

## New tech promises revenue boost for drug makers

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Australian drug delivery technology company Imugene has developed Linguet, a drug delivery technology platform, to improve efficacy and safety of existing prescriptions and over-the-counter medicines. Imugene emphasizes that pharmaceutical companies face threat of significant revenue loss from patent expiries, and need to reformulate their existing drugs to gain the market share back.

Through reformulation, a drug company alters characteristics of a brand-name drug just enough to qualify for a new patent under examination procedures of regulatory authorities, while keeping the characteristics of the drugs same as before. Dr Nick Ede, executive director, Imugene, explains how the new technology can be a big revenue booster to drug companies.

### What is Linguet drug delivery technology?

Imugene is working on a strategy to reformulate the existing medicines that are currently or soon to become off-patent. Linguet enables the active ingredient of drugs to be absorbed straight into the bloodstream when placed inside the cheek (via the buccal mucosa) or under the tongue (sublingual). The technology uses hydrophilic PEG (polyethylene glycol) molecules to enhance penetration across mucosal membranes. Besides, the technology can also control the amount and rate of drug to be delivered.

The technology was developed by Dr Richard Stenlake and Dr Alan Hewitt, from Sydney-based Stenlake Compounding. In August 2011, this technology was acquired by Conseгна and later sold to Imugene in August 2012.

**Why should a big pharmaceutical company be interested in integrating Linguet into their drug delivery mechanism?**

Imugene takes existing drugs, with known and established safety and efficacy profiles, and reformulates them into improved products. This helps avoid excess time, risk and cost associated with the traditional new drug discovery and development process.

It is of interest to the pharmaceutical companies, that are losing market share due to loss of patent, to regain the market position using an enhanced drug delivery technology. This would also protect the company against future generic competition and significantly extend the life-cycle management of its successful product. We view companies such as Novartis, GSK, Teva Pharmaceuticals as potential acquirers of Imugene's technology.

**Which drugs are currently being reformulated by Imugene and what are the costs involved?**

Imugene has invested \$2 million in the new technology, which has resulted in two patents and positive clinical results for Linguet formulations of naproxen (Naprogesic) and ibuprofen (Nurofen). Imugene, in collaboration and deal opportunities with big pharmaceutical companies, has selected three large initial targets in the areas of vitamin D deficiency, over-the-counter pain relief medication and Parkinson's Disease.

Also, Imugene is committing \$1.5 million to take forth its three chosen targets for regulatory approval in the UK and limited EU territories initially. Once approved in Europe, we plan to apply for regulatory approval in Australia followed by selected Asian countries.

**What is the regulatory landscape for getting approval for a drug delivery technology that reformulates an existing drug?**

Imugene's focus is on developing drugs for the EU market, which offers a more streamlined path for regulatory approval. EU approvals also provide a strong flow on effect for other regulatory markets including Australia and selected Asian countries. Our first target, a Linguet form of Vitamin D has now completed feasibility testing and formulation development. We are ready to file for regulatory approval in the UK and license the product to a third party in 2014. In addition, strengthening our IP in Asian markets, we have been allowed key Chinese and Japanese patents for Linguet.

**What are the challenges you see in enabling this technology for pharmaceutical companies?**

All drug development processes come with risks and challenges, be it technical, market driven or access to capital. Therefore, we undertake rigorous approach to mitigating risk and creating value for our technology. This includes establishing clinical efficacy, developing a 'go to market' strategy, clarifying regulatory pathways, and strengthening Linguet's IP.

**What difference can this drug delivery technology bring to the healthcare sector?**

Linguet offers multiple benefits to patients, governments and the healthcare sector. The technology allows drugs in the tablet form to be delivered straight into the blood stream via the buccal mucosa or through sublingual method, thus, accelerating the onset of action, and reducing the side effects of absorption in the stomach.

Patients can expect quicker onset of desired therapeutic activity, while being on low drug doses. The delivery method is painless, which improves patient convenience and compliance, and reduces the incidence of over dosing. In addition, oral medicine is the largest segment of pharmaceuticals yet there are few solutions for the dysphagia (swallowing problems) in the market. Linguet tablets provide a solution to this by being absorbed through the lining of the mouth.