

## Results of Competition: Biomedical Catalyst 2019 Round 1: Early and Late Stage Awards

Competition Code: 1901\_BMC\_R1\_2019\_ELS

Total available funding is £8,983,020

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
Lunac	Development of First-In Class Small Molecule Preclinical Candidate Anticoagulant Targeting Activated Factor XII with Minimal Risk of Bleeding	£2,370,535	£1,659,374
MEDICINES DISCOVERY CATAPULT LIMITED		£174,753	£174,753
University of Leeds		£1,356,630	£1,356,630

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## Project description - provided by applicants

Current treatments for patients who have a risk of forming blood clots are effective but carry a significant increase in the risk of bleeding. Anticoagulants taken by mouth include vitamin-K dependent antagonists (e.g. warfarin), direct thrombin inhibitors and FXa inhibitors \[Non-vitamin K Oral Anticoagulants (NOACs)\]. Studies have shown that NOACs significant reductions in stroke, bleeding in the brain, and death than warfarin but there is increased bleeding in the gut with a similar numbers of patients having major bleeding events (of which 1 in 8 result in death) compared with warfarin\[Lancet.2014;15;383(9921):955-62\]. Furthermore, because of the risk of bleeding, it is not possible to completely stop clots from forming in patients on treatment. As a result, patients on the new anticlotting treatment (NOACs) are still having blood clots (2.2-3.8%) and bleeding (3.6-20.7%) events with some resulting in death(Nat Rev Cardiol.2014,11(12):693-703).

The objective of this proposal is to develop highly specific compounds which block an activated clotting enzyme, Factor XII (FXIIa) and for which there is strong evidence that inhibition will not increase the risk of bleeding. This exciting development will allow patients to be treated more safely, without the need for monitoring and enable safe dose escalation in high risk patients, unlike current medicines that have a small window between beneficial effects and undesirable bleeding events. The aim is to produce an orally administered once or twice daily treatment.

The team at Lunac Therapeutics Limited, working with a UK based contract research organisation (sub-contractor), have generated a quality lead series of potent and highly selective agents which block the effects of FXIIa. These agents produce a high level of protection against clotting without the risk of bleeding in comparison with current medicines when tested in our experimental systems with very good anti-clotting effects. Thus, these compounds validate the idea that blocking the effects of FXIIa will deliver high protection against clotting in the absence of a significant bleeding risk, "the holy grail" of anticoagulant treatment. This project will work in collaboration with the University of Leeds and the Medicines Discovery Catapult using sub-contractors to generate a drug that will be ready for preclinical testing (Preclinical Development) to ensure it is safe to use in man. The deliverable of the award will be selection of a preclinical candidate (drug ready for preclinical development) with carefully designed experiments to improve the chances of success in the next stage of Preclinical Development.

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ISCA DIAGNOSTICS LTD	ISCA Diagnostics: Afu-LFD – a Novel Lateral Flow Device	£133,795	£93,656

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Project description - provided by applicants

ISCA Diagnostics, an innovative UK SME, is a leader in its field in developing innovative point-of-care (POC) diagnostic tests for fungal diseases.

The proposed project seeks to develop a novel test for rapid diagnosis of invasive pulmonary aspergillosis (IPA), a life-threatening lung disease of immunocompromised humans which accounts for >300,000 deaths globally each year.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
PHION THERAPEUTICS LTD	Development of a Therapeutic mRNA HPV Vaccine using Phion's Delivery Technology	£474,711	£332,298

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## Project description - provided by applicants

Infection with the human papilloma virus (HPV) leads to genital warts, pre-cancerous lesions and cancer. HPV is the most common sexually transmitted disease, yet all current vaccines are designed to prevent the disease and there is no effective treatment for those currently infected. Given that worldwide there are 200 million currently infected with HPV there is a clear need to create a vaccine that can treat the disease and clear the infection and that is the main focus of this project.

To make a vaccine therapeutic a particular type of immunity is required known as a CD8+ response. Phion Therapeutics have created a vaccine that produces a CD8+ response. We get this response because we can deliver the vaccine into the correct cells using a cell penetrating peptide as a delivery vehicle. We are the only company to have this peptide to deliver the vaccine. The vaccine itself is a genetic cargo (mRNA) designed to code for the antigens in a particular disease.

To date, we have produced and published data proving our prototype vaccine can eradicate target infected cells in vivo. This project is designed to build a vaccine specifically for HPV using genetic mRNA antigens termed E6/E7. We aim to clear HPV infections from small and large animal models of disease. We will also gather key information on the best dose and when to give the vaccine to get the best therapeutic response. The vision is to take our technology along the pipeline so that by the end we are ready to commence large-scale toxicology studies. The data pack achieved from this project is essential for us to raise further funds for these toxicology studies and this is also critical for the success of Phion's internal pipeline of projects. This is a highly innovative project as the first of its kind peptide/mRNA vaccine that can be used to treat HPV. Additionally, key information from this project can be applied to build therapeutic vaccines for viral infections such as Herpes Simplex Virus (HSV) and Human Immunodeficiency Virus (HIV). The development of the technology in this project could be the catalyst for a new generation of vaccines designed to clear viral infections on a global scale.

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ENESI PHARMA LIMITED	Enabling the Scalable Aseptic Manufacturing and In-Vivo Testing of Novel, Solid Unit Dose, Viral Vector Vaccines for Administration by Enesi's Needle Free Implavax® Delivery Technology	£1,243,455	£870,418

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## Project description - provided by applicants

Vaccines are one of the most cost-effective ways of delivering lasting benefit to human health and healthcare systems worldwide - it is estimated that they save 9 million lives each year.

Today, vaccines are not only being used to prevent common childhood infectious diseases such as measles, polio, and whooping cough. Modern developments in biology have led to the creation of a range of highly targeted vaccines based on vector delivery vehicles such as *\_vaccinia\_* and *\_adenovirus\_* that can be tailored for optimum effectiveness. With such efficiency and specificity, vector-based vaccines are being developed for diseases as broad as influenza, small pox, HIV, other lethal and rare infectious diseases, allergy, biodefence, cancers, and even ultra-personalised medicines tailored to the exact needs of a patient.

Most vaccines available today are delivered in a liquid/suspension form with a needle and syringe. Whilst established practice there are significant challenges innate to this presentation including needle-stick injury, cross contamination risk, sharps disposal risk, dosing error, subject pain and stress, poor thermal stability, and excessive wastage.

Additionally, multiple injections are generally required to generate a lasting effect on a subjects' immune system. Ensuring an individual's compliance to a 'Prime-Boost' dosing schedule is challenging, especially when dosing is often days if not weeks apart.

Enesi has developed a game changing technology that has the potential to revolutionise vaccination worldwide. Rather than delivering a vaccine in the traditional liquid form, our Implavax(r) technology allows the facile delivery of highly effective unit solid dose vaccine implants to the subject.

Comparative pre-clinical studies using a range of classical vaccines have demonstrated that Implavax(r) solid dose vaccines outperform liquid equivalents with a superior and faster immune response, regimen sparing, and enhanced thermal stability. Human factor studies also indicate a strong preference (91%) for the needle-free Implavax(r) delivery system across all subject groups evaluated with ease and speed of administration scoring very highly.

This project seeks to build on these foundations and will include the development of a robust aseptic-capable solid dose implant manufacturing processes, testing the implants on stability and conducting focused non-clinical immunogenicity studies to demonstrate the performance of the solid dose vaccine in-vivo.

Success will give a high confidence that such a process can be applied to all vector-based vaccines with all associated Implavax(r) benefits and the potential become a mainstay of both prophylactic and therapeutic treatment in human health.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
RE-VANA THERAPEUTICS LTD	Development of a novel implantable biodegradable device for sustained ocular drug delivery	£276,532	£193,572
Queen's University of Belfast		£141,869	£141,869

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## Project description - provided by applicants

In the UK, every day more than 250 people start to lose their sight - creating a major health challenge to the NHS and global healthcare systems. The growth of new blood vessels and leak fluid below or within the retina contributes to severe ocular diseases, such as age-related macular degeneration (AMD) in adults over 65 yrs. old. For example, in the UK, nearly 400 individuals are diagnosed with AMD every day. Nearly 48% of the UK adults are blind due to AMD - which affects the central vision in the elderly making simple daily tasks such as reading, watching TV, driving or recognising faces difficult. With increasing lifespan and the incidence of obesity, the prevalence of these diseases will continue to rise.

Currently, ophthalmologists treat their AMD patients by direct injection of expensive aqueous formulations of biologics into the eye. However, the need for monthly injections leads to poor patient compliance due to several unwanted effects including bleeding in the eye, discomfort, redness, irritation and increase in intraocular pressure. A major issue is the travel to and from the hospital, with 62 % of patients requiring escort -- leading to poor adherence. The rise in the number of AMD patients combined with the need for monthly injections puts pressure on a stretched NHS. Surveys by the Macular Society, the Royal College of Ophthalmologists, and the Royal National Institute of Blind People, have consistently show that many clinics fail to meet recommended waiting times for AMD treatment; and some clinicians frankly admit that patients have lost sight as a result.

Re-Vana has developed a novel disruptive photocrosslinked proprietary biodegradable sustained release drug delivery implant, EyeLief. The implant will provide significant clinical benefits over current monthly intravitreal injections. Following injection into the eye, the implant would provide a continuous release for effective AMD treatment over a 4-6 months period. Therefore, the impact of this research will offer major benefits to a wide variety of users such as patients, scientists, clinicians, industry and healthcare providers.

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XERION HEALTHCARE LIMITED	Oxilia - Towards clinical translation of nanoparticle enhanced radiotherapy for inoperable and difficult to treat cancers	£1,251,022	£875,715

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## Project description - provided by applicants

Xerion Healthcare Ltd ("Xerion") have developed a highly innovative and cost-effective nanoparticle technology, Oxilia. This technology is intended to augment standard radiotherapy to provide more effective treatment for patients with inoperable cancers, with the primary focus on head and neck (HNC) and pancreatic cancers. Current therapies are not adequate for effective treatment of such cancers, and this improved treatment regime is likely to offer a significantly better prognosis for patients, extending lives of patients with previously untreatable cancers, while considerably reducing treatment costs.

Oxilia is made up of novel titanium dioxide nanoparticles, doped with a rare earth metal, giving it unique properties and allowing the generation of free radicals from water during radiotherapy. This permits treatment of aggressive and challenging hypoxic tumours, which are deficient in the very oxygen required to generate the cancer killing free radicals, during conventional radiotherapy. This innovative approach has shown increased cancer cell death in lab studies, with 1.9x the cell killing capacity of conventional radiotherapy in pancreatic cancer cells. To translate these results obtained from preclinical studies to clinical practice, Xerion have to obtain authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) to commence clinical trials. The main aims of this project are to meet MHRA requirements by:

- Completing animal efficacy and dose response studies, and pharmacokinetic, biodistribution and toxicity studies;
- Demonstrating that production quality requirements can be met.

The defined outcomes of Oxilia project are:

- Demonstration that the current process can be scaled 20-fold in a compliant clean production environment, capable of producing up to 8,000 complete treatment kits per annum per reactor,
- MHRA authorisation for a pilot clinical trial using the complete treatment kits developed within the project,
- Capability to serve 100% of UK and 25% of EU unresectable HNC market, demonstrating feasibility of increasing the manufacturing scale.

Successful completion will allow Xerion to undertake clinical tests and commercialise Oxilia for HNC and pancreatic cancers. By 2028, Xerion expect to be treating up to 15,000 HNC patients across the UK and the EU, thereby significantly improving the quality of life for many people suffering from unresectable cancers.

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BRAINWAVEBANK LTD.	ANTONA-MH: Accelerating New Therapies with Objective Neurophysiological Assessment for Mental Health	£909,681	£636,777

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## Project description - provided by applicants

Mental health conditions like depression and schizophrenia affect millions of citizens in the UK, and have consequences for their quality of life, as well as families and wider communities. One reason that mental health conditions are difficult to treat is that it is hard to diagnose them precisely, or to know when a possible treatment is working, as that is based mostly on what a patient tells their doctor. This means that it can take weeks or months for GPs and consultants to find the best treatment for each patient, and even then many people do not respond to any treatment without unacceptable side effects. Drug companies are developing new medicines to improve this, but they have the same difficulties in finding the right volunteers for trials, and in measuring whether their new therapies work.

In this project, BrainWaveBank will develop a new device to detect mental health diseases, track how symptoms develop over time, and evaluate the efficacy of therapies in treating the disease. It is an easy-to-use wearable headset, accompanied by games that test different mental capacities like emotional processing, memory, concentration, etc. and yields brain-based biomarkers of neurophysiological mechanisms and cognitive functions. This will support a transformation in psychiatric drug development, helping to enable better, cheaper, and faster drug development, and improved tailoring of therapies to an individual to improve patient outcomes and reduce cost of care.

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VASGEN LIMITED	Development of the therapeutic candidate monoclonal antibody targeting ADAM15 for the treatment of ocular neovascular diseases	£568,596	£398,017
CENTRE FOR PROCESS INNOVATION LIMITED		£228,521	£228,521

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## Project description - provided by applicants

Sight-threatening diseases such as age-related macular degeneration and macular oedema affect the central vision of over 1.0 million people in the UK and millions more across the world. These diseases can lead to blindness, impacting upon the quality of life of the elderly and vulnerable and imposing a significant healthcare burden due to treatment costs (NHS £475 million/year) and associated injuries (NHS cost estimate £500 million/year). Vision deterioration is due to the unregulated growth and leakage of blood vessels beneath or within the retina leading to fluid build-up and swelling in the central region or macula. Current therapies employ drugs that turn off a master switch called VEGF that drives blood vessel growth and leakage (anti-VEGFs) and that are injected into patients' eyes on a monthly basis. Anti-VEGFs have succeeded in stopping vision decline and have improved vision significantly in about a third of patients, although these vision gains are lost after several years of treatment. Therefore, new therapies that enhance treatment outcomes by improving vision for longer while reducing the number of injections per year are urgently needed. This proposal is seeking funding for a collaborative project between Vasgen and the Centre for Process Innovation to develop a new therapy in readiness for human trials. Vasgen is developing a monoclonal antibody medicine that blocks the biological function of a molecular scissor called ADAM15. ADAM15, like VEGF, promotes blood vessel growth and leakage but does so via an independent mechanism. Vasgen's preliminary studies using proto-type drugs in models of disease suggest that blocking ADAM15's activity could lead to a superior therapy. Vasgen now seeks to develop a clinical trial-ready drug candidate in the current project in preparation for future clinical trials. It is envisaged that our company's new therapy can exceed the performance of existing treatments improving vision in more patients either when used alone or when combined with existing anti-VEGF drugs. This should in the long term lead to reduced costs borne by the NHS and other payers, while increasing the quality of life of patients.

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REDX PHARMA PLC	Pre-Clinical Validation and Translation of a Novel Anti-Fibrotic	£376,185	£225,711
MEDICINES DISCOVERY CATAPULT LIMITED		£338,039	£338,039

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## Project description - provided by applicants

Several prominent researchers in fibrosis have estimated that 1:2 deaths are caused by complications associated with fibrosis. The prototype fibrotic disease is Idiopathic Pulmonary Fibrosis (IPF), characterised by altered lung architecture and loss of respiratory surface area leading to increased deposition of extracellular matrix in the lung interstitium.

Current treatments are primarily to limit progression and treat symptoms rather than treat the disease or underlying causes. Pharmaceutical therapies (Esbriet, Ofev) have significant side-effects and only act to slow disease progression.

The need for new anti-fibrotic medication is therefore of paramount importance in sustaining human health and preventing premature deaths.

If left ignored the combination of a growing aged population and diseases, such as fibrosis, will become a crippling public health crisis. Successful project delivery will improve quality of life and enable those affected to continue to work, thereby improving social and economic outcomes (productivity and healthcare costs).

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TOPIVERT PHARMA LIMITED	A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of TOP1890 Oral Single Ascending and Multiple Doses in Healthy Volunteers	£2,082,386	£1,457,670

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## Project description - provided by applicants

This project involves a first-in-human clinical study with TOP1890, a water-soluble enzyme inhibitor with the potential to treat inflammatory bowel diseases (IBD). This compound produces broad and potent anti-inflammatory effects by targeting multiple components of inflammatory pathways/systems simultaneously. TOP1890 has been designed such that, when given by mouth, it acts locally in the intestine without being absorbed into the blood, thereby avoiding unnecessary exposure to other parts of the body that might lead to toxicity.

In this study, TOP1890 will be given by mouth to healthy male volunteers in order to determine its safety, tolerability and blood concentration with a view to facilitating later clinical studies in IBD patients. In order to demonstrate a truly local, topical, mode of action, an innovative approach will be employed wherein samples will be taken serially from subjects' colons so that TOP1890 concentrations can be measured and compared over time to the effects of the drug on various markers of biological activity.

There will be two parts to the study. In the initial single ascending dose (SAD) part, TOP1890 or the corresponding placebo, containing no active ingredient, will be given as a single split dose (2 divided oral doses, 12 hours apart) to 4 sequential groups of 12 healthy volunteers wherein the drug dose is increased to the next higher level only after approval by a Dose Escalation and Safety Committee (DESC). In the ensuing multiple ascending dose part, twice daily TOP1890 or placebo will be given orally over 5 days to a group of 12

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healthy volunteers initially at a low dose, determined from emergent data from the SAD part, which will be increased to a higher level in a second group following DESC approval. In both parts of the study, the use of serial sampling from the same subjects, to measure colonic compound levels while evaluating local biological action, will be essential for demonstrating a local, topical, mode of action.

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