

A group of women are gathered in a meeting, engaged in conversation. One woman in the center is smiling and looking towards another woman on the right. The setting appears to be a professional office or conference room with posters on the wall.

COMMERCIALISING A BLOOD TEST TO TRANSFORM BREAST CANCER DIAGNOSIS

BCAL Diagnostics Limited
Investor Presentation – July 2021

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A black and white photograph of two women standing on a beach, viewed from behind. The woman on the left has short, light-colored hair and is wearing a striped t-shirt. The woman on the right has long, dark hair and is wearing a dark t-shirt and jeans. They are both looking out at the ocean. A dark blue horizontal bar is overlaid across the middle of the image, containing the text '1. INTRODUCTION'.

1. INTRODUCTION

BCAL DIAGNOSTIC OVERVIEW



A viable blood test for breast cancer diagnosis: BCAL Diagnostics has developed a non-invasive blood based diagnostic approach to complement current imaging technologies



Patient, clinician & health provider focused: Additional information at the screening stage can improve early and accurate detection, help minimise patient anxiety and reduce overall health costs



Novel approach: Breast cancer detected via confirmation of a fingerprint of lipid markers from blood powered by proprietary AI algorithms demonstrated in early studies

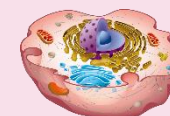


Potentially transformative: Real potential to be a cost-effective test for all women regardless of age, race or geographic location

BCAL Diagnostic Test



Blood collected at standard blood collection point



Extracellular vesicles (EV) enrichment from blood plasma



Extraction of markers for evaluation



Evaluation by Liquid Chromatography Mass Spectrometry (LCMS)



Data analysis of markers (AI algorithm to drive higher accuracy and sensitivity)

WHY BCAL

Breast cancer blood test product ready for major patient study



Blood test for range of breast cancers

No comprehensive blood test exists for breast cancers where mammography is the current gold standard

(70% accuracy with 20% false positives)



Promising results to date

Showed accurate identification of cancer especially in early stages, independent of age

(91% Specificity and 87% accuracy in set 5)



Widens population for screening

Suitable for under 40s, those in rural regions, those that have self-excluded from mammography

(approx. 50% of female population)



Staged rollout strategy

Initial stage will be as an adjunct test with mammography, before rollout as a monitoring tool and screening tool for breast cancer



Initial territories defined

Clinical pathway with Australia, US and EU as initial target territories, with opportunities in Middle East and India



Highly experienced team

Experienced Board, management team & Scientific Advisory Board with extensive expertise in breast cancer



2. INDUSTRY & MARKET

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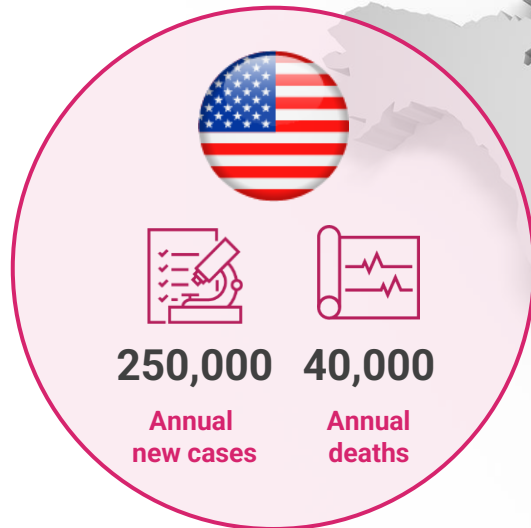
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INCIDENCE OF BREAST CANCER

Estimated 1-in-7 women at risk of a breast cancer diagnosis

Follow-on market

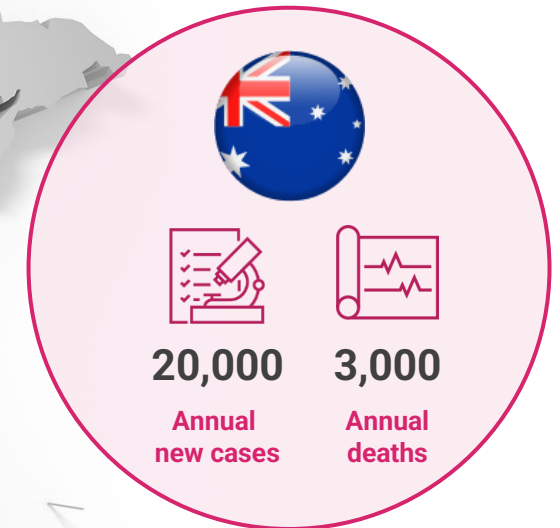
US



Follow-on market

Initial market

Australia



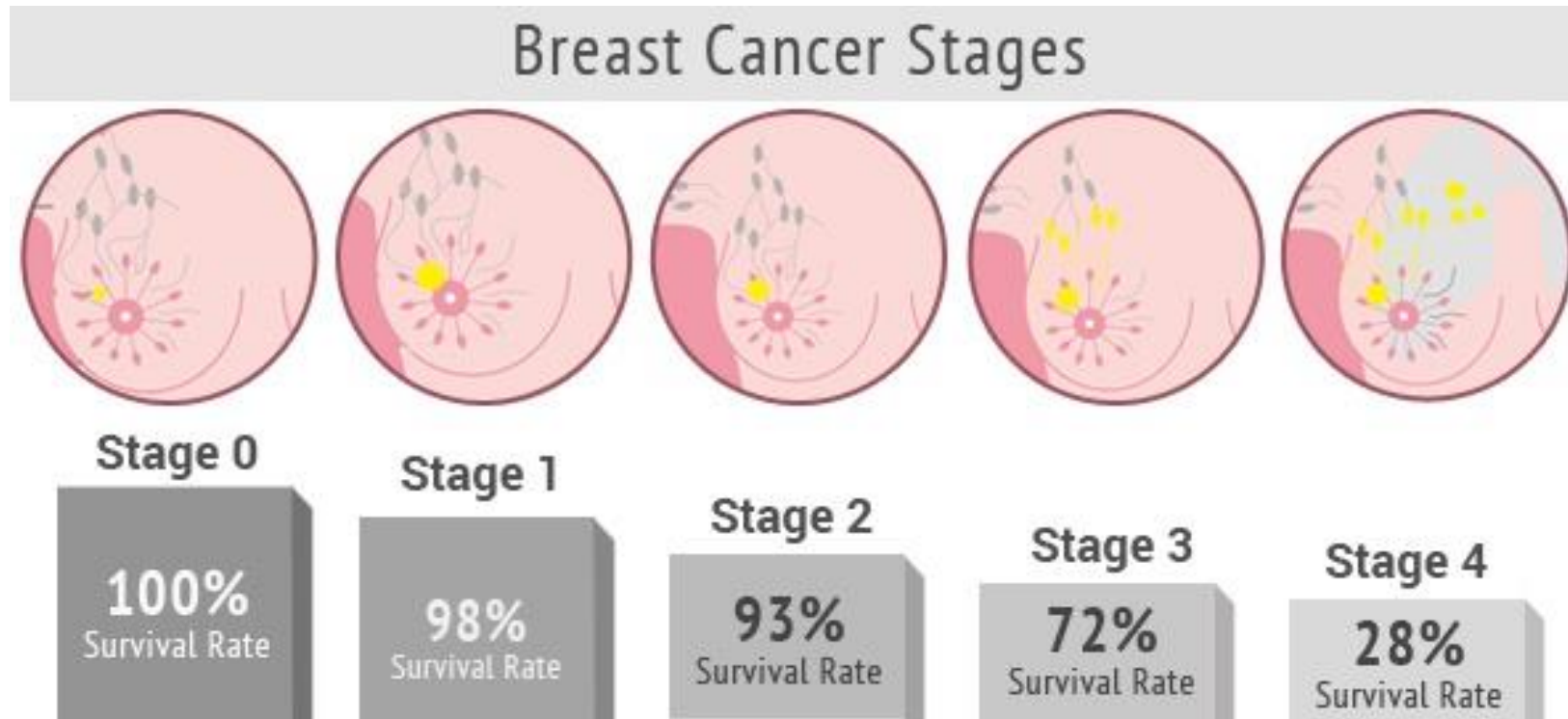
Initial market



50% of breast cancer cases and 58% of deaths come from developing economies

EARLY DIAGNOSIS IS IMPORTANT

Early breast cancer diagnosis leads to better survivability

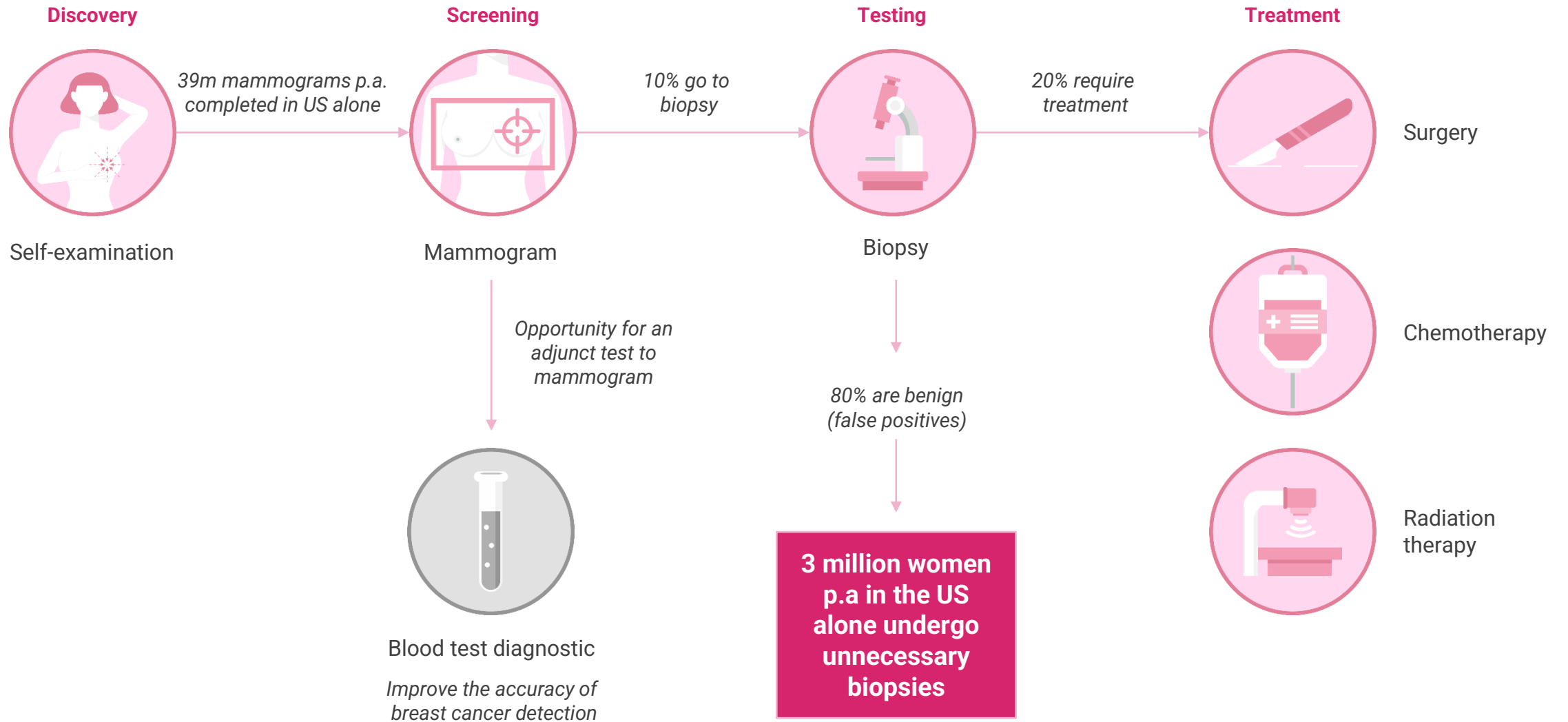


Breast cancer stage 1-4 survivability

Source: <https://www.pinkribbon.org.pk/stages-breast-cancer/>

CURRENT SCREENING PROCESS

Early breast cancer diagnosis leads to better survivability



LIMITATIONS OF MAMMOGRAPHY

50% of women choose to self-exclude

Not definitive (20% of breast cancers are missed – false negatives)

Limited accuracy (prone to false positives)

Over 40 y/o only



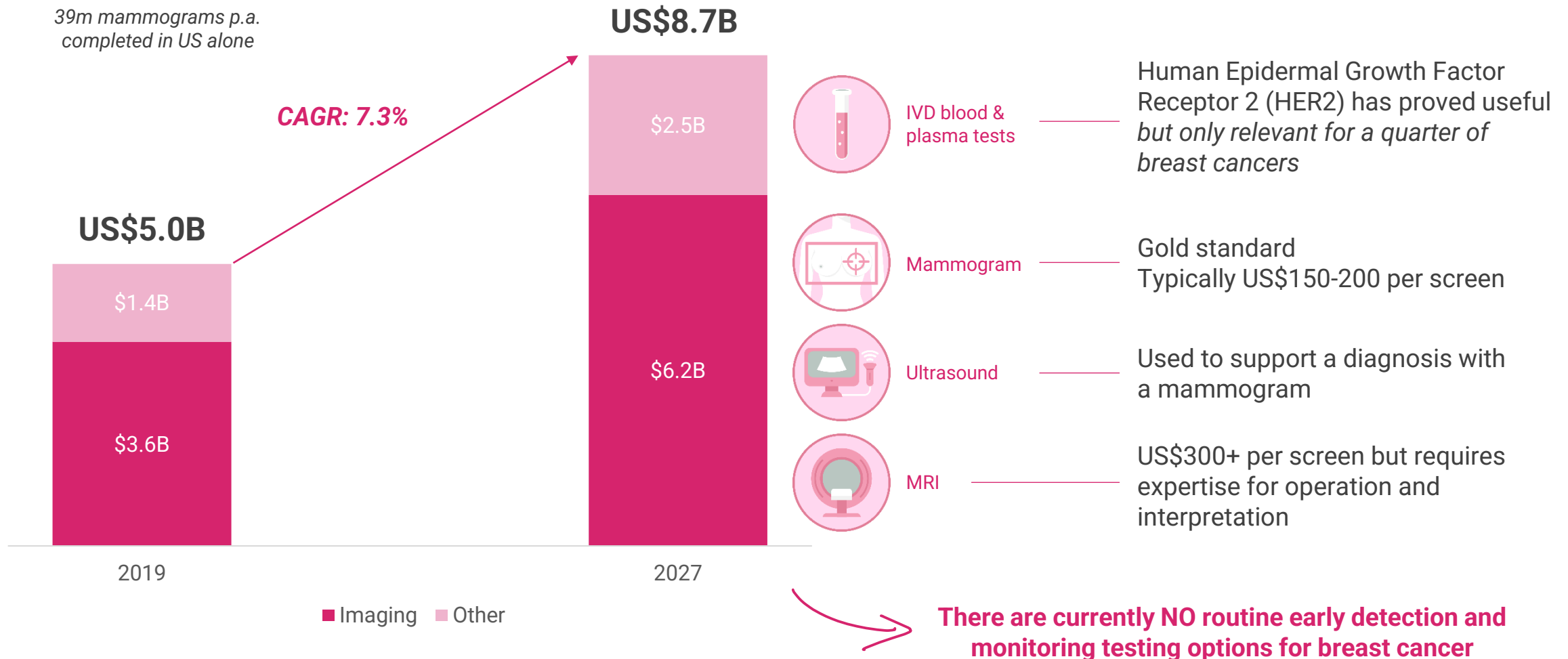
Prone to self-exclusion (painful, uncomfortable, cultural reasons)

Limited by breast density

Limited remote access

BREAST CANCER DIAGNOSTICS GLOBAL MARKET SIZE

No blood test for breast cancer diagnosis



NO ROUTINE MONITORING & EARLY DETECTION TESTS IN HIGH RISK GROUPS LEADS TO DRASTIC ACTION

Some women who carry the BRCA1 and BRCA2 gene elect to have mastectomies

Angelina Jolie has double mastectomy due to cancer gene

14 May 2013 | Comments



Hollywood actress Angelina Jolie has undergone a double mastectomy to reduce her chances of getting breast cancer.

The 37-year-old mother of six has explained her reasons for having the surgery in the New York Times.

She said her doctors estimated she had an 87% risk of breast cancer and a 50% risk of ovarian cancer. "I decided to be proactive and to minimise the risk as much I could," she wrote.

- If a woman has inherited a fault in their BRCA1 and BRCA2 genes, she has a high chance of developing breast or ovarian cancer
- Currently, some women are opting for breast mastectomies (breast removal) as a preventative measure
- **There are no current routine monitoring and early detection diagnostics tests in the market**

Sharon Osbourne has double mastectomy after discovering genetic defect that leaves her at greater risk of breast cancer

ROLLOUT STRATEGY

Clinical studies will provide data to support each of these claims

Strategy defined to provide a sequenced path to market

Adjunct test

1. Adjunct test to traditional mammogram screening

Improves mammography results to better accuracy

Monitoring

2. Monitor breast cancer patients through the disease lifecycle

No monitoring diagnostic currently in the market for women who have had breast cancer

Early Warning

3. Monitor women who carry the BRCA1 and BRCA2 gene

No safe routine early detection diagnostic currently in the market with women opting for breast removal

Diagnostic

4. Comprehensive breast cancer screening for all patients

Improvements of AI* algorithm positions as a diagnostic long term

* Harnessing the power of AI to build algorithms that continue to learn from new samples added to achieve higher accuracy of detection over time

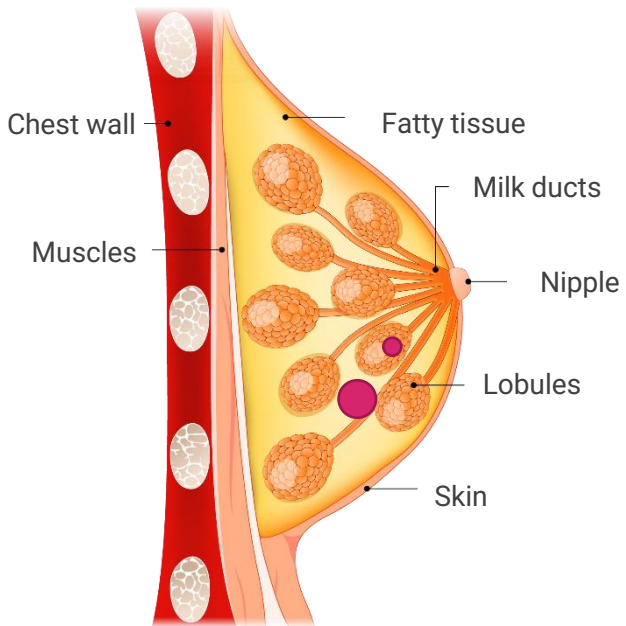
OPPORTUNITY FOR BLOOD TEST

Altered lipid expression can be detected using a relatively simple process to the user

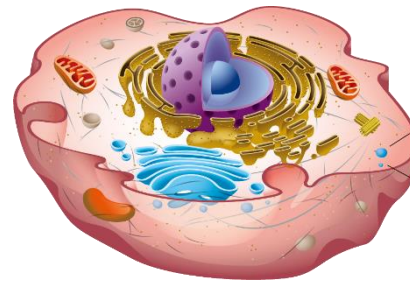
Breast cancer cells emerge exhibiting a difference to non-cancerous cells

18 lipid candidate markers that reveal differences between breast cancer and non-breast cancer patients

Plasma contains vesicles. **Breast-cancer altered lipids can be detected in a blood test using BCAL's lipid biomarker algorithm**



Breast



Cell



Blood-Plasma

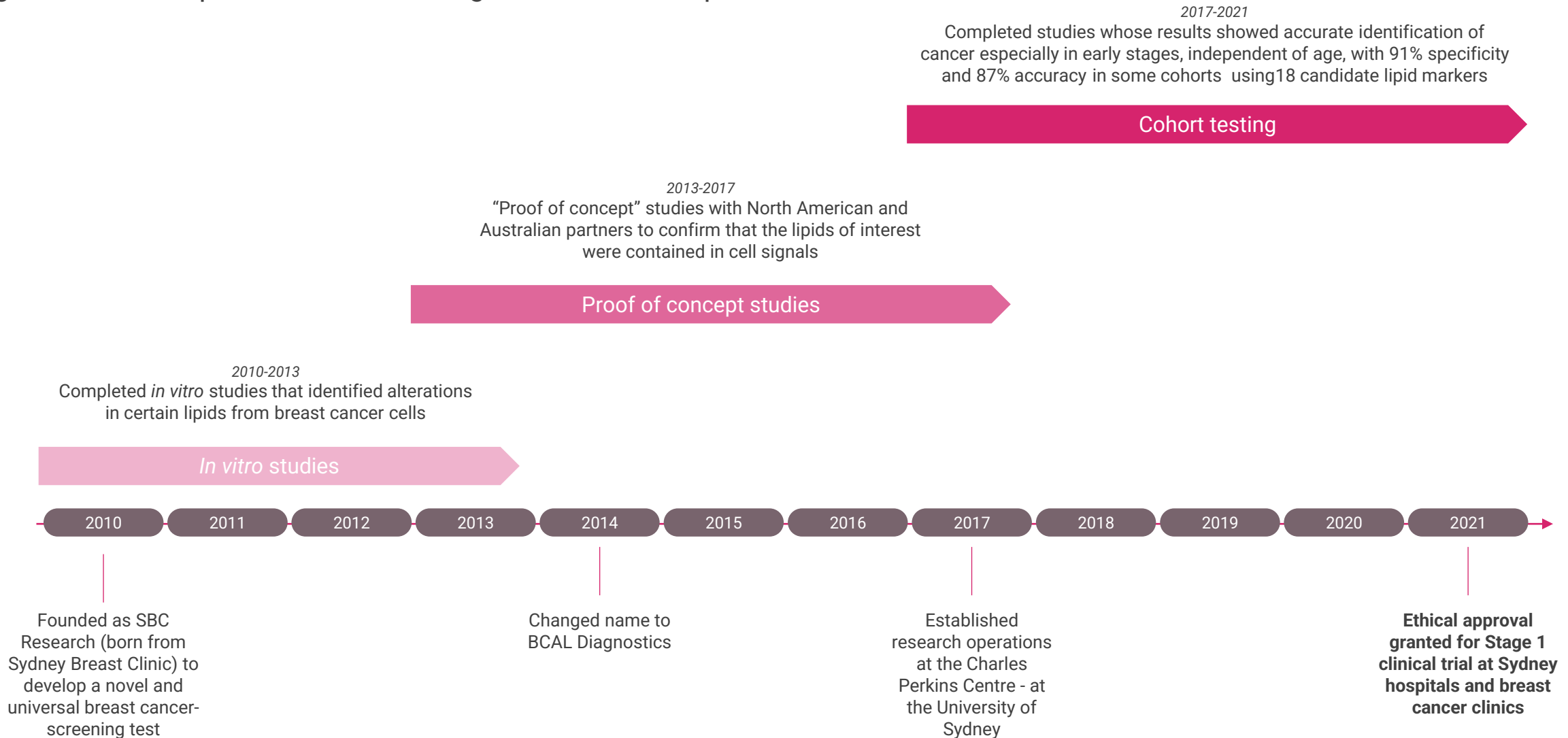
Plasma (55% of total blood)
White blood cells & platelets (<1%)
Red blood cells (45%)



3. COMPANY OVERVIEW

KEY DEVELOPMENT/SCIENTIFIC MILESTONES

Significant development to date to bring BCAL to current position



2017-2021 TESTING RESULTS

Reproduced and replicated in Australia results from US proof-of-concept testing from 2013 to 2017

Findings

- Identified 2 panels of 18 candidate lipid markers
- Robustly and reproducibly discriminate between control and cancer (**91% Specificity and 87% accuracy in Set 5**)
- Demonstrated in early stage Invasive Ductal Carcinoma (IDC)



	Breast cancer disease segment	Lipid markers identified	Accuracy	Sensitivity	Specificity
* Cohort 1 (88 people)	IDC – up to 80% of invasive breast cancer cases diagnosed	<ul style="list-style-type: none"> • 392 lipids analysed, 25 candidate markers identified 	83%	73%	86%
Cohort 2 (200 people)	Focused on IDC early Stage 1 and Stage 2	<ul style="list-style-type: none"> • 450 lipids analysed, 12 candidate markers identified 	83%	81%	84%
Cohort 3 Set 5 (Partial: 108/201 people)	Focused on IDC early Stage 1 and Stage 2	<ul style="list-style-type: none"> • 800+ lipids analysed, Reproducible in cohort 2 & 3 • 450 lipids analysed, 12 candidate markers identified • 18 candidate markers from cohort 2 + “improved 18” using cohorts 2 & 3 	87%	83%	91%

- Cohort refers to a group of people who share a certain characteristic, in this case presence of absence of breast cancer at ~ 50:50 ratio
- A marker is a specific lipid whose level is helpful in distinguishing between breast cancer and healthy samples
- Cohort 4 includes 301 samples currently being analysed

CLINICAL STUDY PROGRAM



	Study 1, Stage 1	Study 1, Stage 2	Study 2
Collection type	Single	Single	Multiple
Aim	Feasibility of BCAL as adjunct test to mammogram and establish workflow	Test as adjunct test to mammogram	Monitoring tool for recurrence
Target findings	<ul style="list-style-type: none"> Initial performance of 18 candidate markers Optimise algorithm Establish workflow 	<ul style="list-style-type: none"> Assess performance of algorithm from Stage 1 Compare results to mammogram 	<ul style="list-style-type: none"> Evaluate 18 markers before and after surgery Evaluate before and after post-treatment to track recurrence Identify better markers for disease monitoring
Clinical partners	<ul style="list-style-type: none"> Lead breast care surgeons and clinicians at NSW BreastScreen in Sydney Local Health District at the Royal Prince Alfred Hospital Chris O'Brien Lifehouse Sydney Breast Clinic (SBC) NSW Health Statewide Biobank GenesisCare 		
No of Participants	1,000	2,000	2,500



Results to support claim as adjunct test to traditional mammogram screening

Results to support claim to monitor breast cancer patients through the disease lifecycle

KEY PARTNERSHIP – GENESISCARE

CRO and Market entry partner in Australia, UK, Spain and the USA



Master Services Agreement signed with GenesisCare as Contract research organisation (CRO) and market entry partner



Currently participating in over 120 investigator-led and sponsored clinical trials

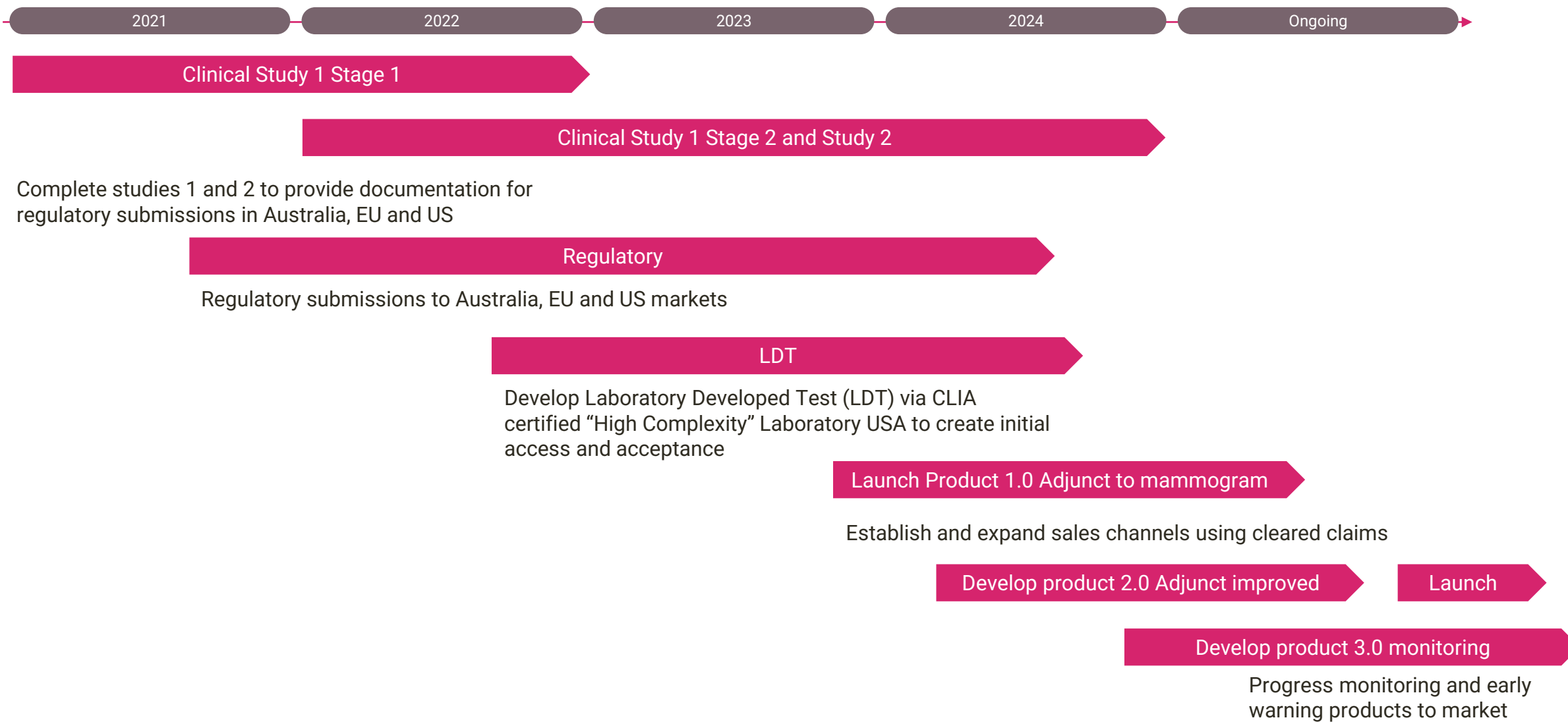


Clinical network of more than 6,000 doctors, specialists and support staff reaching over 440,000 patients globally

Over 440 centres globally including in key territories



COMMERCIAL PATHWAY



KEY PARTNERS

Strong group of university and commercial partners to accelerate commercialisation



University of Louisville (USA)

IP owners provides rights to BCAL to 2031

Patents granted in Australia, EU and Japan. Patents pending in USA and Canada



Izon (New Zealand)

IVD kit research



Australian Proteome Analysis Facility (Australia)

Research facility

Insight Stats



The Sydney Breast Clinic (Australia)



GenesisCare (Australia)



Royal Prince Alfred Hospital (Chris O'Brien Lifehouse) (Australia)



Cancer Institute of NSW (Australia)



University of Wollongong (Australia)



GenesisCare (Australia)

Market entry partner in Australia, UK, Spain and USA



Thermo Scientific (Australia & USA)

IVD kit production

PATENT SUMMARY

Application title	Filing date	Application number	Status
Methods for Detection Cancer	371 date ¹ : Dec. 19, 2012	US 13/805,352	PENDING – Notice of Appeal filed May 6, 2019; response to outstanding final Office action due December 6, 2019
Methods for Detection Cancer	Dec. 21, 2012	CA 2,803,865	PENDING – Waiting for next action by CIPO; Next annuity due June 22, 2020.
Methods for Detection Cancer	Dec. 20, 2012	JP Patent No. 5944385 (App. No. 2013-516721)	GRANTED – Next annuity due June 3, 2020
Methods for Detection Cancer	Jan. 7, 2013	AU Pat. No. 2011270968 (App. No. 2011270968)	GRANTED – Next annuity due June 22, 2020
Methods for Detection Cancer	Jan. 23, 2013	EP Pat. No. EP 2585833 (App. No. 11798823.8)	GRANTED – National entries finalized in DE, GB, FR, BE, IT, NL, DK, FI, SE, IE, ES; Next annuities due June 22, 2020
Methods for Detection Cancer	July 5, 2013	HK Pat. No. 1180764 (App. No. 13107899.2)	GRANTED – Next annuity due June 22, 2021
Methods for Detection Cancer	May 29, 2015	JP Patent No. 6092302 (App. No. 2015-109485)	GRANTED – Next annuity due Feb. 17, 2020
Methods for Detection Cancer	Aug. 12, 2016	AU 2016213855	GRANTED – Next annuity due June 22, 2020
Methods for Detection Cancer	March 27, 2017	EP 17163073.4	PENDING – Written Response to Summons to Oral Proceedings due September 4, 2019; Next annuity due June 22, 2020

¹ The 371 date is the date the application met 35 U.S.C. § 371 requirements for U.S. national stage entry, which may be relevant to the patent term adjustment calculation. The filing date for prior art purposes for a U.S. national stage entry application is the filing date of the corresponding PCT application.



4. KEY PEOPLE

BOARD OF DIRECTORS



Jayne Shaw
Executive Chair

- Co-owner of Sydney Breast Clinic and a co-founder of BCAL Diagnostics with Ron Phillips
- Experienced healthcare Board member including Cardiology, Orthopaedics, and Women's Health
- Previously established an Australian and international consulting business which was sold to Healthsouth a large USA Healthcare company, and was co-founder of Vision Group, that was successfully listed on the ASX
- Continues to work with private equity firms on local and international healthcare transactions
- Current Board positions are The Woolcock Research Institute, The Citadel Group, Corum Group (ASX: COO) and Mabel Technologies



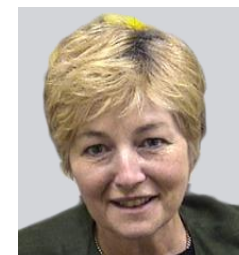
The Hon. Ron Phillips AO
Non-executive Director

- Co-owner of Sydney Breast Clinic which was recently sold to Healthscope and a co-founder of BCAL Diagnostics
- Previously developed a successful consulting business in the Health and Aged Care Industry
- Recently retired as Chair of the Sydney Local Health District and as Director of Westmead IVF
- Served 15 years in the NSW Parliament which included serving as Minister for Health and Deputy Leader of the Opposition



Jonathan Trollip
Independent Non-executive Director

- A globally experienced Director with over 30 years of commercial, corporate, governance and legal and transactional expertise
- Currently non-executive Chairman of ASX listed Global Value Fund Ltd Future Generation Investment Company Ltd , Antipodes Global Investment Company Ltd and Plato Income Maximizer Limited
- He is a non-executive director of ASX listed Kore Potash Limited, Propel Funerals Limited and holds private company directorships in the commercial and not-for-profit sectors
- Previously a partner with law firm Herbert Smith Freehills
- A Fellow of the Australian Institute of Company Directors



Dr. Marilyn Sleigh
Independent Non-executive Director

- Over 30 years' experience as a senior executive and non-executive director in Australia's biotechnology sector
- Previously Chief Executive Officer and Managing Director of EvoGenix Limited, that listed on the ASX before acquisition by a larger company
- Held non-executive director positions with ASX-listed companies Clover Corporation, Tyrian Diagnostics Ltd and Adalta Ltd
- Formerly Dean of the Faculty of Life Sciences, University of NSW; Director of Research & Development at Australian biotech Peptech Ltd and a research scientist and senior manager with CSIRO
- Holds a Doctorate in Philosophy and is a Fellow of the Australian Institute of Company Directors



Mark Burrows AO
Independent Non-executive director

- An advocate for early diagnosis of breast cancer and other cancers
- Cofounded Baring Brothers Burrows & Co in Australia in the early 80s, then in 1999 was appointed the Managing Director / Deputy Chairman of ING Barings in London. Joined Lazard as a Managing Partner and was appointed Lazard Australia's inaugural Chairman
- Has been a principal financial advisor to some of the most significant and transformative corporate and government transactions in Australia
- Served as a Non-Executive Director for Australian and UK public companies including as Chairman and Deputy Chair of Brambles, Fairfax Media and Telstra
- Advised the United Nations, G20 and corporates on climate initiatives relating to the financial sector

KEY PEOPLE



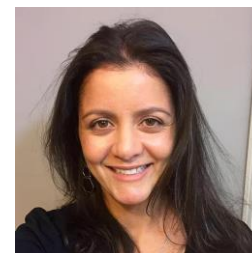
Dr. Jane Ryan, PhD
Chief Product Development Adviser

- Over 30 years of international pharmaceutical and biotechnology experience
- Worked in Australia, the USA and UK with companies including Peptech, Roche, Cambridge Antibody Technology and Biota Holdings
- Led many successful fundraising campaigns and licensing initiatives including the awarding of a \$230m USA Government contract
- Chairs the Advisory Board of the i3 Institute at the University of Technology Sydney (UTS)
- A Non-executive Director at ASX listed, Anantara Lifesciences
- Previously a Board Member of the Victorian Endowment for Science Knowledge and Innovation (veski), Diabetes Victoria, TechInSA, and the Diabetes Vaccine Development Centre



Guy Robertson
Chief Financial Officer & Company Secretary

- A Finance Director/Chief Financial Officer for a number of companies within the Jardine Matheson Group over a period of 16 years
- Provided CFO consulting services to many large corporations and SMEs
- CFO/Company Secretary for a number of Australian public companies including Evogenix Limited and is currently a Director of ASX-listed entities Metal Bank Limited and Hastings Technology Metals Ltd
- Company Secretary for Bioxyme Limited, Artemis Resources Limited and Truscreen Limited



Dr. Amani Batarseh
Chief Scientist

- Graduated magna cum laude from La Roche College in Pennsylvania where she had a Pacem in Terris scholarship for academic excellence
- Received a fellowship to pursue her PhD at Georgetown University, Washington, DC in Biochemistry and Molecular & Cellular Biology
- Completed post-doctoral studies at Harvard University, McGill University and Wollongong University
- In Canada managed and established two mass spectrometry laboratories at the Research Institute of McGill University Hospital and The Glen Hospital in Montreal, respectively
- Expertise combines molecular biology with lipidomics and mass spectrometry to answer biological questions



Alison Cook (Mew), MSc
Regulatory and Commercialisation Manager

- Management and leadership experience of more than 30 years across the biopharmaceutical, diagnostic and health service sectors
- Previously CEO of Genetic Technologies Ltd, and spent 13 years in senior executive roles at CSL Limited
- At CSL Limited, served in senior executive positions across the Animal Health, Biosciences and Pharmaceutical Divisions
- Consulted widely across the life sciences industry, including in technical operations, strategy and management, and is familiar with healthcare's complex technical and regulatory requirements
- Holds a Master of Science (Microbiology) and graduated from the Executive Development Program at Melbourne Business School

SCIENTIFIC ADVISORY BOARD



Dr. Kim Ekroos
PhD, Lipidomics Consulting



A/Prof. Craig Gedye
BSc(Hons), MBChB, FRACP, PhD



Dr. Sanjay Warriar *(Associate Prof.)*
BSc (Med) MBBS FRACS MS



Prof. Peter Meikle
PhD, Baker IDI Lipidomics Melbourne



Dr. Mary Rickard OAM
MBBS, BSc(Med)(HonsII), DRACR, DDU, MPH, RANZCR

- Founder and CEO of Lipidomics Consulting Ltd., a consulting business providing unique services for customers globally in the field of Lipidomics with over 20 years academics, healthcare and industry expertise
- Received his Ph.D. in biology from the Technical University in Dresden, Germany. His expertise includes high-throughput technologies for the precise assessment of lipidomes enabled by advanced mass spectrometry, automation, and software tools towards discovery of biological architectures and of diagnostic biomarkers for clinical purpose
- Has a number of patents for biomarker discovery, numerous peer-reviewed publications and an editor of a widely read Lipidomics book.
- Current president of the newly founded International Lipidomics Society.

- A medical oncologist and cancer researcher working for people with melanoma, brain, prostate, bladder and kidney cancers at the Calvary Mater Newcastle, and is the Clinical Research Director at the NSW Health Statewide Biobank
- His research in the School of Medicine and Public Health at the University of Newcastle/Hunter Medical Research Institute focuses on complexity and heterogeneity in cancer.
- Leads several national cancer clinical trials for the ANZUP and COGNO trials groups, and is a member of the Mark Hughes Scientific Advisory Committee, HNEHLD Clinical Trials Ethics Subcommittee and ANZUP Cancer.
- Has been awarded numerous scholarships, fellowships, grants, investigator-initiated clinical trials, publications, conference presentations and prizes.

- Consultant Breast Oncology and Oncoplastic Surgeon at Chris O'Brien Lifehouse, Royal Prince Alfred and Mater Hospitals. He is also a Visiting Medical Officer at BreastScreen NSW.
- An Associate Professor of the University of Sydney with the Royal Prince Alfred Academic Institute. He is lead researcher at the Institute with goals of developing and creating a culture of academia within the Breast Department.
- Won the Patron's Prize at the Royal Prince Alfred Hospital for best scientific research. Sanjay has also published many papers and co-authored articles in peer reviewed journals and magazines.
- Sanjay is Chairman of Post-Fellowship Training for BreastSurgANZ, a role that involves training future breast surgeons in Australia and New Zealand.

- Peter is an NHMRC Senior Research Fellow at the Baker Institute.
- He leads the Obesity and Diabetes Program and is Head of the Metabolomics laboratory.
- He is also Editor in Chief of the journal Metabolites and holds affiliate positions at the University of Melbourne, Monash University and the NHMRC Clinical Trials Centre, University of Sydney.
- The Metabolomics laboratory uses state of the art tandem mass spectrometry to obtain metabolic profiles from cell and animal models in addition to clinically relevant human samples. This approach is providing an improved understanding of disease mechanisms leading to new biomarkers for improved diagnosis and risk assessment as well as new therapeutic strategies in the areas of obesity, diabetes and cardiovascular disease.

- Received a Member of the Order of Australia award in 2002, for service to medicine through the integration of population-based screening for early detection of breast cancer, and the development of education programs for health professionals.
- Involved in consulting with numerous breast screening and diagnostic training programs across South East Asia, in particular Singapore, Indonesia, Malaysia, Thailand, Japan and most recently Mongolia.

