

## Results of Competition: Biomedical Catalyst 2018 Round 1: Early Stage Award

Competition Code: 1803\_BMC\_R1\_EARLY

Total available funding is £8,000,000

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
KHEIRON MEDICAL TECHNOLOGIES LTD	Mammo - Mammography breast cancer screening software for radiologists	£606,883	£424,818
Leeds Teaching Hospitals NHS Trust		£107,030	£107,030
University of Leeds		£51,539	£51,539

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## Project description - provided by applicants

**\*\*Challenge\*\*** -- Breast Cancer (BC) is the UK's most common cancer (Cancer Research UK, 2018). The NHS screens 2.2m UK women annually and detects 18K BCs. Early detection is critical for survival but mammogram assessment is challenged by staffing crisis (high levels of retirement with low recruitment) and difficulty in assessment (including indentifying minute BC indications, workload and breast density). Given the pressure associated with this critical role, radiologists are understandably cautious. Of the 2.2m UK women screened annually, 89K are recalled, however only 45.2% of those require further investigations (cytology, core/open biopsy) (NHS, 2018).

**\*\*Project -\*\*** This project will conduct early stage R&D including research, Health Economics, developing the Platform, Interface, Prototype, Testing and demonstration in an NHS screening setting.

**\*\*Positive impacts -\*\*** Mammo could help radiologists and breast units deliver a better breast-screening service (faster, reduced unnecessary recalls/biopsies and lower anxiety). Reduced recalls will save NHS significant unnecessary costs.

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Echopoint Medical Ltd	Optical microcatheters for coronary physiology assessments	£869,708	£608,796

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## Project description - provided by applicants

This project is focused on the development of a new medical device to improve diagnosis and treatment of Coronary Heart Disease (CHD). CHD remains the leading cause of death worldwide. Patient symptoms occur when a build-up of plaque restricts coronary blood flow. Clinicians' decisions about treatment are often guided by data from medical devices placed inside the arteries of the heart. Currently, these devices provide information about differences in blood pressure on either side of plaque build-up, to determine whether to place a stent.

We are developing a new medical device that provides direct information about both blood flow and blood pressure. Direct measures of blood flow have been shown to be valuable to improve clinical decision-making about whether to place a coronary stent. Our solution will be compatible with clinical workflow, and by providing direct measures of blood flow, it will lead to more accurate assessments about whether stent placement is required, which will improve patient outcomes and reduce costs to the healthcare system.

One of the innovative aspects of our device is a novel fibre-optic sensing platform that comprises a highly miniaturised, fibre-optic flow and pressure sensor, and a single-use miniature microcatheter device into which the sensor is integrated.

The technology has been validated in the benchtop laboratory and in early-stage pre-clinical models. The aim of this project is to develop advanced prototype devices and to test them in clinically-realistic settings. The project will fulfil a key development step: the progression to clinically-validated pre-clinical prototypes to enable commercial manufacturing for future clinical trials.

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ARTERIUS LIMITED	Preclinical Development and Testing of Innovative Bioresorbable Stents to Treat Patients with Severe Peripheral Arterial Disease	£500,603	£350,422
University of Bristol		£498,734	£498,734

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## Project description - provided by applicants

Peripheral vascular diseases (PVD) are caused by the formation of atherosclerotic plaques/blockages in arteries, which reduce blood supply to brain, heart, kidneys, liver/gut and limbs causing strokes, heart attacks, kidney failure and limb amputations. This condition is also known as peripheral artery occlusive disease or peripheral artery disease (PAD).

The risks of PAD to patients has been reduced with the recent advent of thin-strut permanently implanted metallic balloon-expandable stents delivered percutaneously over a wire through a needle in the diseased/blocked peripheral artery. However, the presence of a permanent endovascular device in the artery is associated with a series of problems that can lead to re-narrowing/re-blockage (restenosis) of the arteries and stent clotting (thrombosis). Significant advances in the technology of biodegradable materials have made it possible to make vascular stents that are fully dissolvable over 18-24 months, also called bioresorbable stents (BRS). BRSs are able to mechanically keep opened/support the blockage of the diseased artery wall as well as elute a drug for a predetermined time period after which they are absorbed into the vascular wall. BRS are appealing to NHS clinicians, with potential to become the percutaneous treatment of choice for millions of PAD patients worldwide. Key developmental needs are: biodegradable materials, device/stent profile, wall thickness, thrombogenicity, degradation rate, biomechanical performance, and advanced in-vivo testing by clinical NHS experts, all key aspects that require an advanced multidisciplinary team of experts to ultimately deliver a new generation of BRSs that are safe, at much lower risk of late mechanical fracture and restenosis/thrombosis with a view to improve patient life expectancy and reduce markedly NHS costs.

To this end, Arterius Limited, as the only UK company developing the next generation biodegradable coronary stents, has paired up with the Translational Biomedical Research Centre at the University of Bristol, as the only UK institutional preclinical research facility developing new drugs and biomedical devices at NHS, Home Office and GLPMA standards, to develop, test, and translate to bed side the new BRSs for vascular clinical applications. Together Arterius and TBRC Bristol create a unique UK based partnership able to take on this challenge to expand Arterius's product portfolio and achieve a global clinical reach beyond the already established coronary disease for patient, societal and economical benefits. In turn, this partnership will help TBRC to enhance its national/international projection as the only institutional advanced preclinical research centre in the UK/EU partnering with Industry.

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TRUEINVIVO LIMITED	Development of a 3D cavity dosimeter and image analysis software for in-body invivo dose measurement of organs at risk to make radiotherapy safer for patients and more efficient for clinicians	£270,767	£189,537
Portsmouth Hospitals NHS Trust		£20,689	£20,689
Royal Surrey County Hospital NHS Foundation Trust		£20,936	£20,936

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## Project description - provided by applicants

It is currently estimated that 1 in 2 people will have cancer and of these around 40% will receive radiotherapy treatment (cancerresearchuk.org). Radiotherapy involves using ionising radiation to treat tumours and has been a key element of cancer treatment for decades. However 10-25% of radiotherapy patients are damaged or failed by their treatment often because currently there is no way to measure the actual radiation received in-body and compare it to the planned dose, Our vision is to provide medical devices to measure the radiation at the tumour - and surrounding organs - quickly, cheaply and simply so that radiotherapy can be applied more safely and effectively.

TRUEin vivo has developed a device that uses strings of micro (1mm) glass beads to measure the actual dose within 1mm and  $\pm 3\%$  accuracy. This device named DoseMapper, and the associated automated reader, is still in development and so not yet available for patients but should be available by the end of 2019.

The aim of this project, and the major innovation, is to develop a 3D version of DoseMapper, still using the same glass TLDs strung on a stretchy thread but wrapped around a balloon or insert. Its envisaged this could find application for measuring received dose at an accessible tumour (e.g. mouth cavity for head and neck cancers) or organs at risk (e.g. measuring the dose at the rectal wall when treating prostate cancer). Once the dose levels have been measured in one session, the clinician has the information to adjust the dose, minimising radiation exposure to the patient and damage to healthy tissue.

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HOX THERAPEUTICS LIMITED	Preclinical toxicological evaluation of HTL-001, a novel cancer therapeutic agent targeting HOX genes	£561,355	£392,948

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## Project description - provided by applicants

Homeobox or 'HOX' genes are an important family of genes encoding HOX proteins that control cell and tissue growth in the embryo. After birth, these genes are normally silenced, however, they can be re-activated in tumours in which they have a role in promoting cancer cell proliferation and survival. Importantly, in cancer, these genes are not mutated but overexpressed or 'switched on' and act through partnership with other proteins to drive cancer proliferation. Our novel drug is a small peptide which stops HOX proteins binding to their key partner protein, PBX, resulting in rapid cancer cell death. Our agent, HTL-001, has been tested in cancer cells representative of 14 different malignancies, in human cancer tissue in the 'test tube' as well as in animals. It has consistently demonstrated selective toxicity for cancer cells, sparing normal cells/tissue. A study of increasing doses of HTL-001 given once to rats and rabbits has already demonstrated that HTL-001 is safe and not toxic. The second study proposed here will test the safety of multiple doses of HTL-001 in animals since this is in line with how the drug would be used in human clinical trials. If successful, this is a vital scientific and compulsory regulatory step would allow us to define the starting dose of HTL-001 for human trials which could commence in December 2018. There is an urgent unmet need for new cancer therapies with novel mechanisms of action as current treatments for advanced disease are largely palliative. We have shown HOX gene dysregulation is very common in most cancers, and a rational target for new treatments.

We have recently shown that HTL-001 doubles the survival in mice which have been seeded with glioma (brain cancer). This development is very promising and the results are at least as good if not significantly better than other drugs tested at this stage - particularly as we are optimistic that HTL-001 will be well tolerated. Although not as common as many cancers, around 11,500 patients are diagnosed with brain cancer in the UK every year, of which only about 40% survive after one year. It is a condition of very high unmet medical need and this project, which will ensure that our drug is safe for patients' use in a clinical trial, has the potential to be of major benefit to patients - in brain cancer initially and hopefully in other cancers in the longer term.

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PEPGEN LIMITED	Application of a novel peptide delivery platform to nucleic acid therapeutics in degenerative and rare diseases	£3,546,260	£2,482,382

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## Project description - provided by applicants

Nucleic acid drugs are genomic medicines with the potential to transform human healthcare. Research has indicated that such therapeutics could have applications across a broad range of disease areas, including degenerative disorders, rare disorders and cancer. The use of this technology is highly promising, yet **the main challenge impeding the clinical translation of nucleic-acid based drugs is drug delivery itself**. The aim of PepGen is to meet this delivery challenge.

The technology underpinning PepGen's approach is to **harness the drug delivery properties of small protein fragments known as cell-penetrating peptides (CPPs)**. These peptides can be attached to nucleic-acid based drugs in order to improve the delivery of these cargo molecules to their site of action. Antisense oligonucleotides (ASOs) are a subtype of nucleic acid drugs that modulate how the information within a gene is processed in the cell. ASOs bind to specific sites in the genome and allow genetic information to be 'skipped' over in order to mask underlying mutations. This project supports the development of a CPP-ASO conjugate drug.

The advantage of PepGen's novel CPPs is that **efficacy and toxicology are decoupled in these peptides**. As such, our CPPs are known to elicit highly effective delivery with dramatic reductions in the associated side effects often seen with other molecules in this class. It should be emphasised that this is a **truly innovative step-change**, and puts PepGen at the forefront of both drug delivery technology and nucleic acid therapeutics. This 20-month project funds the work needed for PepGen to advance a lead candidate towards the clinic, with the support of Innovate UK having a considerable impact on the development timelines of this project.

To conclude, the major barrier to realising the full potential of nucleic acid drugs across a broad range of therapeutic areas is drug delivery. This project will develop a disruptive technology that delivers nucleic acid drugs to their site of therapeutic action, and we expect this work to have a transformative impact on human healthcare.

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MEDISIEVE LTD	Magnetic Blood Filtration for the Treatment of Sepsis	£1,414,054	£989,838

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## Project description - provided by applicants

MediSieve is a medical device company developing "magnetic blood filtration": a revolutionary treatment for blood-borne diseases which removes pathogens directly from the bloodstream. Our technology is like dialysis, circulating a patient's blood through an external loop to remove disease causing targets. While dialysis relies on non-specific size based filtration, MediSieve uses magnetic particles coated with antibodies (Ab-MP) to target specific components, and a magnetic filter to extract them.

The patented MediSieve Filter (MF) can safely remove magnetic components from the bloodstream. It is already developed as a treatment for severe malaria (Ab-MPs are not required for malaria, since malaria infected cells exhibit naturally occurring magnetic properties). The MF has completed pre-clinical testing and will enter first-in-man clinical trials in 2018\.

This project concerns the development of the Ab-MP to apply our technology to Sepsis. Sepsis is caused by an infection that creates a dysregulated immune response which can escalate to septic shock. The destruction of bacteria by the immune system or antibiotics creates large quantities of endotoxins (LPS), which aggravate the immune response, causing the over-production of inflammatory cytokines and cascade towards septic shock. Antibiotics kill pathogens, but do not remove them from the bloodstream, so the immune system's overreaction continues.

Our Ab-MPs target LPS, gram-negative bacteria, specific cytokines and a damage associated molecular patterns (DAMP) rapidly reducing the levels in a patient's bloodstream. Used in combination with antibiotics, it could help eliminate the infection, and reverse the escalation to septic shock. Treatment of sepsis with antibiotics increases the LPS load in the bloodstream, since LPS persist after the pathogens have been killed. LPS, inflammatory cytokine and DAMP levels correlate with clinical outcomes, and their removal would be beneficial in helping to treat the disease.

Sepsis is one of the world's leading causes of death, exerting a huge human and economic toll. Sepsis kills 44,000/year in the UK. Globally, there are over 20M total cases and over 6M newborns and children are affected annually. Global incidence has been increasing rapidly. With mortality over 30%, there is a clear need for better treatments especially as current antibiotic therapies are increasingly vulnerable to antimicrobial resistance.

This project will focus on the development of the Ab-MP to target LPS, cytokines and DAMP, proving their safety and efficacy in both laboratory and pre-clinical safety and efficacy trials, and performing the biocompatibility testing required in order to progress the treatment to first-in-man clinical trials.

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EVOX THERAPEUTICS LIMITED	Exosome therapy for rare paediatric disorder Argininosuccinic Aciduria	£1,181,777	£827,244
University College London		£391,749	£391,749

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## Project description - provided by applicants

Argininosuccinate lyase (ASL) deficiency is the second most common urea cycle defect. In the most severe form of the disease, symptoms present early in the new-born period progressing to coma and consequent death if untreated. Later presentation can present with aspecific neuro-disability. Patients are managed by pharmacological and dietary intervention, but ultimately patients require a liver transplantation for long-term survival. However, liver transplantation is associated with its own risks, i.e., mortality, morbidity and life-long need for immunosuppression.

Delivering a functional copy of the mutated genetic material or protein offers an attractive alternative to liver transplantation. Exosomes are emerging as a highly effective drug delivery system. Evox Therapeutics Ltd (EVOX) has developed a 'unique' exosome delivery system that can carry biopharmaceuticals across the blood brain barrier to treat neurological diseases. Thus, EVOX uses its proprietary technology to genetically engineer cells that produce bespoke exosomes, ~100nm extracellular vesicles, that can carry proteins, small molecules or various forms of RNA. Moreover, these engineered exosomes have protein decorated surfaces that enables entry into the brain across the blood brain barrier. EVOX has several programs in its pipeline for developing exosome-based therapeutic interventions to treat lysosomal storage disorder and importantly the neuro-pathology of these diseases, and the ability to alter the exosome membrane allows targeting precisely some organs or cell types and to cross the blood-brain barrier when administered in the bloodstream. EVOX's in-house R&D programs and commercialisation efforts are led by a team of over 2 dedicated scientists and field experts with a passion for developing novel therapies that will transform the treatment and management of numerous CNS diseases with significant unmet medical need.

Innovate UK Strand 1 award will enable EVOX to test its ASL protein-enriched or mRNA-enriched engineered exosomes in vitro and in vivo in collaboration with UCL. Tests will be carried out on human hepatocyte cell lines *\_in vitro\_*, ASLD-derived cells differentiated in hepatocytes and neurons to assess the efficacy *\_in vitro\_*, and in mice with/without ASL deficiency to test the optimal dose range, the duration of effect and frequency of re-injection and distribution across the body. This will provide pivotal data to enable further development for first-in-man clinical use.

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FREELINE THERAPEUTICS LIMITED	Using adeno-associated virus gene therapy to treat rare kidney disease	£1,564,444	£938,666

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## Project description - provided by applicants

Inflammation is at the root of numerous prevalent and rare diseases. While inflammatory pathways exist to provide protection from infection and aids in wound healing, when dysregulated these same pathways can have catastrophic effects. The negative impacts of inflammation are widely recognized in diseases such as heart disease and arthritis, but less appreciated on a broad scale in the context of rare diseases. Certain rare diseases are directly caused by dysregulation of an inflammatory system called complement and the impact of the disease on patients' lives is tremendous. In one form of complement-mediated disease, called C3 glomerulopathy, 50% of patients will suffer kidney failure within 10 years of diagnosis due to excessive inflammation resulting in a need of a kidney transplant. There is no effective therapy for this disease and this significant unmet clinical need is what we aim to treat with our novel therapy. FREELINE(r) is a new company focused on the development of liver-directed gene therapies; our gene therapies contain all of the biological instructions required for the liver to make new proteins. In the context of inflammatory kidney disease, our novel gene therapy will "instruct" the liver to produce anti-inflammatory proteins that will re-balance the dysregulated inflammatory pathways that cause kidney failure in C3 glomerulopathy. Government investment into this project and into Freeline will have a direct and measurable impact on the lives of patients with inflammatory diseases that have a high unmet clinical need and on the reputation of Freeline as a gene therapy leader anchoring this innovative technology within the UK.

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