PromarkerD Development Advances in China

Chinese Patent Granted

Highlights

- PILL and its Chinese partner Newsummit Biopharma have secured funding towards development of an In vitro Diagnostic (IVD) kit for PromarkerD in China.
- Chinese patent granted for PromarkerD as a predictive and diagnostic test for diabetic kidney disease.
- Initial tranche of funding under the PILL-NSB agreement will support the first stage of PromarkerD IVD kit manufacture.
- China is a key global market for PILL – WHO estimates 120m Chinese have diabetes and are at risk of kidney disease.

Life sciences company Proteomics International Laboratories Ltd (ASX: PIQ) (the Company, PILL) is pleased to announce significant advances towards commercialisation of PromarkerD as an In vitro Diagnostic (IVD) test in China, with the grant of a key patent and funds secured to initiate kit manufacture.

PromarkerD is a unique test that uses protein biomarkers in the blood to provide an early detection of the onset of diabetic kidney disease. Approximately one-third of adult diabetics have chronic kidney disease.

The development of an IVD kit for the PromarkerD technology, for use in clinical pathology laboratories, is pursuant to PILL’s agreement with Chinese biopharmaceutical company Newsummit Biopharma Co. (NSB) to commercialise and market PromarkerD in China, which was entered into in February 2015.

The staged agreement, with a $1.3 million budget, provides for manufacture of the unique antibody components, development and validation of an ELISA (Enzyme-linked immunosorbent assay) kit, and registration with the Chinese Federal Drug Administration. As part of the process significant groundwork has already been laid with engagement of Key Opinion Leaders and Hospitals, who will facilitate validation of the completed kit.

PILL now advises that NSB has secured the initial tranche of funding, being an amount of $100,000, to implement the first stage of kit manufacture. This development pathway will run in parallel to PILL’s own development activities announced 7 March 2016. This dual approach will maximise PILL’s opportunity to develop a commercial IVD test, whilst also producing kits tailored for their respective markets.

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On-going development of PromarkerD by NSB utilises PILL’s novel intellectual property and coincides with the grant of its Chinese patent, effective 11 May 2016. The patent provides protection for the use of PromarkerD as both a predictive (prognostic) and diagnostic test in China, and is valid until 20 September 2031.

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The patent is entitled, “Biomarkers Associated with Pre-diabetes, Diabetes and Diabetes Related Conditions (Chinese Patent no. ZL201180053583.9). The grant of a patent in China is a key milestone for PILL and paves the way for commercialisation of PromarkerD in this massive market.

Chinese Market Opportunity

China represents a key component of PILL’s global marketing strategy. World Health Organisation (WHO) figures indicate 120 million Chinese have diabetes and are at risk of kidney disease. The incidence of diabetes in China has increased significantly in recent years and continues to rise.

The funding was secured from Government sources after NSB was granted approval, in April, by the National Health and Family Planning Commission of the People’s Republic of China to undertake diabetes prevention and treatment projects, under the Chinese government’s ‘Prevention and Treatment of Major Diseases’ initiative.

This is significant because it acknowledges the growing incidence of diabetes and related conditions as a major health issue in China. It will provide further opportunities for PILL, under its agreement with NSB, to access funding and continue its development and commercialisation plans for PromarkerD in China.

Diabetes has been declared one of the Chinese Ministry of Health’s four pillars for investment, with hundreds-of-millions-of-dollars planned to be invested in prevention and treatment measures over the next few years.

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About Proteomics International Laboratories (PILL)
PILL is an ASX listed (ASX: PIQ) life science company focused on the area of proteomics – the industrial scale study of the structure and function of proteins. In the last few years, proteins have become the drug class of choice for the pharmaceutical industry because of their intimate role in biological systems. Thus proteomics technology is now playing a key role in understanding disease, from finding new diagnostic biomarkers to determining drug targets, and discovering new biopharmaceutical drugs.

PILL is recognised as a global leader in the field of proteomics. It received the world’s first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the art facilities at the Harry Perkins Institute of Medical Research in Perth, Western Australia. The Company’s business model uses its proprietary technology platform across three integrated areas, each massive growth markets:
1. **Diagnostics:** Biomarkers of disease and personalised medicine - focus on diabetic kidney disease.
   By 2020 the biomarkers market is estimated to double in size to $45.6 billion, and the personalised medicine market is forecast to be worth over $149 billion.

2. **Analytical services:** Specialist contract research fee-for-service model – focus on biosimilars QC.
   The global biosimilars market is expected to reach $6.2 billion by 2020, almost trebling from its 2015 level, as it seeks to replicate the multiple billion dollar blockbuster drugs that are coming off patent.

3. **Drug discovery:** Therapeutic peptide drug discovery - focus on painkillers and antibiotics.
   The global peptide therapeutics market is currently estimated to be worth $18 billion and is expected to increase at over 10% per year during 2016-2025.

In combination these areas offer, respectively, medium term products, near term cash flow, and blue sky potential by harnessing one complementary workflow centred on proteins and peptides.

Today, biopharmaceuticals comprise 20% of the pharma market, generating global revenues of $163 billion. Biopharma is growing at twice the rate of conventional pharma because biopharmaceuticals offer a better safety profile and an ability to treat previously untreatable conditions.