

## Proteomics International Laboratories Ltd

PIQ: ASX: A\$0.24

Recommendation: Buy

Price Target: A\$0.45



SA Capital Pty Ltd

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- Commercialisation in 2016 with first licensing deals
- Cash flow positive in 2017
- First profit forecast for 2018\*
- Significant profit forecast for 2019\*

### Capital Structure

Share Price	A\$0.24
Fully Paid Ordinary Shares	50.6M
Listed Options	12.6M
Fully-Paid Market Cap	A\$12.7M
Less: Cash (as at 30 June)	A\$0.6M
Add: Debt (as at 30 June)	A\$0.4M
Enterprise Value	A\$12.5M
R&D Tax Incentive	A\$0.6M

### Board & Management

Chairman	Mr Terry Sweet
Managing Director	Dr Richard Lipscombe
Non-Executive Director	Dr John Dunlop
Company Secretary	Ms Karen Logan
Research Manager	Dr Scott Bringans
Contract Services Manager	Ms Andreja Livk
Business Development	Mr Chuck Morrison

### Top Shareholders

Richard Lipscombe	16,141,281	31.91%
Xylo Pty Ltd	6,277,594	12.41%
John Dunlop	5,305,188	10.49%

### Share Performance



### Company Overview

- Established 2001
- Life Science Company
- Global leader and innovator in the field of **proteomics**
- Discovery and development of diagnostic assays
- Discovery of biopharmaceutical drugs
- Revenue generating company
- Strong management team
- World's first company to receive ISO 17025 laboratory accreditation for proteomics services
- Proven technology with established IP
- Operates from state-of-the art facilities at the Harry Perkins Institute of Medical Research in Perth

#### What is Proteomics?

- The large scale study of the structure and function of proteins

#### Growth markets

- Diagnostics market – personalised medicine market is forecast to be worth over \$149 billion
- The global biosimilars market is expected to reach \$6.2 billion by 2020
- The global peptide therapeutics market is currently estimated to be worth \$18 billion

### Financial Summary

Year end 30 June	2015A	2016A	2017E	2018E	2019E
Total Revenue (A\$m)	0.6	0.8	1.2	1.7	2.2
EBITDA (A\$m)	(1.1)	(1.3)	(0.3)	0.3	1.0

Above estimated earnings only attributed to analytical services business

\* Potential revenue from licensing technology not counted - ref .Page 2

**BUSINESS MODEL**

Proteomics International Laboratories Ltd (PILL) operates in three integrated areas unified by its proprietary proteomics-based technology platform: diagnostics, analytical services and drug discovery. This sustainable business model sees the Company use revenue generated from analytical services to fund pioneering research into next generation diagnostic assays and drug discovery.

**GLOSSARY**

Proteomics	Large-scale study of proteins
Biomarker	Protein fingerprints in the blood
Biosimilar	A copycat drug
ELISA test	Test using antibodies
In vitro	In test-tubes
Peptide	Small proteins
Therapeutic	Treatment, therapy or drug

The Company generates revenue from the analytical services division through contractual projects for protein analysis and biosimilar drug analysis. PILL works closely with university research centres, pharma companies and other Contract Research Organisations (CRO's). Revenue from analytical services is growing year-on-year at 33%, which funds R&D for biomarker development and drug discovery. R&D investment is critical for future growth, and through commercialisation PILL is forecast to be cash flow positive by 2017.

Biomarkers are used in diagnostic assays for the diagnostics and personalised medicine markets. Biomarker diagnostic assays are commercialised through partnerships with global diagnostic companies or directly through diagnostic laboratories. An example of this is the recently developed assay, PromarkerD, a predictive and diagnostic test for diabetic kidney disease. PILL has recently signed its first partnership with Omics Global Solutions, based in the US territory of Puerto Rico, for the rights to commercialise PromarkerD in the Dominican Republic. This partnership may also serve as an entry into the US market. Revenue just from this partnership is calculated as having a NPV of US\$1.5M.

Future biomarker discovery efforts will focus on other complications of diabetes such as heart degeneration and retinopathy (eye disease). New discovery programs are underway for biomarkers to diagnose endometriosis (inflammation of the female reproductive organs) and mesothelioma (asbestos-related lung cancer).

**\* FUTURE COMMERCIALISATION LICENSING TARGETS**

The Omics Global Solutions licensing agreement is a commercial template for future licensing. Dominican Republic has a population of 10.6 million and the licensing agreement is worth US\$1.5M. PILL is targeting the US/North America, Japan and Europe; each should be worth US\$50M.

An agreement with a Chinese diagnostic developer signed in 2015 should also start to bear fruit in the foreseeable future. Whilst timing on any of these potential company-making agreements is hard to predict, having “broken the ice” with Dominican Republic, we believe other companies will have increased interest and confidence.

The foregoing is targeted revenue for just the PromarkerD assay. New Promarker tests for other diseases have now commenced development.

SA Capital’s financial forecasts assume modest expansion of the analytical business area with future partnerships and licencing forecast to provide the company self-sufficiency. Company making agreements whilst difficult to forecast have set PILL on the path to significantly reward all stakeholders but in particular shareholders.

## STRATEGIC AREAS

### PromarkerD – commercialising a diagnostic test

PILL continues to focus on the commercialisation of PromarkerD, the world's first proteomics-derived predictive and diagnostic test for diabetic kidney disease. This unique test uses protein biomarkers in the blood to provide an early detection of the onset of diabetic kidney disease, a condition that affects approximately one-third of adult diabetics. The test was created by looking at proteins in the blood of people with and without the disease. The research started with just 30 individuals before the study was scaled up to involve more than 500 people, each of whom has been tested three times over four years.

The International Diabetes Foundation estimates that there are currently 382 million people living with diabetes worldwide and expect the number to rise to 592 million people, or one in 10 of the world's population, by 2035.

PILL is pursuing the adoption of PromarkerD through three complementary commercialisation pathways: a Laboratory Developed Test (LDT); standard clinical pathology in vitro Diagnostic Test (IVD); and Companion Diagnostic (CDx). Work has already begun on sourcing the components needed to build the in vitro diagnostic test kit, and discussions are underway with groups to develop the assay on their technology platforms.

In August 2016, PILL announced the first commercialisation deal for the PromarkerD assay. This agreement will see an exclusive licence granted to Omics Global Solutions and its sister company Macrotech Farmacéutica to distribute the diabetic kidney disease test in the Dominican Republic. A key facet of the deal is that the kits will be manufactured in the US territory of Puerto Rico and thus, can come under the umbrella of the US FDA guidelines. This first agreement therefore has the potential to act as a stepping-stone into the US market, and to pave the way for other global markets including China, India and Japan.

The company has also forged an agreement with Chinese biopharmaceutical company Newsummit Biopharma to commercialise PromarkerD. This \$1.3 million staged agreement with Newsummit provides for manufacture of the unique antibody components, development and validation of an ELISA kit and registration with the Chinese Federal Drug Administration. To date \$200,000 in funding has been secured towards the Chinese development pathway, which is running in parallel to PILL's own development activities. This dual approach maximises the opportunity to develop a commercial test while producing kits tailored for their respective markets.

### Promarker D patents

PILL has been granted patents for PromarkerD as a predictive and diagnostic test for diabetic kidney disease in the key markets of the US and China, and also in Singapore and Australia. These patents represent key milestones in the development and commercialisation pathway for PromarkerD.

The US patent was granted in October 2015 and gives PILL access to the world's largest health care market. This protein-based patent is particularly significant as there is an increasing level of stringency being applied to diagnostic applications – US Federal Courts and the Australian High Court have determined that DNA sequences can no longer be patented. PromarkerD patents in Australia and Singapore were granted in the same quarter as the US patent.

The Chinese patent became effective May 2016 and paves the way for commercialisation of PromarkerD in the massive Chinese market, where the World Health Organisation estimates 120 million people have diabetes and are at risk of kidney disease.

All patents are valid until September 2031. PILL is also seeking patent protection for PromarkerD in other major global markets including Europe and India.

## **OTHER DIAGNOSTICS**

PILL is currently expanding its diagnostics portfolio using the Promarker platform, and is investigating proteins associated with endometriosis, mesothelioma and other conditions. This is the first step in the development of simple blood tests for these diseases, which have the potential to replace current invasive diagnostic techniques.

Endometriosis occurs when the tissues that line the uterus spread and surround other organs. The condition causes chronic pain and infertility, and affects one in ten women in their reproductive years. On average, it takes 8.5 years for women to be diagnosed from their first symptoms. Currently the gold standard for detection is an invasive laparoscopy, where a camera is inserted into the pelvis through a small cut in the abdominal wall.

Mesothelioma is thought to kill 59,000 people annually according to the World Health Organisation. The average person is diagnosed with the asbestos-related cancer at age 74 and will survive for only one to two years after diagnosis.

Following careful vetting of opportunities PILL has secured access to clinical samples essential to search for biomarkers associated with these diseases. The endometriosis patients are from a private collection, while the mesothelioma study will be undertaken in collaboration with the University of Western Australia Medical School.

The Company continues to investigate potential biomarkers for Alzheimer's disease. Data analysis on the initial discovery phase is continuing and PILL is also exploring access to further clinical samples to extend the study.

PILL's technology can be used on any biological source, and the company has also recently mapped samples from the gastro-causing parasite Giardia to distinguish between infectious and non-infectious strains. This proof-of-concept study was conducted in collaboration with Murdoch University and on a fee-for-service basis with a leading US veterinary company. The next stage is to assess the commercial viability of the protein fingerprints discovered.

## **ANALYTICAL SERVICES**

PILL has seen strong traction in the analytical services stream, with a 33% increase in revenues across the past financial year. This growth rate continues a five-year average which exceeds 30% and was underpinned by new contracts to test biopharmaceutical drugs, including biologics which are the original protein drugs, and generic protein drugs or biosimilars.

PILL has one of the few global ISO 17025 laboratories accredited to accurately analyse the make-up of biosimilar drugs as being like-for-like with the brand name drugs they seek to replace. The sector is being driven by a desire to replicate the multi-billion dollar blockbuster biopharmaceutical drugs that are coming off patent, and the company has won a series of recent biosimilar testing contracts including for an allergic asthma drug in Europe, anti-cancer and multiple sclerosis drugs in India and a tissue repair drug in the Middle East.

## **DRUG DISCOVERY**

The company has restarted its innovative therapeutic drug discovery program targeting new analgesic or painkilling and antibiotic drug compounds. The program is testing between 50 and 100 animal venoms with PILL's proprietary proteomics-based technology platform, which is significantly faster and more-cost-effective than the traditional drug discovery process.

'Lead' compounds identified in the program are expected to undergo testing in Q4, 2016, and the best molecules will enter pre-clinical development on the path towards clinical testing and potential commercialisation. This drug discovery stream is a low cost activity but offers a major growth opportunity for PILL long term, with the peptide therapeutics market currently estimated to be worth \$18 billion.

## **BUSINESS DEVELOPMENT ACTIVITIES**

PILL has maintained a strong business development focus throughout the year and continues to promote its disruptive proteomics-based services in the world's largest health care markets.

### **Expansion in Indian market**

PILL has expanded its operations in the massive Indian biotechnology market, which is forecast to be worth US\$100 billion by 2025. The company conducted a trade visit to India in April 2016 to drive uptake of biosimilars analytics and biomarker services, and was delighted with the interest shown in its expanded, quality testing portfolio. The visit included meeting key decision makers in the biotech centres of Mumbai, Pune, Ahmedabad, Hyderabad and Bangalore, and a series of invitation only events in Mumbai, Hyderabad and Bangalore hosted in conjunction with the Australian Trade Commissioner.

India represents a rapidly growing global biotech hub, and PILL visited and reviewed product pipelines and testing requirements with over a dozen major biopharmaceutical companies. Fee-for service work has already started to flow from this marketing initiative. A full-time sales and marketing manager based in Delhi has also been appointed to develop sales on the subcontinent.

### **Asia Pacific and United States visits**

As part of its alliance with inVentiv Health, one of the world's largest contract research organisations (CRO), PILL conducted roadshows in the US and APAC in March and June 2016. Both series targeted key bio-analytical sector decision makers at invitation only events in Boston, San Francisco and San Diego, and Taipei, Seoul and Tokyo. PILL presented its PromarkerD and companion diagnostics (CDx) technology alongside its biosimilars/biologics testing services. The company received strong levels of interest and will continue to seek to expand these areas of its business.

## **EVENTS**

The company actively marketed its diagnostics and analytical services businesses at a number of targeted industry events over the year including the Australian Peptide Conference, the Australasian Life Sciences and Healthcare Showcase in Seoul, South Korea, the International Biologics and Biosimilars Conference in Baltimore, US, and the World Diabetes Congress in Vancouver, Canada.

### **WA Industry and Export Awards win**

PILL won the Health and Biotechnology Export category of the Western Australian 2015 Industry and Export Awards in October 2015. The award recognises outstanding international success in medical, healthcare, and biotechnology fields for products, technology, equipment or services, and was presented to PILL for the international success of the company's analytical services business. PILL was also a finalist at the 2015 Australian Export Awards and the 2015 Western Australian Innovator of the Year Awards.

### COMPETITIVE POSITIONING

PILL is unique in Australia as the only listed proteomics-based commercial facility, and so local peer comparison is not possible. PILL is also one of only a handful of laboratories worldwide with ISO accreditation to carry out proteomics analysis, and in fact was the first to achieve this.

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#### International Competitors are:

Proteome Sciences	AIM listed, UK based, Market Cap \$45M.
Caprion Proteomics	Bought by Venture Capital Group for est. \$30M Canada based.
Applied Proteomics	Private, raised \$50M. US based.
M-Scan	Bought by world's biggest testing company SGS for undisclosed sum – UK based.

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PILL concentrates its marketing efforts for analytical work in Asia, and particularly India, which has the world's second biggest pharmaceutical industry (after US).

SA Capital is strongly of the view that PILL is due a significant rerating on the ASX as it achieves fresh milestones through additional licencing and commercialisations from its current market capitalisation of around \$12 million.

## IMPORTANT INFORMATION

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SAC has an indirect equity interest in Proteomics International Laboratories Ltd. The analyst responsible for this research report certifies that all of the views expressed reflect his personal views about the securities and the issuer.

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