Proteomics International
LABORATORIES LTD

**ASX Release**
**18 July 2022**

**ASX code: PIQ**

# Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased release a copy of its latest investor presentation updated for recent developments in the Promarker diagnostics pipeline along with the Company's key milestones for FY23.

Authorised by Dr Richard Lipscombe (Managing Director) and Mr Neville Gardiner (Non-Executive Chairman) on behalf of the Board of PIQ.

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# Proteomics International
LABORATORIES LTD

## *Investor Presentation*

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**July 2022**

**Dr. Richard Lipscombe**
Managing Director

# Disclaimer

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# Proteomics International Laboratories Ltd

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## A medical technology company at the forefront of precision medicine and predictive diagnostics

### Diagnostics

**PromarkerD**

- Predictive test for early identification of diabetic kidney disease (DKD)
- Cost-effective, easy to use, patented technology

Strong pipeline of novel tests in development – Endometriosis, Asthma & COPD, Oesophageal cancer, Gastro, Diabetic retinopathy, Oxidative Stress

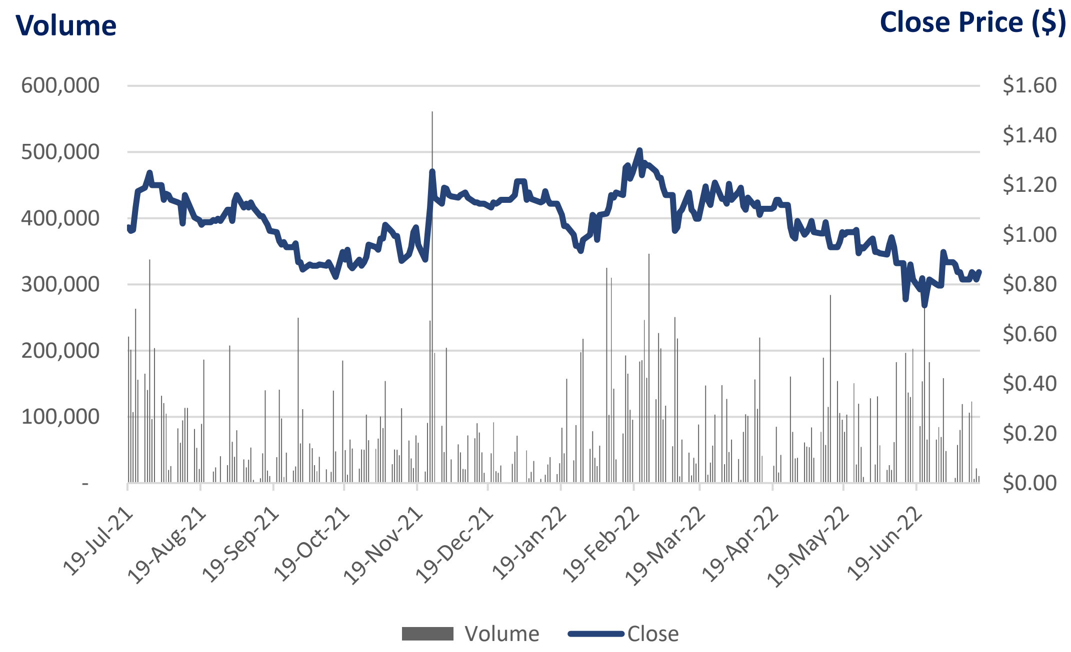
### Bioanalytical Services

- Growing demand from industry for specialised analytics
  - Thriving sectors of pharmacokinetic (PK) testing and biosimilars
- State-of-the-art capabilities with >$4m invested in cutting-edge facility
- Revenue partially offsets the cash burn from R&D and product development

### Financial & Corporate

- Senior management team expanded (Jun 21) + Board renewal (Nov 21)
- R&D tax incentive rebate of ~A$1.5 million to be received in Q4 CY22
- $0.4m for manufacturing - Medical Research Future Fund initiative (May 22)
- Implementing expansion strategies to accelerate growth

| Corporate Snapshot – 16/07/2022 | |
|---|---|
| ASX code | PIQ |
| Share Price | A$0.85 |
| Shares on issue (+8.4m options) | 106m |
| Market Capitalisation | A$90m |
| Cash (31 March 2022 + ~$1.5m R&D to be received Q4 CY22) | A$3.3m |
| Revenue & other income – FY21 | A$3.0m |
| Net cash burn – FY21 | A$2.9m |
| Directors Shareholding | 19.6% |



# Board of Directors

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**Neville Gardiner** BBus (Accounting and Business Law) (Curtin), CA, MAICD, Non-Executive Chair

Seasoned finance professional with over 30 years' experience providing corporate advice to Boards of public and private companies. He was Co-Founder and MD of Torridon Partners, an independent corporate advisory firm, which was acquired by Deloitte in 2016, where he became Partner in their M&A Advisory team.

**Dr Richard Lipscombe** PhD (London), MA (Oxon), Co-Founder & Managing Director

Led the Company from foundation through listing in 2015 to today. 30 years biotechnology experience in R&D and product commercialisation in academic and commercial entities. Technical expertise in chemistry, immunology, biomarker discovery & clinical proteomics.

**Roger Moore** R (Denmark), BPharm (U.Syd), Non-Executive Director

International pharmaceutical industry experience spanning 40 years, including almost 30 years as President of Novo Nordisk Japan. From 2000, he was appointed Novo Nordisk's Senior Vice President, Japan & Oceania Region. He has also served as a member of the Senior Management Board, Novo Nordisk A/S.

**Paul House** GAICD, BCommerce (UWA), Non-Executive Director

Over 25 years with multi-national corporations, CEO of Imdex (ASX:IMD), prior role as MD of SGS India for 8 years. Previously held CFO and COO roles, and was Senior Manager at a leading global management consultancy firm.

**Dr Robyn Elliott** PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

Proven track record in product development, clinical trials, regulatory affairs, audits, quality management, project management and operational strategy. Dr Elliott is Executive Director, Strategic Fractionation Program Delivery at CSL Behring, a subsidiary of CSL Limited. She is also a non-executive director of PolyNovo Limited (ASX:PNV).

# Promarker – Platform Technology

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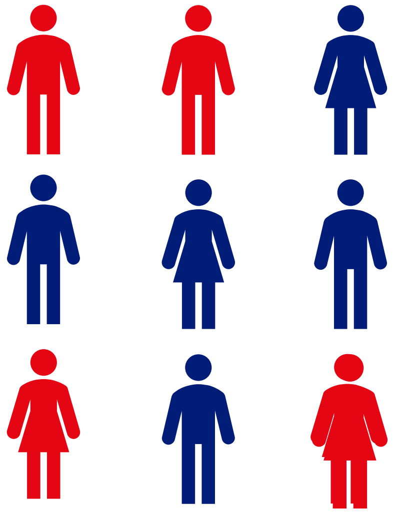
Promarker™ is a platform technology that can identify unique protein biomarkers 'fingerprints'



The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

Promarker D

WE'RE CHANGING LIVES

*A new blood test for predicting diabetic kidney disease*

# Problem & Solution

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## The Problem

- **537 millions diabetics globally**
- **1-in-3 diabetic** adults have chronic kidney disease
- **Kidney disease is a silent killer** - kidney function can **fall below 15-20% with no symptoms**
- Damage to kidneys is **irreversible**, therefore **early detection** is paramount
- Diabetic kidney disease leads to renal failure which requires **dialysis (US$72,000 p.a.) or kidney transplant**
- Total cost of diabetic kidney disease = **US$130 Bn** per year in USA alone

**Roadblock**

### Current standard-of-care diagnostics

- Existing tests (known as eGFR and ACR) can only detect chronic kidney disease once it is already present
- Current standard-of-care tests cannot **predict** the onset of diabetic kidney disease
- **If unchecked, patients ultimately require dialysis and/or a kidney transplant**

Diseased Kidney

**Solution**

### PromarkerD

- PromarkerD can **predict** the onset of disease **before** clinical symptoms appear (up to four years prior)
- **Doctors can then prescribe an early therapeutic treatment to slow or stop the onset of disease**
- Kidneys remain healthier for longer, **saving healthcare systems billions of dollars** and **improving quality of life** for patients

Healthy Kidney

International Diabetes Federation 2021
US Renal Data System 2020

# PromarkerD is Revenue Ready

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## The PromarkerD predictive test is poised to roll-out in markets globally

| | | |
|---|---|---|
| **Enormous Market** | ✓ | 537m adults have diabetes globally: 1-in-3 currently have diabetic kidney disease (DKD) |
| **High Statistical Performance** | ✓ | Peer reviewed publications – Clinical & analytical validity proven (Sensitivity 86%); PromarkerD significantly outperforms current standard of care |
| **Big Pharma Collaboration** | ✓ | janssen (J&J) – global multi-centre clinical study - assessing PromarkerD vs treatment options |
| **Therapeutic Treatments Available** | ✓ | SGLT2-inhibitor class drug (canagliflozin) improves PromarkerD risk scores – potential as Complementary Diagnostic (CDx) [drug class already used for type 2 diabetes & now approved as new treatment for DKD] |
| **Simple Technology Platform** - PromarkerD Immunoassay | ✓ | Clinical pathology laboratories can easily introduce the PromarkerD immunoassay as an IVD kit or LDT |
| **Regulatory Approvals** | ✓ | CE Mark (Europe) registration received for the PromarkerD Immunoassay; Secured ISO 13485 certification for the manufacture of medical devices |
| **Manufacturing scale-up** | ✓ | Technology transfer completed to ISO 13485 certified kit & assay manufacture |
| **Reimbursement** | | Identified pathway to obtain a unique reimbursement code & payment coverage in the USA; engaged with NHS (UK) and MSAC (Australia): Economic Health Benefit & Clinical Utility demonstrated |
| **Regulatory Approvals - ongoing** | | Engaging with partners and national regulators [US sales to utilise the Lab Developed Test (LDT) pathway with CLIA laboratories, prior to FDA approval] |
| **Generate Sales Revenue** | | First distribution agreements for PromarkerD immunoassay signed – initial sales pending |

# PromarkerD – Simple Integration & Utilisation

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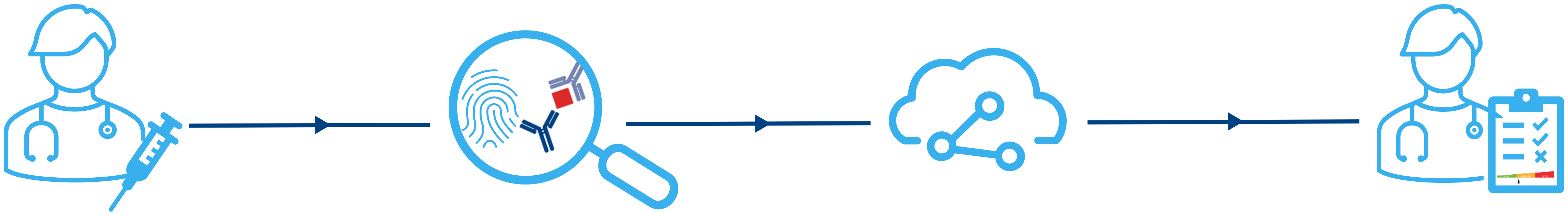

| **Blood sample drawn** | **Biomarkers analysed** | **Results analysed by PromarkerD Hub software** | **Results and intervention plan delivered** |
|---|---|---|---|
| Sample is drawn at clinic or pathology laboratory | Laboratory uses a standard technology platform<br><br>Advanced rapid immunoassay measures three plasma proteins<br><br>*combined with*<br>three simple clinical factors (age, cholesterol, eGFR) | Cloud based algorithm, the "PromarkerD Hub" calculates the patient's kidney disease risk score<br><br>Employs a traffic light system for optimal performance, classifies patients as:<br>▪ low risk<br>▪ moderate risk<br>▪ high risk | Clinician delivers results to patient<br><br>Depending on results, intervention may include:<br>• change of lifestyle; and/or<br>• therapeutic drugs |

# PromarkerD – Results & Intervention

## How PromarkerD™ results are delivered


**Prognostic** **16%** indicates a **moderate** risk of decline in kidney function*

| Risk Score | Intervention | | Testing Regimen |
|---|---|---|---|
| Low Risk | • Standard diabetes management | | Test Annually |
| Moderate Risk | • More frequent monitoring<br>• Optimisation of lifestyle<br>• Review of glycemic targets and management | • Review non-glycemic risk factors<br>• Avoidance of potentially nephrotoxic drugs | Test every 6 months |
| High Risk | • Very close monitoring<br>• Intensive management strategies based on those for 'Moderate risk' above<br>• Utilisation of therapeutic drugs | | Test every 3 months |

*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m$^2$) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m$^2$, then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

# PromarkerD in the Clinic

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## PromarkerD significantly enhances diabetic kidney disease diagnosis and management

**Peer reviewed**

PromarkerD tested on **over 5,000 patients** in 4-year clinical studies

**High Accuracy**

PromarkerD **predicted 86%** of otherwise healthy diabetics who went on to develop chronic kidney disease (‘incident DKD’) within 4 yrs [Diabetes Care (2017), J Diabetes Complications (2019)]

**International validation**

Janssen (J&J) collaboration stage 1 – global clinical study - PromarkerD predicted ‘incident DKD’ in the completed CANVAS clinical trial; high-risk patients **13.5 times more likely** than low-risk to develop DKD (P = $1.3x10^{-104}$) [J Clinical Medicine (2020)]

**New DKD treatment options identified**

Janssen collaboration stage 2 – assessed the drug treatment effect of canagliflozin versus placebo on PromarkerD risk scores in the completed CANVAS 4 year clinical trial:

***Aim***: Do ‘at-risk’ patients continue to decline, or stabilize, or recover?

***Results:*** Patients predicted at baseline by PromarkerD to be **high-risk** for developing DKD -

- Treated **with canagliflozin** had **significantly lower scores** at Year 3 (Δ score: -5.6%; p<0.001)
- Patients **on placebo remained high** (Δ score: 3.2%; p=0.17) (Time*TRT p=0.002) [ADC (Aug 2021)]

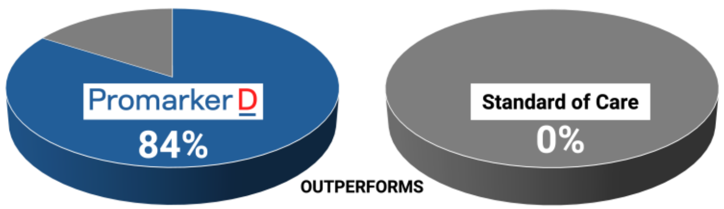
***Conclusion***: PromarkerD can identify ‘at-risk’ patients who are asymptomatic for DKD, with canagliflozin offering a potential treatment that can improve their renal risk profile

**Outperforms Standard of Care**

PromarkerD compared to standard of care tests (eGFR and ACR) for predicting DKD.

Community based study of type 2 diabetes patients (N=857);

Patients tested for existing DKD at baseline: 497 had normal kidney function, but of these 9% (N=45) developed ‘incident DKD’ in the next 4 years – **all were missed by standard of care tests** whilst PromarkerD identified 84% (N=38) of these [ASN (Nov 2021)]



# PromarkerD Market Opportunity

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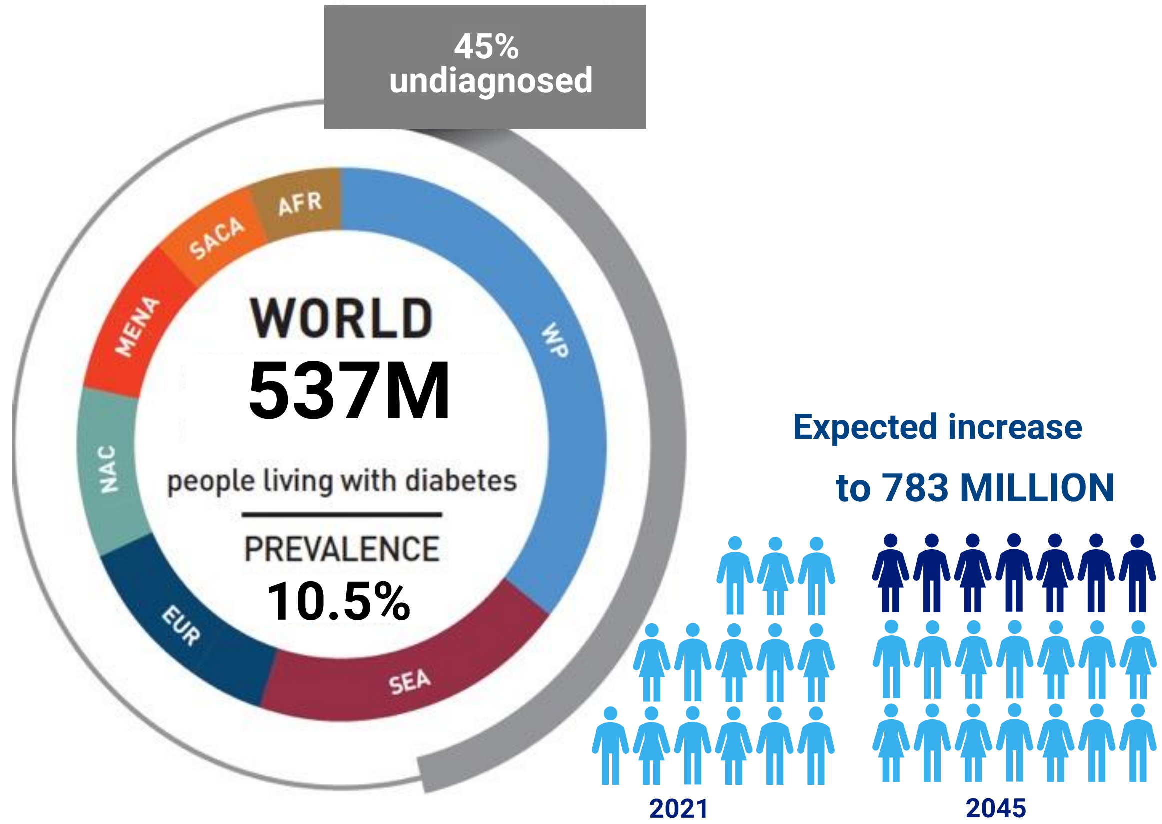
## Diabetes incidence and Patent portfolio

| Country | Patent/Application No | Patent Status | No. Diabetics[1] |
|---|---|---|---|
| **Australia** | 2011305050 | Granted | 1,491,800 |
| **Brazil** | BR112013006740 | Granted | 15,733,600 |
| **Canada** | 2811654 | Granted | 2,974,000 |
| **China** | ZL201180053583.9 | Granted | 140,869,600 |
| **Europe**[2,3] | 3151012 | Granted | 61,425,100 |
| **Hong Kong** | 18115912.3 | Pending | 686,000 |
| **India** | 3012/DELNP/2013 | Granted | 74,194,700 |
| **Indonesia** | W00 2013 01585 | Granted | 19,465,100 |
| **Japan** | 2013-528474 | Granted | 11,005,000 |
| **Russia** | 2596486 | Granted | 7,392,100 |
| **Singapore** | 188527 | Granted | 711,800 |
| **USA**[2,4] | US 9,146,243 | Granted | 32,215,300 |
| | | | **~340 million Total** |

1. International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
2. Australia, Europe, USA patent family also covers use of the test for **any form of kidney disease** (NB further studies are required to prove efficacy of PromarkerD for applications beyond DKD)
3. Covers France, Germany, Italy, Spain, Turkey and the United Kingdom, which cumulatively have 32.8m adults with diabetes
4. USA patent further extended to cover **method for identifying drugs for abnormal kidney function** using one of the PromarkerD biomarkers (CD5L)




## Market assumptions

- Patent family & Trademark covers 387m diabetics[1]
- **Test is performed once per year per patient on average**
- **Test price of US$150** [based on stakeholder engagement responses in a market access study]
- **Standard industry royalty rates range from 5-15%**

# PromarkerD – Route To Market

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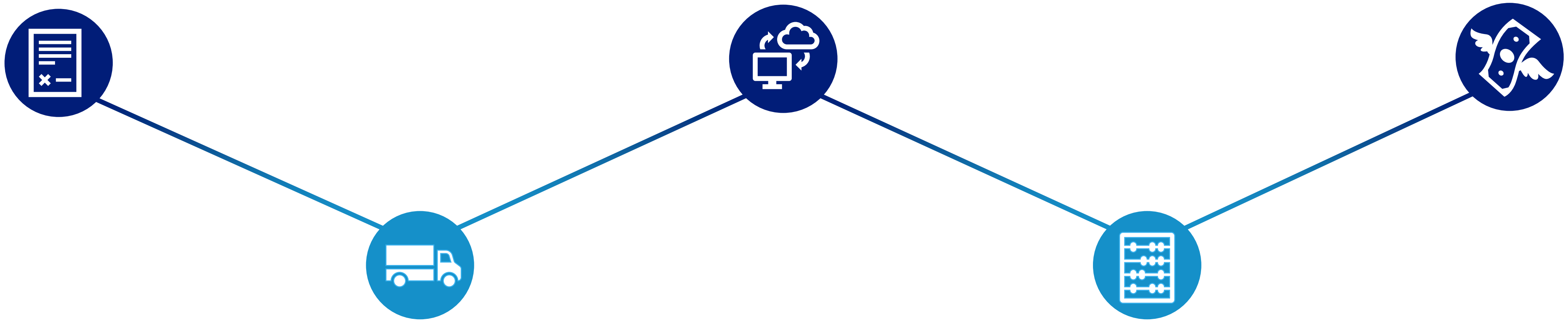


## Completed Licensing Transactions

### Great Britain

- Licence with Apacor Ltd for immunoassay test
- 4.8m type 2 diabetics (7%)
- Test registered with Medicines & Healthcare products Regulatory Agency

APACOR

### Italy

- Licence with Medical Horizons SRL for immunoassay test
- 3.7m type 2 diabetics (8%)
- Test registered with Italian Ministry of Health

### Israel

- Licence with Zotal Ltd for immunoassay test
- 0.6m type 2 diabetics (12%)
- Product registration on-hold pending ISO 13485 manufacturing

## Targeted Licensing Transactions

### United States

- Discussions ongoing with national/global US companies

### RoW

- Actively targeting potential partners in key global jurisdictions

# Diagnostics Pipeline

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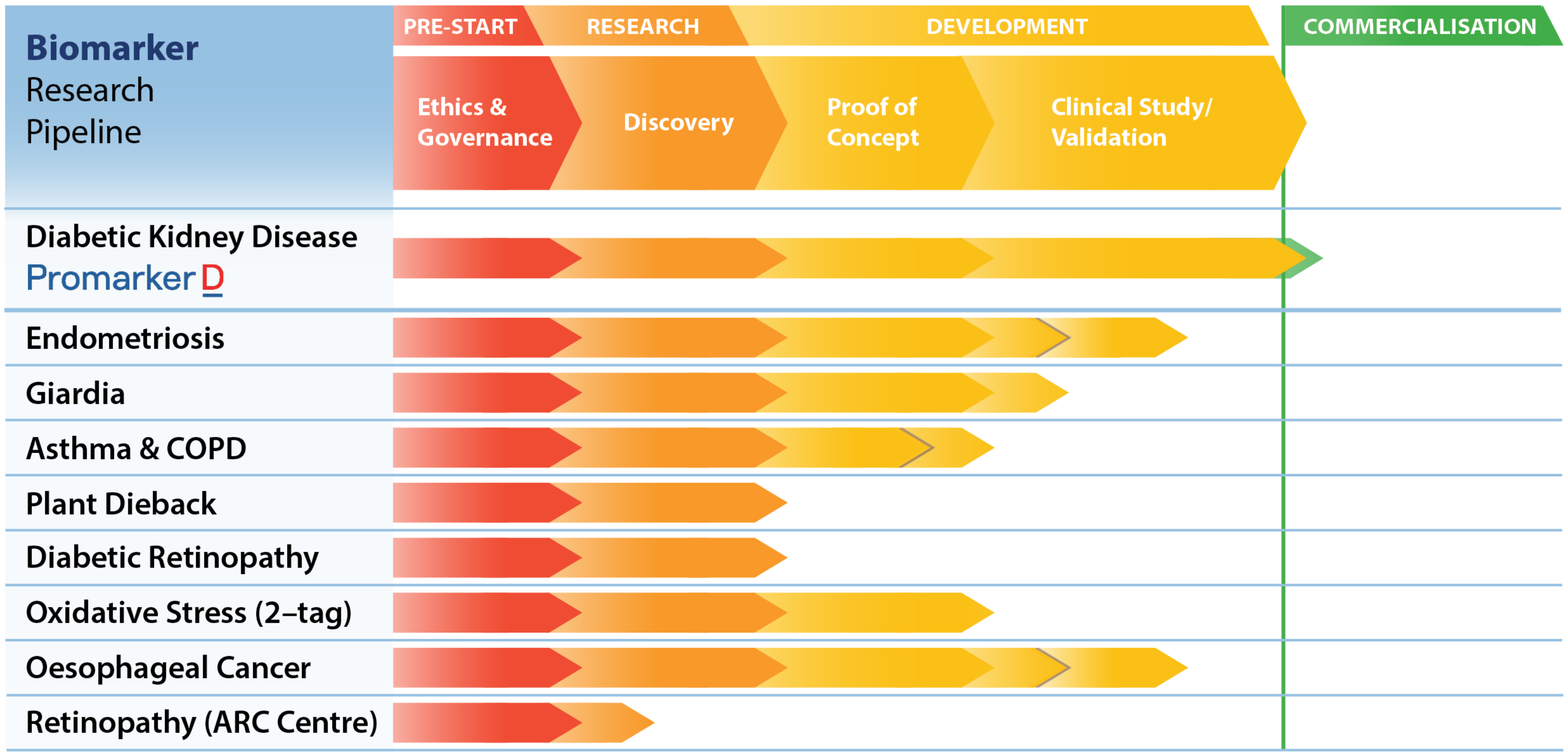
### The Promarker™ Research Pipeline & Timeline

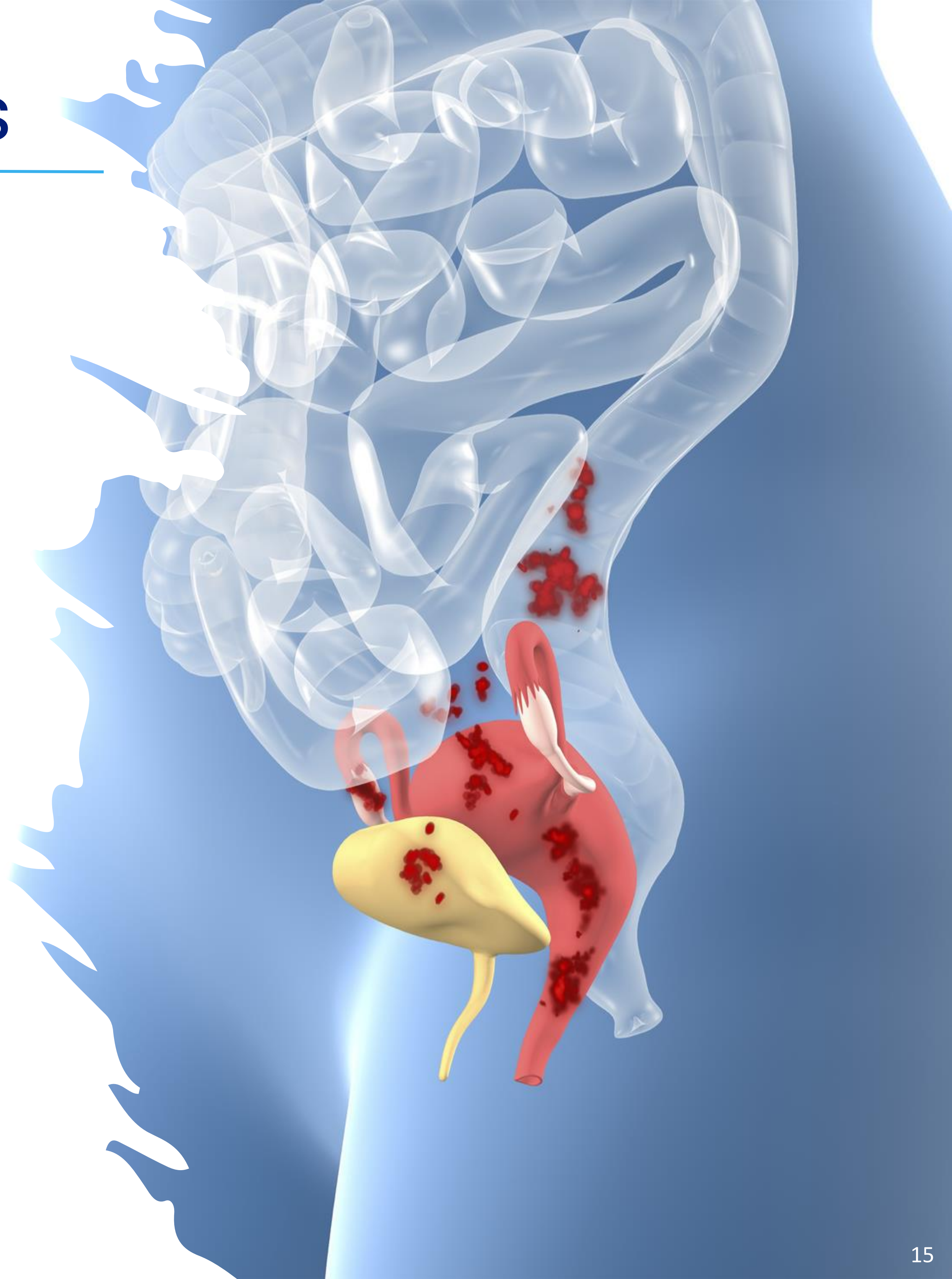

## Further Global Potential in New Markets

- Employs the Promarker™ technology platform to develop novel intellectual property
- Targeting new diagnostic tests in areas of significant unmet need
- Enormous markets and revenue potential

**DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE**



# In Development: Endometriosis



## What is Endometriosis?

- A debilitating condition in which tissue that normally lines the uterus grows outside the uterus (on the ovaries, fallopian tubes or the intestines)
- The most common symptoms are chronic pain and menstrual irregularities
- Diagnosis typically takes 7-12 years due to the lack of a diagnostic tool beyond invasive surgery = **Significant unmet medical need**
- **Affects 1 in 9 women and costs Australia over AU$10 billion a year – Global opportunity significantly higher**

## Promarker$^{TM}$ for Endometriosis

- **Clinical validation study identified panel of proteins as statistically significant biomarkers for endometriosis**
- Collaboration with Royal Women's Hospital and University of Melbourne analysed 857 samples
- Results confirm proof of concept study performed on 54 women; Patent filed for invention
- **Statistical modelling to assess accuracy of test ongoing – initial results to be presented at Fertility Society ANZ, 30 July**
- Biomarkers identified via the Promarker™ platform offer potential world-first blood test for endometriosis

www.endometriosisaustralia.org / www.clinicalomics.com

# Timeline & Milestones

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## 2021 Achievements

***23 April 2021***
Proteomics International receives ISO 13485 certification for medical device manufacture

***29 April 2021***
US FDA 513(g) application submitted

***13 May 2021***
Study demonstrates major economic health benefit of PromarkerD

***18 May 2021***
Major analytical services contract for PK testing

***10 June 2021***
Senior management team expanded: CCO & CFO appointed

***25 June 2021***
Health Economics presented at American Diabetes Association

***16 July 2021***
Successful results from Janssen Stage 2 study: *Canagliflozin lowers PromarkerD risk scores*

***22 July 2021***
Abcam (UK) engaged to produce specialist reagents for PromarkerD immunoassay

***4 August 2021***
Partnership with Royal Women's Hospital & Univ. Melbourne targets endometriosis clinical validation study

***12 August 2021***
Biotem (France) engaged for ISO 13485 manufacture of PromarkerD immunoassay Kit

***18 October 2021***
Clinical Utility Study shows PromarkerD significantly impacts clinical management decisions

***5 Nov 2021***
Results show PromarkerD significantly outperforms standard of care tests

***16 Nov 2021***
Board strengthened

***23 Nov 2021***
Distribution agreement for PromarkerD immunoassay – Britain

***24 Nov 2021***
FDA advises De Novo pathway for PromarkerD

## 2022 Targets & Achievements

***4 Feb 2022***
Identified & validated biomarker panel for Oesoph. cancer (OC)

***7 Feb 2022***
Asthma/COPD unique biomarkers identified

***12 April 2022***
PromarkerD Clinical Advisory Board / KOLs appointed

***2 Jun 2022***
TGA regulatory submission

***16 Jun 2022***
Manufacturing transfer to ISO 13485 completed

***21 Jun 2022***
Exclusive licence to OC biomarkers secured

***30 Jun 2022***
Clinical validation study confirms biomarkers for Endometriosis

Major licensing deals for PromarkerD with diagnostic, pharmaceutical, or services providers

First Sales of PromarkerD immunoassay

Development of new Dx tests using Promarker platform

Reimbursement (Medicare) Code for PromarkerD in the US

# Value Inflection Points

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## Exceptional Global Opportunity

- Disruptive, cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented, revenue ready
- Test rolling-out in easy-to-use, scalable, low cost format with high margins
- Whole of market appeal: pharma, clinical pathology labs, diagnostic platform developers, diabetes service providers, physicians and patients
- Deep pipeline of potential globally significant tests in development
- Vibrant corporate activity in the precision medicine, diagnostics and CRO (clinical trials) sectors

## Share Price Catalysts FY23

| Milestone | Sep'22 | Dec'22 | 1H CY23 | Impact |
|---|---|---|---|---|
| **PromarkerD** | | | | |
| **Licensing Deals** | | | | Drive global uptake and future revenue |
| **First Sales** | | | | Drive revenue |
| **Reimbursement - US** | | | | CPT PLA code & Payor coverage |
| **Reimbursement - Aus & UK** | | | | MSAC & NHS assessment |
| **Regulatory Submissions & Approvals** | | | | Build user confidence in product & assist of global roll-out |
| **Promarker™** | | | | |
| **Endometriosis Dx Results II** | | | | New first-in-class diagnostic test |
| **Oeophageal Cancer Dx Results II** | | | | New first-in-class diagnostic test |
| **Diagnostics Pipeline Updates** | | | | New IP (validation & proof of concept results) |
| **Analytical Services** | | | | |
| **New Contracts** | | | | Off-set cash burn & engages potential future partners |

# Peer Comparison

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| | | Stock Code | Company Focus | Market Capitalisation | Share Price | FY21 Revenue | FY21 Net Profit/Loss |
|---|---|---|---|---|---|---|---|
| RENALYTIX AI | **Renalytix AI** | RENX.LSE RNLX.US | DKD test based on AI and a combination of predictive blood-based biomarkers, genetic factors and electronic health records. Expensive (US$950 per test), non-mass market. | **~A$141m** | 107.5p | ~A$2.1m | ~A$43m loss |
| RHYTHM BIOSCIENCES | **Rhythm Biosciences** | RHY.ASX | Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO. | **A$278m** | A$1.30 | Nil | A$6.6m loss |
| AnteoTech | **AnteoTech** | ADO.ASX | Develops, commercialises, manufactures and distributes products for the life sciences research, diagnostics and medical device markets | **A$141m** | A$0.071 | A$0.9m | A$6.2m loss |
| Lucid diagnostics | **Lucid Diagnostics Inc** | LUCD.US | Commercial-stage, cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer. | **~A$135m** | US$2.63 | ~A$0.3m (9 months to 30 Sep 21) | ~A$23m (9 months to 30 Sep 21) |
| INOVIQ | **Innoviq Ltd (renamed from Bard1)** | IIQ.ASX | Early stage in-licensed IP for various cancer diagnostics. | **A$54m** | A$0.59 | A$0.5m | A$12.3m loss |
| PIL Proteomics International LABORATORIES LTD | **Proteomics International Laboratories** | PIQ.ASX | Predictive blood test measuring novel protein biomarkers for DKD; simple, cost effective, commercial ready. Pipeline of novel diagnostic tests in development for chronic diseases. | **A$90m** | A$0.85 | A$1.5m | A$2.9m loss |

Source: Company filings. Market data as at 16 July 2022, exchange rates of GBP:AUD 1.75 and USD:AUD 1.47

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PILL

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LABORATORIES LTD