals explain how the relevant element will be delivered to the standards required, throughout the term.  The proposals are clear, precise and robust.  The explanation is sufficient to give a high degree of confidence that the relevant aspects of the specification will, for the most part, be delivered. To the extent that the explanation is not sufficient to give that high degree of confidence, the explanation does not raise concerns. | | 60% | In respect of each element of the Services identified in the question, the proposals explain, to some extent, how the relevant element will be delivered to the standards required, throughout the term.  The proposals are clear, but there are some concerns around precision and / or robustness.  The explanation is sufficient to give confidence that the relevant aspects of the specification will, for the most part, be delivered. To the extent that the explanation is not sufficient to give that confidence, the explanation raises one or more concerns but no material concerns. | | 40% | In respect of each element of the Services identified in the question, the proposals explain, to some extent, how the relevant element will be delivered to the standards required, throughout the term, but for certain elements the explanation is very limited.  There are concerns around the clarity, and around the precision and / or robustness, of the proposals.  The explanation is sufficient to give confidence that the relevant aspects of the specification will be delivered to some extent. To the extent that the explanation is not sufficient to give that confidence, the explanation raises one or more concerns, one of which is a material concern. | | 20% | In respect of one or more elements of the Services identified in the question, the proposals fail to explain to any extent how the relevant element will be delivered to the standards required, throughout the term; and / or the proposals are mainly or wholly unclear; and / or the explanation is insufficient to give confidence that the relevant aspects of the specification will be delivered and / or the explanation for any one or more of the elements raises multiple material concerns. | | 0% | No response or response is irrelevant to the question asked. | |
| **Date for Contract Decision (i.e. how long before the SME will inform the successful respondent)** | 8 August 2022 |