

Proteomics International Laboratories Ltd

PIQ: ASX: A\$0.24

Recommendation: Buy

Price Target: A\$0.45 retained



SA Capital Pty Ltd

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- Launch of its PromarkerD diagnostic test in February 2018
- Potential strong deal flow and cash flow from PromarkerD in 2018
- Cash flow neutral in 2018
- Significant profit forecast for 2019

CAPITAL STRUCTURE

| | |
|----------------------------|-------------------|
| Share Price | A\$0.24 |
| Fully Paid Ordinary Shares | 58,998,710 |
| Market Capitalisation | A\$14.2M (at 24c) |
| Listed Options* | 17.2M |
| Cash (as at 30 Sept) | A\$1.5M |
| Debt (as at 30 Sept) | A\$0.7M |
| Enterprise Value | A\$15.0M |

* Options exercisable at \$0.20c each on or before 31 March 2018 to raise A\$3.4M

BOARD OF DIRECTORS

| | |
|------------------------|----------------------|
| Chairman | Mr Terry Sweet |
| Managing Director | Dr Richard Lipscombe |
| Non-Executive Director | Dr John Dunlop |
| Non-Executive Director | Mr Roger Moore |
| Non-Executive Director | Mr Paul House |

TOP SHAREHOLDERS

| | |
|------------------------|-------|
| Richard Lipscombe | 27.5% |
| Dunlop/Randolph Res PL | 9.2% |
| XYLO PL | 9.0% |
| HSBC Nominees | 3.1% |
| Sparrow Holdings PL | 1.8% |

Share Performance



COMPANY OVERVIEW

- Specialist MedTech and Life Sciences company focused on the application of **proteomics** - the industrial scale study of the structure and functions of proteins
- Global leader in Predictive Diagnostics and Analytical Services
- Revenue generating - Established 2001
- Western Australia Exporter of the Year 2016
- World's most accredited protein testing laboratory
- Proven technology with established IP

HIGHLIGHTS

- PromarkerD - world leading predictive diagnostic test for diabetic kidney disease to launch in Q1 2018
- Launch likely to trigger more PromarkerD licensing deals and potential roll out in the massive US market
- New Analytical Services launched in fast growing clinical trials market - boost to future revenue streams
- Growing revenue from Analytical Services drives development of new Diagnostic tests
- Experienced Board and Management team recently strengthened by Paul House joining as a Non-Executive Director.

Financial Summary

| Year end 30 June | 2015A | 2016A | 2017A | 2018E | 2019E |
|----------------------|-------|-------|-------|-------|-------|
| Total Revenue (A\$M) | 0.6 | 0.8 | 1.1 | 1.7 | 2.2 |
| EBITDA (A\$M) | (1.1) | (1.3) | (1.5) | (0.5) | 1.0 |

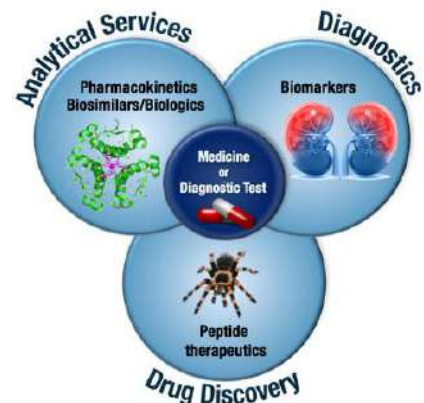
NB Does not include any PromarkerD Licencing revenue



BUSINESS MODEL

Proteomics International Laboratories Ltd (Proteomics International) is a medical technology company focused on **proteomics** – the industrial scale study of the structure and function of proteins.

The Company capitalises on this in three integrated business areas which are each massive growth markets: **diagnostics**, **analytical services** and **drug discovery**. The synergy arises through its proprietary technology platform, **Promarker™**, which can be applied to each area simultaneously. The first fully-developed diagnostic test is PromarkerD, specifically for diabetic kidney disease.



COMPETITIVE POSITIONING

Proteomics International's business model allows it to continue the commercialisation of PromarkerD while expanding its Analytical Services business with the aim to be cashflow neutral by the end of the 2017-18 financial year.

SA Capital is strongly of the view that Proteomics International is due a significant rerating on the ASX as it achieves fresh milestones (additional licencing and commercialisation) from its current market capitalisation of AUD\$14.2 million.

- World leading diagnostic test for diabetic kidney disease, PromarkerD launching in Q1 2018.
- Further licencing deals for PromarkerD likely to follow in its focus markets of US, Japan, Australia, China and Europe. Potential market size of 422 million people worldwide.
- Boost in revenue streams anticipated with its offering of expanded Analytical Services.
- New diagnostic tests in the development pipeline.
- Increasing interest in this sector-

Rhythm Bioscience: Medical diagnostics company with biomarker-based diagnostic test in early stage development for colorectal cancer. Successful IPO on 6th Dec 2017, raising A\$9M with a current market cap of A\$26M.

Vivopharm: Laboratory offering only preclinical pharmacology, toxicology and bioanalytical services acquired by Cancer Genetics (New Jersey, USA) for A\$15.3M.

FUTURE COMMERCIALISATION LICENSING TARGETS

The commercial launch for PromarkerD test is scheduled for February 2018. Proteomics International's first licensing agreement with Omics Global Solutions (Puerto Rico, USA) for PromarkerD as an In Vitro Diagnostic (IVD) test in the Dominican Republic is a commercial template for future licensing. The first commercial sale in this test market will trigger a milestone payment, then royalties on each test sold, as part of the exclusive licensing agreement which has a net present value of US\$1.5 million over its first nine years.

It is anticipated that this revenue stream will continue to grow as the IVD kit is commercialised in much larger markets. Proteomics International is targeting the US, Japan, China and Europe. Whilst timing on any of these potential company-making agreements is hard to predict, having "broken the ice" with the Caribbean launch, it is foreseeable that other companies will have increased interest and confidence. The Dominican Republic has approximately 505,000 adults with diabetes. This compares to a diabetes incidence of approximately 1

million in Australia, 29 million in the US, and 110 million in China, all markets in which Proteomics International has been granted patent protection.

Proteomics International is also in discussions with several US commercial certified laboratories (Clinical Laboratory Improvement Amendments CLIA service laboratories) for licensing of PromarkerD as a Laboratory Developed Test (LDT). This is a way to introduce the mass spectrometry assay for earlier commercialisation than would be expected for a fully developed IVD test. Commercialisation of an LDT in the US market is expected to be realised in 2018.

From any such licensing deal Proteomics International could receive upfront licence fees, milestone payments and subsequent minimum annual royalties.

| Example of deal | No. tests/ year | \$ at \$50 per test | 10% Royalty - Year 1 | 10% Royalty - Year 2 |
|----------------------|-----------------|---------------------|----------------------|----------------------|
| US Regional CLIA Lab | 100,000 | \$5 million | \$500,000 | \$500,000 |
| US National CLIA Lab | 1,500,000 | \$75 million | \$7,500,000 | \$7,500,000 |

This targeted revenue is for just the PromarkerD assay. The pipeline of new Promarker™ tests for other diseases is advancing.

PromarkerD – a world-leading test for diabetic kidney disease

- **Commercial launch of PromarkerD scheduled for Q1 2018**
- **PromarkerD identified as the world's leading test for diabetic kidney disease by independent global research firm Frost & Sullivan**
- **Key Opinion Leaders engaged as PromarkerD test results published in leading scientific journal Diabetes Care and presented at major US conference**
- **PromarkerD US and Europe patents expanded to cover all kidney disease**

Proteomics International continues to focus on the commercialisation of PromarkerD, the Company's revolutionary test that can diagnose and predict the onset of diabetic kidney disease better than any current measure.

A report by global research house Frost & Sullivan singled out Proteomics International as the world leader in diagnostics for diabetic kidney disease. The March 2017 report, titled "Biomarkers Enabling Diabetes and Obesity Management, says novel biomarker research "is likely to transform the future of obesity and diabetes management". It goes on to highlight PromarkerD, Proteomics International's novel test for diabetic kidney disease, noting its "high adoption potential". There is currently no available test for predicting the onset of diabetic kidney disease and Frost & Sullivan suggest Proteomics International is one of only two companies in the world developing such a test.

According to the World Health Organisation, globally 422 million adults have diabetes. One in three people (141 million people) suffering from diabetes already have chronic kidney disease, with dialysis treatment in the US costing US\$72,000 per person per year. Early detection with PromarkerD allows early intervention and may enable the onset of disease to be delayed or prevented altogether, with potentially dramatic savings for global healthcare systems.

As a new technological innovation, part of the journey towards successful commercialisation of PromarkerD is changing the accepted standard of care. Key Opinion Leaders are key in influencing the adoption of the new test. Accordingly, Proteomics International's strategy is to provide strong scientific validation of the test.

In August 2017, clinical study results were published in *Diabetes Care*, one of the top two diabetes journals globally. The publication provides an important verification of the PromarkerD test. The independent review and credibility awarded by this publication builds on the February 2017 foundation publication of the PromarkerD technology, and the presentation of the latest clinical results to the American Diabetes Association (San Diego) in June 2017.

This increased visibility of PromarkerD within the Diabetes community appears to have led a significant increase in discussions with potential partners in US, Mexico, Japan, Australia, China and Europe. The Company continues to pursue the commercialisation of PromarkerD as specialist laboratory testing (LDT) and standard clinical pathology test (IVD). The LDT permits fast adoption of a new test in advanced markets, whereas the IVD will follow a traditional regulatory process. The use of dual technology platforms enables the roll out of the test tailored to respective markets.

Another route to market for PromarkerD is as a companion diagnostic test (CDx), whereby it is used to monitor patients during clinical trials to measure whether drugs are having a positive effect. Currently there are 21 drugs in clinical trials for diabetic kidney disease. According to the FDA a CDx provides information that is essential for the safe and effective use of a corresponding drug.

Separate licences to the PromarkerD technology would be granted for each route to market, each can attract upfront fees, milestone payments (e.g. at first sale) and royalties per test. Deal size is normally dependent upon the size of the market and whether a deal is exclusive.

| PromarkerD Licensing Milestones | 2017-18 | | | |
|------------------------------------------|---------|---------|---------|---------|
| | Jul-Sep | Oct-Dec | Jan-Mar | Apr-Jun |
| First licensing deal/partnership for LDT | | | ■ | |
| First licensing deal/partnership for CDx | | ■ | | |
| Second licensing deal for IVD | | | ■ | |

Proteomics International signed its first IVD commercialisation deal with Omics Global Solution for the Dominican Republic. A key facet of the deal is that the diagnostic kits will be manufactured in the US territory of Puerto Rico, a major manufacturing hub for the US mainland, and therefore has the potential to act as a stepping-stone into the US market. This could pave the way for other global markets including China, Japan and Europe. The first commercial sale of the kit is targeted for the first quarter of 2018. The slight delay from the initial timeframe (end of 2017) was due to production time lost as a result of Hurricane Maria in Puerto Rico.

A staged agreement between Proteomics International and Chinese biopharmaceutical company, Newsummit Biopharma continues to provide for manufacturing and validation of PromarkerD in China.

Promarker D patents

The commercialisation of PromarkerD is underpinned by solid intellectual property protection. The Company's patents for PromarkerD as a diagnostic test for diabetic kidney disease now have been granted in the US, Australia, Russia, Singapore and China, covering a potential market size of 153 million adult diabetics (patent expiry 2031). Patents are pending in Brazil, Canada, Indonesia, India, Japan and Europe, which if granted will cover an additional 151 million diabetics. In total this represents 304 million of the world's estimated 422 million diabetic population.

The patent protection has been further extended to any kidney disease in US, Europe and Australia. In the US alone, the expansion of the US PromarkerD patent to cover all kidney disease represents a potential doubling in size of the addressable market for the test. Kidney disease is the ninth leading cause of death in the US, accounting for 48,000 deaths a year and related healthcare spending in excess of US\$50 billion annually. Whilst further research is required to prove the effectiveness of PromarkerD for all kidney disease.

ANALYTICAL SERVICES

- **New analytical service launched for pharmacokinetic testing in pre-clinical and clinical trials**
- **Largest analytics contract to date (worth A\$200,000) was signed**
- **Proteomics International extended its accreditation and sits as the world’s most accredited protein testing laboratory**
- **Proteomics International named WA Exporter of the Year in 2016**

Proteomics International uses its specialist know-how and proprietary Promarker™ platform technology to test and validate the protein or molecular composition of clients' samples.

Proteomics International was the first facility in the world to receive ISO 17025 accreditation for proteomics services in 2009. ISO 17025 is a worldwide formal recognition of a laboratory’s competence and technical expertise. In May 2017, the Company was awarded with ISO 17025 Research & Development certification, which includes compliance with the OECD Principles of Good Laboratory Practice (GLP). This new certification solidifies Proteomics International's position as world’s most accredited protein testing laboratory.

A major market for the Company's services is the testing of biopharmaceutical drugs (generic protein drugs or biosimilars). In July 2017, Proteomics International won a major contract in a new biosimilars area, entering into a long-term partnership with Dutch/Australian company BiosanaPharma on a treatment for allergic asthma. The Company will conduct characterisation analysis of BiosanaPharma’s product over a period of 12 months, including what is known as long-term and accelerated stability testing. The agreement marks Proteomics International’s largest biosimilars contract to date, and is worth in excess of A\$200,000.

Proteomics International has launched a new service with the introduction of pharmacokinetic testing targeting pre-clinical and clinical trials. The Company signed a partnership agreement with Linear Clinical Research (Linear), in which Proteomics International can conduct analytical testing for clinical trials performed at Linear. The Company tests the patient’s response to drugs (pharmacokinetic testing), analysing blood samples to determine how long a drug stays in a person’s system. It is one of only three companies to provide this specialist testing in Australia. The launch of the new pharmacokinetic services has the potential to double the Company’s fee-for-service revenue.

The Company also has an on-going analytical contract with global a2 Milk Company. Proteomics International provides specialist quality control testing for a2 Milk branded fresh milk products.

Proteomics International’s outstanding international success was recognised at the 2016 Western Australian Industry and Export Awards, with the Company taking out the WA Exporter of the Year award. Proteomics International beat Fortescue Metals Group and shipbuilding giant Austal to take out the top prize, and also won the Health and Biotechnology category for the second year running.

BUSINESS DEVELOPMENT ACTIVITIES

Proteomics International announced last month the appointment of a new Board member along with engagement of two industry experts to promote business expansion and PromarkerD commercialisation.

| | | |
|----------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mr Paul House | Proteomics International <i>Non-Executive Director</i> | Brings a wealth of commercial and management experience, having had senior roles with SGS, the world’s largest laboratory and testing group. Mr House was most recently M.D. SGS India, with over 4000 employees, and an in depth involvement with the massive Indian pharmaceutical industry. |
|----------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



| | | |
|------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------|
| Mr Eric Button | NeoMark Ventures, USA <i>Consultant</i> | Specialises in the development and commercialisation of emerging diagnostic technologies. |
| Dr Masafumi Yoshimoto | PhamaBDL, Japan <i>Consultant</i> | Experience in business development and licensing opportunities. |

The appointments of these world class executives add strength to the Company's management team and deepen its ability to target its key analytical markets of the US, Japan and India. This extends the Company's previous international strategy of appointing a regional sales manager in India for the local market expansion.

OTHER DIAGNOSTIC TESTS

To extend its product pipeline, Proteomics International is continuing to invest in research and development of other potential Promarker™ diagnostic tests in areas of unmet medical needs. Just this month the Company joined forces with the Busselton Population Medical Research Institute to target improved diagnosis and treatment of lung conditions such as asthma and chronic obstructive pulmonary disease (COPD).

Proteomics International has on-going programs for endometriosis and mesothelioma. which are expected to deliver results in 2018. These build upon the Promarker™ technology platform which produced PromarkerD. The Company is now in a strong position to apply Promarker™ to targeting other chronic diseases with massive market potential.

| | | |
|----------------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Endometriosis | Reproductive condition | Affects 1in 10 women in their reproductive years; Costs \$12,000 per year per person; Incidence and health burden are comparable with diabetes. |
| Mesothelioma | Asbestos related cancer | Kills 59,000 people annually; Cost of treatment, compensation and settlement upwards of A\$667,000 per person. |
| Lung disease | Asthma | Affects 1 in 9 people in Australia; Cost of the condition in Australia alone in 2015 was A\$27.9 billion |
| Lung disease | COPD | 5-15% of adults in industrialised countries have COPD; Estimated cost to the US health care system exceeds \$30 billion |

Proteomics International's Promarker™ platform can be used on any biological source, and the Company has been mapping samples from the gastro-causing parasite Giardia in collaboration with Murdoch University and a leading US veterinary company. A licence agreement is already in place to ensure Proteomics International receives a royalty stream from the sale of any test developed from this research.

DRUG DISCOVERY

Whilst Proteomics International focused on the commercialisation of PromarkerD and the provision of analytical services, the Company's drug discovery programme has been put on-hold pending full commercialisation of PromarkerD.

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Analyst Certification

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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