Institution: University of East Anglia

Unit of Assessment: 3A - Allied Health Professions, Dentistry, Nursing and Pharmacy: Pharmacy

a. Context

Research within the School of Pharmacy lies at the boundary between physical and life sciences and has an impact on the general public in both these disciplines. The School was only five years old in 2008, but we have already developed a range of translational outputs from our research during the REF period. These include the identification and validation of new therapeutic targets, the design of biologically potent molecules, innovative new formulations and advances in food security. As such, research from the School also has an impact on the pharmaceutical industry and on the National Health Service. Much of our research is interdisciplinary in nature, as exemplified by the two case studies describing improvements in salmon farming and the commercialisation of a chemical biology tool.

b. Approach to impact

The School has an ethos of encouraging the development of impact from its research. While the primary focus of our research is on human healthcare, we recognise that the basic science may benefit society in other areas, as exemplified by one of our impact case studies. Impact is nurtured in the following ways:

- The School hosts presentations by the Research and Enterprise Sevice to improve awareness of impact and commercial potential.
- Enterprise and engagement are criteria, along with teaching and research, considered in staff appraisal and promotion.
- The School has an Enterprise and Engagement Committee that meets regularly to oversee the strategic planning of impact as well as identifying research outputs with the potential for impact at an early stage.
- The School's faculty have extensive collaborations and links with non-academic beneficiaries that include biotech and pharmaceutical companies and government organisations (see below).
- UEA has a "Proof of Concept" Fund to pump-prime short-term translational research with a view to generating impact and IP for commercialisation, and members of the pharmacy faculty have been active in gaining support for research with commercial potential through this mechanism (**Ganesan**, **Hamilton**, **Searcey**, see below). Further support for commercialisation and larger sums of money are available through the University's membership of the ICENI venture capital fund (**Wright**, see below).
- The School's research is used in the training of Pre-Registration Pharmacists throughout the East of England, under the influence of the General Pharmaceutical Council (GPhC). We train Pre-Registration Pharmacists for the NHS, the National Pharmaceutical Association and pharmacy retailers such as *Waremoss*.

Intellectual property: Within the REF period, Wright and Craig (the latter now at University College London) have filed several patents on drug formulations suitable for patients with swallowing difficulties (dysphagia). These have been granted in the EU and China with a priority filing in the US. Wagner (now at King's College London) has filed patents on glucosyltransferase and protein binding assays. The School's Enterprise and Engagement Committee and the University's Research and Enterprise Service closely monitor research to protect intellectual property.

Industrial interactions: The School holds consultancies with seven major companies- *BioInnovation SA*, *Boots*, *Evotec*, *Marine Harvest*, *Pfizer*, *Schulke* and *Servier*. It has also received inward R&D investment from business research contracts with the pharma sector including work with:

- *GlaxoSmithKline* – repositioning compounds that have failed in clinical trials to investigate their effects on G-protein coupled receptors.
- *Pfizer* – assessment of a novel drug delivery system to the anterior eye.

- *Merck Serono* – development of a decision tree for pharmaceutical formulation by hot melt extrusion.
- *Evotec* and *Servier* – *in vitro* assessment of ocular toxicity.
- *CalpainTherapeutics* – assessment of calpain inhibitors as anti-cataract drugs.
- *Novabiotics* – investigating the mucolytic action of Lynovex on pulmonary mucus.
- *Neurolixis* – testing their compounds for activity against the serotonin receptor 1a.
- *TA Instruments* – for the development of new thermal analytical methods.
- *Numark* – evaluating community pharmacy services and the development and trial of a community pharmacist-led eczema clinic.
- *Rosemont Pharmaceuticals* – improving formulation selection for patients with dysphagia and advice on products and formulations to bring to market.
- *Xeolas Pharmaceuticals* – designing validated questionnaires to estimate the acceptability of oral drug formulations.

In an interesting example of how enterprise is embedded in the School, such that our links reach beyond the traditional pharmaceutical science sector, **Qi** recently carried out consultancy work for the iconic local car manufacturer *Lotus*, investigating the degree of curing of car roof materials using thermal analysis. This approach to enterprise that reaches outside the human health/pharmacy sector is also exemplified in our first case study, where research on the human eye led to savings in the salmon farming industry, amounting to almost €30 million per year in Norway alone.

We have numerous postgraduate studentships funded by industrial sponsors, including *AstraZeneca* (Development of an *in vitro* model for assessment of drug toxicity in the human retina), *Bristol-Myers Squibb* (solid state NMR), *Evonik* (developing methods for predicting physical stability of hot melt extruded formulations), *ECOspray* (exploring mechanisms and applications of garlic oils as pesticides), *Novartis* (i-motif DNA, delivery of ultra-potent cytotoxins to the lung, inhaled drug delivery) and *Rosemont* (development of an electronic tongue). Research by Hamilton led to the discovery of bacillithiol, a bacterial metabolite and potential starting point for the development of new antibiotics. University "Proof of Concept" funding enabled Hamilton to produce bacillithiol on a large scale and to out-license the material to the spinout company *JEMA Biosciences* in San Diego, USA who now offer it for sale worldwide.

Healthcare providers: Research by Wright has identified potentially dangerous current healthcare practice in the UK regarding dispensing medication to patients with swallowing difficulties (dysphagia). His work was widely disseminated through the public media including articles in *Associated Press*, *BBC*, *European Satellite News*, *ITN*, the *Press Association*, *Reuters* and *Sky*. To increase awareness of the subject, he has created a website with information for patients and healthcare providers (www.swallowingdifficulties.com) referenced through the NHS Choices website. His recommendations were published as national NHS guidelines for healthcare practitioners. He and Craig received funding from the ICENI Venture Capital Fund to develop new pharmaceutical formulations to aid in dysphagia, which then led to an MRC Development Pathway Funding Scheme grant and the patents described above.

Additionally, through funding from the National Pharmacy Association, Wright has developed a tool for service evaluation by community pharmacists that is now used nationally. Our staff members actively participate in policy formulation and hold important offices in public advisory organisations, including the British Biochemical Society, the British Pharmacological Society, the British Society for Immunology, the Local Pharmaceutical Forum, the Royal Pharmaceutical Society and the Royal Society of Chemistry. A recent graduate from the School has been appointed to the accreditation panel of the General Pharmaceutical Council.

The School has research contracts with the National Health Service, the National Institute for Health Research and the Norwegian Government Science Office and studentships funded by Colchester General Hospital and non-UK agencies including the Saudi Arabian Government.

c. Strategy and plans

The School is building its impact strategy through further embedding of the enterprise and engagement agenda within the day-to-day life of our academic staff and our student body. Both our established faculty and newer appointments are encouraged to develop the translational aspects of their basic science. We have initiated an 'enterprise club' for the faculty to discuss potential impact

and mechanisms for their development and funding (such as proof of concept applications, presentations to industrial partners and invitations to potential collaborators to visit the School). Two of our recent appointments have first-hand knowledge of the creation of spinout companies, providing valuable advice to other faculty considering this aspect of commercialisation. Ganesan is the co-founder of *Karus Therapeutics*, a drug discovery spinout from the University of Southampton with several clinical candidate inhibitors of phosphatidylinositide 3-kinases (PI3Ks) and histone deacetylases (HDACs) for the treatment of cancer and inflammation. He is a co-inventor of Ned-19, a chemical probe of calcium signalling, sold by several companies and used worldwide. Since arriving at UEA, he has received Proof of Concept funding to develop inhibitors of the epigenetic enzyme lysine-specific demethylase 1 (LSD1) with a view to patenting and demonstrating efficacy in animal models. **Sherwood** is the co-founder of *WntResearch*, a publicly listed spinout from the University of Lund and she is co-inventor of the patent upon which the company was established. In 2013, the company initiated the Foxy-5 Phase I clinical trials for cancer chemotherapy with its lead program.

Several recent appointments have experience of working in the industrial sector. **Atasoylu** was employed at the US pharmaceutical company *Warner Chilcott* while **Howell** and **Waller** worked as analytical scientists at *GlaxoSmithKline* and *HFL Sports Science* respectively. **Khimyak** has extensive collaborations with industry, including the characterisation of pharmaceutical formulations with *Bristol-Myers Squibb*. **Baldelli-Bombelli** and Ganesan are UK partners in large EU consortia working with SMEs on oligonucleotide delivery and neglected diseases respectively. The emphasis on enterprise within the School, coupled with the translational experience of the new appointments, will be further facilitated by recent developments within the unique environment of the Norwich Research Park (NRP), a partnership between UEA, the Norfolk and Norwich Hospital and 4 biomedical research institutes. The NRP has recently received £26M from the UK Government to enhance its enterprise activities. The building of the £15M NRP Enterprise Centre, scheduled to open in 2014, will provide new opportunities for staff to develop the commercial aspects of their research activity. The availability of cross-faculty funding such as NRP studentships will encourage staff to establish interdisciplinary collaborations with a focus on applied research.

Our research strategy for the future is focused on therapeutic indications where the School has a critical mass of staff working on innovative approaches. In particular, the development of anticancer and anti-inflammatory agents benefits from the School's experience in using nucleic acids, peptides and natural products to target specific signalling pathways and epigenetic modifications. The *in vivo* delivery of such compounds will be facilitated by the School's research in drug delivery and pharmaceutical characterisation, including methods for targeted delivery to the eye and lung and nanoparticle formulations.

d. Relationship to case studies

Targeting inflammation by keeping Keap1 away demonstrates the development of chemical biology tools for the development of novel therapeutic agents. It is a good example of the interdisciplinary research culture within the School, as it links the groups of *medicinal chemistry* and *pharmaceutical cell biology*. Realising that this was early stage applied research, with the consequent lack of external funding opportunities, the School funded two PhD studentships, which resulted in a cell-penetrating peptide that blocks the interaction between the proteins Nrf2 and Keap1. The peptide is employed as a chemical biology tool in cellular models by pharmaceutical companies including *Novartis* and *AstraZeneca* and is now being marketed by *Tocris* and *Calbiochem*. University Proof of Concept funding is facilitating the further development of impact, through additional assay development for the protein-protein interaction and identification of small molecule inhibitors by high-throughput screening. *The fisheye lens: a journey from human health to aquaculture* is a striking demonstration of the way that pharmaceutical research can have an impact beyond healthcare. Expertise in human eye models for cataract and glaucoma led to collaborative research with the Norwegian National Institute of Nutrition and Seafood Research to identify the mechanisms that caused an increased incidence in cataract formation in farmed salmon. The research resulted in the supplementation of extra histidine to the fish feed. This demonstrates that the School's ethos of embedding impact into the mind-set of faculty, alongside the multidisciplinary nature of research in Pharmacy, means that our researchers can see how their work can have wider impact than the initial objectives.