The Problem
The administration of 5-fluorouracil (5-FU), folinic acid (FA) and oxaliplatin (FOLFOX regimen) represents “standard of care” first line treatment of metastatic colorectal cancer. However, physical incompatibilities between the three drugs prevent a “single solution” intravenous administration of FOLFOX – instead, each drug is separately administered through a central line. A range of adverse events are associated with FOLFOX treatment, including chemotherapy-induced peripheral neuropathy, phlebitis, catheter blockage and sepsis.

The Solution
Researchers at the University of Wollongong have developed a proprietary 5-FU based formulation that exhibits strong cancer-fighting properties but also offers drastically reduced treatment side effects. The formulation, known as Fluorodex, is an all-in-one, pH neutral solution of 5-FU and FA held in solution by a third API, beta-cyclodextrin.

Applications & Unique Competitive Position
Fluorodex offers the following competitive advantages in the treatment of metastatic colorectal cancer:
- Single administration of all active ingredients - saves clinician time and money
- Physiologically relevant pH - reducing common side effects such as venous inflammation, neuropathic pain and sepsis
- Similar if not improved efficacy compared to current treatments

Achievable Market
Approximately 36% of all colorectal cancer patients are treated with FOLFOX regimen. Combined, the FOLFOX market is estimated to be worth over $US2 billion annually. Oxaliplatin makes up the majority of this market, however faces strong downward price pressure due to it patent expiry in the US in 2013. The Fluorodex formulation offers a unique FOLFOX replacement opportunity with optimized component interaction, reduced adverse event profile and reduced cost of goods.

Business Model and Commercialisation Pathway
A start-up company, WarraPharm Pty Ltd, has been created to commercialise this technology. Ongoing business activity has been funded by a federal government (COMET) grant. The management team is organized and highly motivated and is on track for the first formulation to enter the clinic in 2010.

The Opportunity
The opportunity exists for a pharmaceutical company to co-develop, licence and market Fluorodex for cancer applications on commercial terms. We require funding to support the completion of a Phase 1 clinical trial program.

IP Position
National phase entry patent applications covering the composition and methods of use have been filed in six major jurisdictions (US, EP, CA, AU, CN and IN). A clear IPRP was issued in relation to the invention. Complete chain-of-title is secured.

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