Prospectus

BCAL Diagnostics Limited
ACN 142 051 223
ASX: BDX

For the Offer to issue 32,000,000 shares at an issue price of $0.25 per share to raise $8 million (with the ability to accept Oversubscriptions of up to an additional $4 million)

Lead Manager

Legal Adviser

Important notices

General

The Offer contained in this Prospectus is an invitation to apply to acquire Shares in BCAL Diagnostics Limited (ACN 142 051 223) (**BCAL** or the **Company**).

This Prospectus is dated 4 June 2021 (**Prospectus Date**). A copy of this Prospectus was lodged with ASIC on that date.

The Company will apply to ASX within seven days of the date of this Prospectus for admission of the Company to the Official List and for quotation of its Shares on the ASX.

Neither ASIC nor ASX takes any responsibility for the contents of this Prospectus or the merits of the investment to which this Prospectus relates. No Shares will be allotted or transferred on the basis of this Prospectus after the expiry date. This Prospectus expires on the date that is 13 months after the Prospectus Date.

Note to Applicants

This Prospectus provides information for investors to decide if they wish to invest in BCAL.

The Offer does not take into account the investment objectives, financial situation or needs of particular investors. This Prospectus should not be construed as financial, taxation, legal or other advice. The Company is not licensed to provide financial product advice in respect of its securities or any other financial products.

This Prospectus is important and should be read in its entirety prior to deciding whether to invest in Shares. There are risks associated with an investment in Shares and some of the key risks are set out in Section 5. You should carefully consider these risks in light of your personal circumstances (including financial and tax issues) and seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest in Shares. There may also be risks in addition to these that should be considered in light of your personal circumstances.

Except as required by law and only to the extent so required, no person named in this Prospectus warrants or guarantees the Company's performance, the repayment of capital by the Company or any return on investment made under this Prospectus.

No person is authorised to give any information or to make any representation in connection with the Offer, other than as is contained in this Prospectus. Any information or representation not contained in this Prospectus should not be relied on as having been made or authorised by the Company, the Directors, the Lead Manager or any other person in connection with the Offer. You should rely only on the information in this Prospectus.

Speculative investment

The Shares offered under this Prospectus should be considered highly speculative. There is no guarantee that the Shares offered under this Prospectus will make a return on the capital invested, that dividends will be paid on the Shares or that there will be an increase in the value of the Shares in the future.

Prospective investors should carefully consider whether the Shares offered under this Prospectus are an appropriate investment for them in light of their personal circumstances, including their financial and taxation position. Refer to Section 5 for details relating to the key risks applicable to an investment in the Shares.

Forward looking statements

Various statements in this Prospectus may be in the nature of forward looking statements, including statements of current intentions, statements of opinion and predictions as to future events. Forward looking statements are identified by words such as 'may', 'could', 'believes', 'estimates', 'expects', 'intends', 'considers' and other similar words that involve risks and uncertainties. You should be aware that such statements are not statements of fact and there can be no certainty of outcome in relation to the matters to which the statements relate.

Forward looking statements are subject to various inherent risks and uncertainties (many of which are outside the Company's control) that could cause the Company's actual results to differ materially from the results expressed or anticipated in these statements. As a result, forward looking statements should be read in conjunction with risk factors as set out in Section 5 and other information in this Prospectus.

The Company does not intend to update or revise forward looking statements, regardless of whether new information, future events or any other factors affect the information contained in this Prospectus, except where required by law.

International offer restrictions

This Prospectus does not constitute an offer in any place outside Australia where, or to any person to whom, it would not be lawful to make such an offer. No action has been taken to register or qualify the Shares or the Offer, or to otherwise permit a public offer of the Shares, in any jurisdiction outside Australia. The distribution of this Prospectus outside Australia may be restricted by law and persons who come into possession of this Prospectus should observe any such restrictions. Any failure to comply with such restrictions could constitute a violation of applicable securities laws. See Section 7.11 for more details on the selling restrictions that apply to the Offer outside Australia.

This Prospectus must not be distributed in the United States of America (**USA**). The Shares have not been, and will not be, registered under the US Securities Act of 1933, as amended (**US Securities Act**), and will not be offered or sold in the USA except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and any applicable USA state securities laws.

Defined terms and abbreviations

Defined terms and abbreviations used in this Prospectus are explained in Appendix C. Unless otherwise stated or implied, references to times in this Prospectus are to the time in Sydney, Australia.

Cooling off rights

Cooling off rights do not apply to an investment in Shares acquired under the Prospectus. This means that, in most circumstances, you cannot withdraw your application to acquire Shares under this Prospectus once the application has been accepted.

Electronic prospectus

This Prospectus is available electronically at www.bcaldiagnostics.com. The Application Form attached to the electronic version of this Prospectus must be used within Australia. Electronic versions of this Prospectus should be downloaded and read in their entirety. Obtain a paper copy of the Prospectus (free of charge) by telephoning 1300 288 664 (toll free within Australia) or +61 2 9698 5414 (outside Australia) from 9am until 5pm. Applications for Shares may only be made on the Application Form attached to this Prospectus or in its paper copy form downloaded in its entirety from www.bcaldiagnostics.com.

Exposure period

Under the Corporations Act BCAL must not process Application Forms during the seven day period after the date of lodgement of this Prospectus with ASIC. This period may be extended by ASIC for up to a further seven days. This exposure period enables the Prospectus to be examined by market participants. Application Forms received during the exposure period will not be processed until after the expiry of that period. No preference will be given to Application Forms received during the exposure period.

Contract summaries

Summaries of contracts detailed in this Prospectus are included for the information of potential investors but do not purport to be complete and are qualified by the text of the contracts themselves.

Privacy

By completing an Application Form, you are providing personal information to the Company, and the Share Registry, which is contracted by the Company to manage Applications. The Company, and the Share Registry on their behalf, collect, hold and use that personal information to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included in the Company's public register. The information must continue to be included in the Company's public register if you cease to be a Shareholder. If you do not provide all the information requested, your Application Form may not be able to be processed. The Company, and the Share Registry may disclose your personal information for purposes related to your investment to their agents and service providers as disclosed in the Company's Privacy Policy available at www.bcaldiagnostics.com or as otherwise authorised under the *Privacy Act 1988* (Cth).

You may request access to your personal information held by or on behalf of the Company. You can request access to your personal information or obtain further information about the Company's privacy practices by contacting the Share Registry or the Company. The Company aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact the Company or the Share Registry if any of the details you have provided change.

In accordance with the requirements of the Corporations Act, information on the Shareholder register will be accessible by members of the public.

Currency

Monetary amounts shown in this Prospectus are expressed in Australian dollars unless otherwise stated.

Photographs and diagrams

Photographs used in this Prospectus which do not have descriptions are for illustration only and should not be interpreted to mean that any person endorses this Prospectus or that assets shown in the photographs are owned by the Company.

Diagrams used in this Prospectus are illustrative only and may not be drawn to scale.

Third party publications

The Industry Overview in Section 2 of this Prospectus includes attributed statements from books, journals and comparable publications that are not specific to, and have no connection with, the Company. Except where indicated otherwise, the authors of these books, journals and comparable publications have not provided their consent for these statements to be included in this Prospectus, and the Company is relying upon ASIC Corporations (Consents to Statements) Instrument 2016/72 for the inclusion of these statements in this Prospectus without that consent having been obtained.

This document is important and should be read in its entirety.

Contents

Key dates and key Offer details

Key Event	Date
Lodgement of the Prospectus with ASIC	Friday 4 June 2021
Offer opening date	Monday 14 June 2021
Offer closing date	Friday 2 July 2021 at 4pm AEST
Allotment Date	Tuesday 6 July 2021
Despatch of holding statements	Thursday 8 July 2021
Normal trading of Shares on ASX	Friday 16 July 2021

The timetable above is indicative only. BCAL, in consultation with the Lead Manager, reserves the right to amend any or all of these dates subject to the Corporations Act, the ASX Listing Rules and other applicable laws, including closing the Offer early, extending the Offer, deferring completion of the Offer or accepting late Applications either generally or in particular cases, allotting Shares at different times to investors, or to withdrawing the Offer, all without prior notice. The quotation and commencement of trading of the Shares on ASX remains subject to confirmation from ASX.

Key Offer details

Company making the Offer	**BCAL Diagnostics Limited, a company registered in Australia under ACN 142 051 223**
Proposed ASX code	**BDX**
Securities offered	**Ordinary Fully Paid Shares**
Offer Price (A$)	**$0.25 per Share**
Total number of Shares currently on issue	**160,000,002**
Total number of options currently on issue (and at completion of the Offer)	**11,557,878**
Number of Shares available under the Offer	**32,000,000 Shares, with the ability to accept Oversubscriptions of up to an additional 16,000,000 Shares**
Gross proceeds from the Offer (A$)	**Minimum Subscription Amount of $8,000,000, with the ability to accept Oversubscriptions of up to an additional $4,000,000**
Total Number of Shares on issue at Completion of the Offer	**198,615,633 Shares (based on the issue of 32,000,000 Shares)**[1] **214,615,633 Shares (based on the issue of 48,000,000 Shares)**
Market capitalisation after the Offer (A$)[2]	**$49,653,908 (based on issue of 32,000,000 Shares)** **$53,653,908 (based on issue of 48,000,000 Shares)**

1. Including the Lead Manager Securities (see Section 6.5).
2. Based on the Offer Price.

Chairman's Letter

Dear Investor

On behalf of the Directors of BCAL Diagnostics Limited (**BCAL** or the **Company**), it is my pleasure to invite you to become a Shareholder.

BCAL is developing a new diagnostic approach for breast cancer using an *in vitro* diagnostic (**IVD**) blood test. BCAL's initial focus is to achieve Australian regulatory approval for its breast cancer diagnostic product to be employed alongside traditional mammography. Using sequential trials, BCAL's broader goal is to increase the range of situations in which the product has been proven to be effective, leading towards the position where its use can improve international breast cancer testing for every woman, everywhere.

Breast cancer is the most common cancer among women globally, with more than 2 million new cases of breast cancer registered annually and approximately 627,000 resulting deaths. Improvements in medical and patient awareness have emphasised the importance of early detection for effective treatment with a corresponding growth in global demand for breast cancer diagnostics. The global market for these products was valued at just under US$5 billion in 2019 and anticipated to expand at a compound annual growth rate of 7.3%, reaching US$8.7 billion by 2027.

There are two types of breast cancer evaluation: screening and diagnostic. Primary screening is by mammogram, supported by diagnostic procedures including diagnostic mammography, ultrasonography and breast magnetic resonance imaging (**MRI**). The final step in diagnostic evaluation is biopsy, whereby a sample of suspect breast tissue is removed and evaluated for the presence of cancerous cells. While it is not uncommon for a mammogram to require additional follow up, in part due to suspicious or unclear results, fewer than 10% of those called back for further testing are found to have cancer. Where follow up testing is by away of biopsy, approximately 80% of lesions detected by imaging are shown to be benign. As well as the high incidence of false positive results from mammography, approximately 20% of breast cancers are estimated to be missed when mammography is the only screening method employed, and these false negative results tend to be more common in women who have dense breast tissue.

By adding BCAL's non-invasive test to mammography screening, the aim is to improve the accuracy of breast cancer detection and reduce the rate of false positives and false negatives. BCAL's approach looks for a "fingerprint" of lipid biomarkers in blood which are characteristic of the presence of breast cancer, compared with the lipid profile in the blood of healthy individuals.

The Company was established in Australia in 2010, and completed an initial series of *in vitro* (laboratory) studies identifying alterations in specific lipids in the media of a breast cancer cell line, compared to the profile from a non-cancerous cell line. From 2013 to 2017, BCAL undertook "proof of concept" studies with its USA and Australian partners, to confirm that analysis of these lipids by mass spectrometry could potentially enable diagnosis of breast cancer.

In the next phase of its work, BCAL will undertake studies designed to demonstrate the value of its test in improving diagnosis of breast cancer when it is used alongside mammography as an adjunct test, with its initial regulatory focus on seeking approval from the Australian Therapeutic Goods Administration (**TGA**). The TGA approval sought will be for priority review status for BCAL's IVD test to be used as an adjunct to traditional mammogram screening. BCAL's present and future clinical studies are also designed to support future regulatory approval pathways.

Following successful domestic launch of the test as a diagnostic alongside traditional mammography BCAL will seek further clinical data, both to support broader uses of the technology domestically and consider appropriate pathways to markets in other jurisdictions.

BCAL collaborates closely with leading clinicians in Australia. Funds from the Offer will support the Company's clinical development program using statistically powered sample sizes to meet both clinical evidence and regulatory requirements.

BCAL is led by a small but highly capable and experienced management team, supported by a group of consultants with substantial experience in clinical testing and development and commercialisation of diagnostic tests and related products. Collectively, these technical experts, together with a Scientific Advisory Board and Board of Directors, bring extensive scientific and commercial expertise.

The Company's data and upcoming clinical studies are designed to facilitate multiple market entry pathways, which will run in parallel. The purpose of the Company has been, since inception, to achieve a sequential series of claims or uses for its test as follows, each of which depends on confirmatory data from successful clinical trials of BCAL's technology as:

(1) a screening test for breast cancer as an adjunct to mammography;

(2) from further studies, a monitoring test for breast cancer patients who have been given the "all clear" following treatment; and

(3) monitoring and screening test for women who have the BRCA gene mutation or are otherwise at high risk of developing breast cancer.

Ultimately, BCAL's ongoing clinical data and clinical trials will be utilised and assessed for their clinical utility by leading global key opinion leaders in the breast cancer diagnostic and treatment field. This will support the regulatory approval process for the Company to deliver its end goal of introducing a breast cancer blood test suitable for use by every woman, everywhere.

During this process, BCAL will seek to assess potential applications of its technology for other cancers.

Under this Prospectus, BCAL is conducting its initial public offering of 32 million shares, at $0.25 per share to raise $8 million (**Offer**), with the ability to accept Oversubscriptions of up to an additional $4 million. The Prospectus details information about the Offer, BCAL's operations, performance, financial position and key personnel, as well as the broader industry sector in which the Company operates.

Proceeds raised will support the Company in:

(a) establishment of its mandatory Quality Management System (**QMS**);

(b) concluding and optimising laboratory/analytical evaluation to optimise test performance;

(c) completing its pivotal clinical trial program for the test's initial intended use as an adjunct to mammography;

(d) developing its Health Technology Assessment (**HTA**) and reimbursement strategy;

(e) developing its test for scalability and ease of use;

(f) establishing its software tool for result analysis in a user-friendly manner;

(g) positioning itself for further clinical trial data to:

  (i) broaden the use case for its technology domestically; and

  (ii) explore pathways to regulatory approval in international jurisdictions; and

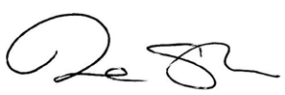
(h) meeting ongoing administration and corporate overhead expenses, including Offer expenses.

Investors should be aware there are significant risks associated with BCAL's business, and an investment in the Company should be considered highly speculative. These risks relate to matters including, but not limited to, regulatory approvals, sufficiency of funding, healthcare insurance and reimbursement, regulatory requirements around clinical trials, patent protection and currency risks. Please see Section 5 for more information on BCAL's key risks.

I encourage you to read this Prospectus in its entirety to gain a full understanding of the Company's operations before making an investment decision.

On behalf of the Board, I commend this Offer to you and look forward to welcoming you as a fellow Shareholder of the Company.

Yours faithfully



Jayne Shaw

Chairman
BCAL Diagnostics Limited

1. Investment overview

1. Investment overview

The information set out in this Section is intended to be a summary only and should be read in conjunction with the more detailed information appearing elsewhere in this Prospectus. In deciding whether to apply for Shares under the Offer, you should read this Prospectus carefully and in its entirety. If you are in doubt as to the course you should follow, please consult your stockbroker, solicitor, accountant, financial adviser or other professional adviser.

1.1 BCAL's operations

Question	Answer	Location in this Prospectus
What are BCAL's aims and objectives?	BCAL is developing a non-invasive laboratory blood test for the detection of breast cancer. The core BCAL technology has evolved from extensive research and investment over approximately ten years by independent groups based in the USA and Australia. Researchers from the University of Louisville Research Foundation, Inc (**ULRF**) were able to show that breast cancer patient samples contain significantly different lipid profiles from those of both healthy volunteers and lung cancer patients; using a defined methodology. In 2011 ULRF filed a patent application using this data. Working independently in Sydney, BCAL's science team observed a similar trend in their own research, and as a result the Company decided in 2013 to license the technology the subject of a patent application from ULRF. While BCAL's first objective is to secure TGA approval for use of a test based on this information used alongside mammography, the Company's data and clinical trials are designed to facilitate sequential market entry points. The purpose of the Company has been, since inception, to achieve a sequential series of claims or uses for its test as follows, each of which depends on confirmatory data from successful clinical trials of BCAL's technology, as: (1) a screening test for breast cancer alongside mammography; (2) a monitoring tool for breast cancer patients who have been given the "all clear" following treatment; and (3) monitoring and screening for women who have the BRCA gene mutation, or are otherwise at high risk of developing breast cancer. Ultimately, the clinical data and clinical trials will be utilised and assessed for their clinical utility by leading global key opinion leaders in the breast cancer diagnostic and treatment field. Successive regulatory approvals and marketing of the BCAL test for a widening range of indications will move BCAL towards its end goal of introducing a breast cancer screening blood test for every woman, everywhere.	**Section 3**

1. Investment overview continued

1.2 Financials

Question	Answer	Location in this Prospectus
What is BCAL's historical financial performance?	The Company's historical results have been set out in detail in Section 4.5.	**Section 4.5**
How does BCAL expect to fund its operations?	The Company's expenditure program sets out its use of funds from the Offer, with which, with existing funds, the Company will have sufficient working capital at the time of its ASX admission to meet its stated objectives for at least the next 24 months. BCAL does not expect to generate revenue in the short term.	**Section 3.11**
What is BCAL's forecast financial performance?	The Directors have considered the requirements of ASIC Regulatory Guide 170 *Prospective financial information* (RG170) to determine if prospective financial information should be included in this Prospectus. The Directors have determined that, as at the date of this Prospectus, BCAL does not have reasonable basis to reliably forecast future earnings and accordingly forecast financial information is not included in this Prospectus. There is uncertainty in relation to the quantum and timing of BCAL's future revenue given the status of its research, resulting in a level of unpredictability in the timing, quantum and recognition of future receipts.	**Section 4.2**

1.3 Industry competitors

Question	Answer	Location in this Prospectus
Who are BCAL's competitors?	There are two types of breast cancer diagnostics: screening evaluation (to indicate the presence of disease and early detection, such as traditional mammogram screening) and diagnostic evaluation (definitive diagnosis, such as biopsy). Breast cancer detection can also be categorised according to the technology used, into the following segments: • imaging, including ionizing breast imaging technologies and non-ionizing imaging technologies; • biopsy; and • IVD blood or plasma tests. Examples of the Company's competitors are set out in Section 2.4.	**Section 2.4**

1.4 BCAL's growth strategy

Question	Answer	Location in this Prospectus
What are BCAL's growth strategies?	BCAL's growth will be based on successive approvals of its IVD test for a range of situations under which non-invasive testing for breast cancer is desirable. If successful, this will result in progressive broadening of the market for the test and income for BCAL. BCAL collaborates closely with leading clinicians in Australia. Funds from the Offer will support the Company's clinical development program using statistically powered sample sizes to meet both clinical evidence and regulatory requirements. In the future, BCAL may elect to explore variations on the test for application to diagnosis of other cancer types.	**Section 2.1**
How will BCAL seek to generate returns for investors?	On securing the regulatory approvals required and exploring additional pathways to market, such as in-house IVD development, the Company will be in a position to generate revenue from its test product(s). The capital value of the business is expected to grow as the test achieves its first regulatory approval and product launch and as areas of use for the test expand. Successful application of a similar test to diagnosis of other cancer types, if pursued, would add further to the Company's income and value.	**Section 2.6**

1.5 Key investment highlights

Question	Answer	Location in this Prospectus
What are the key highlights of an investment in BCAL?	As a diagnostic tool that ultimately seeks to be available for all women, initial studies indicate the BCAL test has 91% specificity and 87% accuracy for invasive ductal carcinoma (**IDC**) breast cancer. This compares favourably with the current standard, mammography, which has historically been more effective as a breast cancer diagnostic tool for older women with less dense breasts.	**Section 2.4**
	BCAL has defined a clinical pathway to access large target markets; initially targeting Australia, the USA and Europe. Globally, there are more than 2 million new cases of breast cancer diagnosed annually, with ~627,000 resulting deaths. The demand for breast cancer diagnostics was valued at just under US$5 billion in 2019.	**Sections 2.2 and 2.3**
	Through various cohort studies to date, BCAL's research has been validated in Australia and by working with the Company's partners in the USA. BCAL's close work with leading breast surgeons has translated into support for BCAL's upcoming clinical studies at Royal Prince Alfred Hospital (Sydney), NSW BreastScreen, and Chris O'Brien Lifehouse.	**Sections 3.8 and 3.9**

1. Investment overview continued

Question	Answer	Location in this Prospectus
What are the key highlights of an investment in BCAL? continued	BCAL recently engaged GenesisCare to act as a Clinical Research Organisation (**CRO**) for BCAL through its clinical trials program. GenesisCare has ~5,000 healthcare professionals and support staff across Australia, the UK, Spain, China and the USA, designing treatments and care for people with cancer and heart disease.	**Section 9.5.3**
	The BCAL test will initially be an adjunct to traditional mammography, seeking to provide physicians with an increase in the sensitivity of breast cancer detection.	
	Using a strategically sequenced roll-out strategy, the BCAL test will seek to open new approaches to breast cancer screening, including women: • under 40, who currently rely on self-examination as primary screening; • who have previously been diagnosed with breast cancer and require annual screening, and those with the BRCA1 and BRCA2 gene mutation; and • who self-exclude for religious or other reasons, noting that mammograms can be painful procedures which often lead to self-exclusion.	**Section 2.4**
	BCAL's platform technology, if successful, will also provide future expansion opportunities into other indications, for example, prostate and lung cancer.	**Section 3.7**
	BCAL has existing intellectual property protections and is focused on broadening that portfolio as the technology is further developed.	**Section 3.10 and 5.3**
	BCAL has a strong and experienced Board and senior management team; as well as a team of experienced technical and commercialisation advisors to support the technology's ongoing development.	**Section 6**

1.6 Key investment risks

Question	Answer	Location in this Prospectus
What are the key risks to BCAL's business?	BCAL is subject to various risk factors, and any investment in the Company should be considered speculative.	**Section 5**
	Some of these risks are specific to the Company's business activities. Others are of a more general nature. Individually, or in combination, these risk factors may affect the future operating and financial performance of BCAL, its investment returns and the value of an investment in the Shares.	
	Each of the risks set out in Section 5, if they eventuate, could have a material adverse impact on the Company's business, financial condition and results of operations.	

Question	Answer		Location in this Prospectus
What are the key risks to BCAL's business? continued	The following is a summary of the key specific risks associated with BCAL's business:		**Section 5**
	Sufficiency of funding	BCAL has finite financial resources and will need to raise additional funds from time to time to finance its operations. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, if at all. If BCAL is unable to raise future funding, this will adversely impact the ability to achieve its milestones and develop its products and technologies.	
	Competition	The Company's competitors include entities with significantly greater financial, technical, human, research and development, and marketing resources than the Company. Given the level of competition, it is possible that the Company's products and technologies may become obsolete or uncompetitive, resulting in adverse impacts on revenue, margins and profitability.	
	Healthcare insurers and reimbursement	In both domestic and foreign markets, sales of BCAL's products are likely to depend in part upon the availability and amounts of reimbursement from third party healthcare payer organisations. No assurance can be given that reimbursement will be provided at all, or in amounts sufficient to enable the Company to sell its products on a profitable basis.	
	Reliance on key personnel	The Company currently employs a number of key management and scientific personnel, and the Company's future depends on retaining and attracting suitably qualified personnel. While certain measures have been taken in relation to recruitment, retention and contracting to secure its key personnel, there is no guarantee that the Company will be able to attract and retain suitability qualified personnel. Such a failure could materially affect the business, operating results and financial prospects of the Company.	

1. Investment overview continued

Question	Answer		Location in this Prospectus
What are the key risks to BCAL's business? continued	**Expenditure program**	BCAL has not yet entered into contracts or obtained binding quotations for some of the material items expected to be covered by its expenditure program. While the Directors are confident that the Company will be able to source suitable suppliers, there is a risk that BCAL may not be able to source those suppliers at the estimated expenditure.	Section 5
	Innovative technological development	The Company's product candidates are at a relatively early clinical stage and further clinical study using larger sample sizes is necessary. No guarantee can be provided that the proposed clinical work will be successful or result in an approved product.	
	Clinical trials – regulatory requirements	There is a risk that relevant regulators will not approve BCAL's proposed applications, which would result in the Company having to undertake further clinical trials, at significant expense and extending current proposed timeframes. Further, if the results of the trials do not support further development or result in a rejection by the relevant regulatory, BCAL may fail to commercialise or out-license its products.	
	Disruption of business operations	The Company is exposed to a large range of operational risks relating to both current and future operations. Disruption of operations may have an adverse impact on the Company's growth prospects, operating results and financial performance.	
	Dependence on service providers	As the Company intends to operate a significant amount of its key clinical activities through a series of contractual relationships with independent contractors and suppliers, there is a risk that the third parties do not fully comply with its or their respective contractual rights and obligations, which may impact on the Company's product development efforts.	
	Laboratory distribution channel	One of the possible regulatory pathways for the Company's product is to distribute the product via LDT in Australia, or in the USA via CLIA approved laboratories. There is no assurance that these laboratories will agree to sell the product, or that their customer base will purchase the product.	

Question	Answer		Location in this Prospectus
What are the key risks to BCAL's business? continued	**Product liability**	There is no assurance that unforeseen adverse events or manufacturing defects will not arise, exposing the Company to product liability claims or litigation.	Section 5
	Currency risk	Revenue and expenditures in overseas jurisdictions are subject to the risk of fluctuations in foreign exchange markets.	
	Contractual and counterparty risks	No assurance can be given that all contracts will be fully performed by all contracting parties and that the Company will be successful in securing compliance with the terms of each contract.	
	The Company's IP	There is no guarantee that the Company's intellectual property comprises or will comprise in the future, all of the rights that the Company may require to freely commercialise its product candidates. There are specific risks associated with the License Agreement relating to its lead product, including in relation to the deadline for commercialisation of the product and the expiry of the underlying patents.	
	The above is not an exhaustive list of the risks associated with the Company or an investment in the Shares. Further details of the risks summarised in this Section and other key risks are included in Section 5, and investors should review all of those risks carefully before making an investment decision. Before applying for Shares, investors should satisfy themselves that they have a sufficient understanding of these matters and should consider whether Shares are a suitable investment for them, having regard to their own investment objectives, financial circumstances and taxation position.		

1. Investment overview continued

1.7 Overview of the Offer

Question	Answer	Location in this Prospectus
What is the Offer?	The Offer is for 32 million Shares at $0.25 per Share to raise $8 million before Offer costs with the ability to accept Oversubscriptions of up to an additional $4 million (16 million Shares).	**Section 7.1**
Where will the Shares be listed?	Within seven days of the Prospectus Date, BCAL will make an application to ASX for admission to the Official List and the Official Quotation of the Shares under the code BDX.	**Section 7.8**
What will the market capitalisation of the Company be upon Listing?	In the event that the Offer is fully subscribed and the Minimum Subscription Amount is achieved, the Company's market capitalisation on listing will be $49,653,908.	**Section 7.1**
How will the proceeds of the Offer be used?	The purpose of the Offer is to raise funds to support the Company in: 1. establishment of its mandatory Quality Management System (QMS); 2. concluding and optimising laboratory/analytical evaluation to optimise test performance; 3. developing its test for scalability and ease of use; 4. establishing its software tool for result analysis in a user-friendly manner; 5. completing its pivotal clinical trial program for the test's initial intended use as an adjunct to mammography; 6. development of a Health Technology Assessment (HTA) and reimbursement strategy; 7. positioning itself for further clinical trial data to: – broaden the use case for its technology domestically; and – explore pathways to regulatory approval in international jurisdictions; and 8. meeting ongoing administration and corporate overhead expenses, including Offer expenses.	**Section 3.11**
Is the Offer underwritten?	No, the Offer is not underwritten.	**Section 7.3**
What are the tax implications of investing in Shares?	The tax consequences of any investment in the Shares will depend upon an investor's particular circumstances. An overview of Australian tax considerations is set out in Section 9.17, however applicants should obtain their own tax advice prior to deciding whether to invest.	**Section 9.17**
How can I apply?	Applications for new Shares offered under the Offer may only be made on the appropriate Application Form attached to and forming part of this Prospectus. Please read the instructions on the Application Form carefully before completing it.	**Section 7.4**

Question	Answer	Location in this Prospectus
When will I receive confirmation that my application has been successful?	It is currently expected that initial holding statements will be mailed by standard post on or about 8 July 2021.	**Section 7.3**
What are the conditions to the Offer?	The Offers under this Prospectus are conditional upon the following events occurring: (a) the Company raising $8,000,000 under its Broker Firm Offer; and (b) the Company being granted conditional approval to list on ASX within three months of the date of this Prospectus (or any longer period permitted by law). There is no guarantee that ASX will grant this approval. If these conditions are not satisfied then the Offer will not proceed and the Company will repay all Application Money received under the Offers, without interest, in accordance with the Corporations Act.	**Sections 7.3 and 7.8**
What is the minimum Application size under the Offer?	The minimum Application size under the Offer is $2,000, being an Application for 8,000 Shares. There is no maximum Application size under the Offer.	**Section 7.3**
Where can I get more information about this Prospectus or the Offer?	Enquiries in relation to this Prospectus may be directed to the Share Registry on 1300 288 664 (toll free within Australia) or +61 2 9698 5414 (outside Australia) from 9am until 5pm (Sydney time) Monday to Friday. Enquiries in relation to the Broker Firm Offer should be directed to your broker. If you are unclear in relation to any matter or are uncertain as to whether the Company is a suitable investment for you, you should seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.	**Section 7.3**

1.8 Directors

Question	Answer	Location in this Prospectus
Who are the directors?	• **Jayne Shaw**, Executive Chair • **The Hon Ron Phillips AO**, Non-independent Non-Executive Director • **Dr Merilyn Sleigh**, Independent Non-Executive Director • **Jonathan Trollip**, Independent Non-Executive Director • **Mark Burrows AO**, Independent Non-Executive Director (to be appointed on the Company's admission to the Official List)	**Section 6.1**

1. Investment overview continued

1.9 Significant interests of key people and related party transactions

<table>
<tr><th>Question</th><th>Answer</th><th>Location in this Prospectus</th></tr>
<tr><td>Who are the substantial shareholders and what will their interests be at Completion of the Offer?</td><td>Following Completion of the Offer, it is anticipated that the following Shareholders (including the interests of their associates) will hold greater than 5% of the share capital in the Company:
<table><tr><th>Shareholder</th><th>Shares</th><th>Percentage interest (approximate)</th></tr><tr><td>Jayne Shaw</td><td>27,569,602</td><td>13.88%</td></tr><tr><td>The Hon Ron Phillips AO</td><td>26,514,567</td><td>13.35%</td></tr><tr><td>The Trust Company (Australia) Ltd</td><td>17,420,171</td><td>8.77%</td></tr></table>The above assumes no additional participation by these Shareholders in the Offer.
Final holdings of all Substantial Shareholders will be notified to ASX on the Company's listing.</td><td>Section 9.14</td></tr>
<tr><td>What relevant interests do the Directors hold in the securities of BCAL and what benefits do they receive?</td><td>Set out below are details of the interests of the Directors in the Shares and other securities of the Company immediately prior to lodgement of the Prospectus with the ASIC for registration. Interests include those held directly by Directors in their own names and indirectly by their associates and/or entities that they control.
<table><tr><th>Name and position</th><th>Annual remuneration</th><th>Shares</th><th>Options</th></tr><tr><td>Jayne Shaw, Executive Chair</td><td>$180,000</td><td>27,569,602</td><td>2,022,638</td></tr><tr><td>The Hon Ron Phillips AO, Non-Executive Director</td><td>$50,000</td><td>26,514,567</td><td>2,022,638</td></tr><tr><td>Jonathan Trollip, Non-Executive Director</td><td>$50,000</td><td>3,147,649</td><td>1,155,793</td></tr><tr><td>Merilyn Sleigh, Non-Executive Director</td><td>$50,000</td><td>Nil</td><td>Nil</td></tr><tr><td>Mark Burrows AO, Non-Executive Director</td><td>Nil</td><td>442,908</td><td>Nil</td></tr></table>Assuming no Director participates in the Offer, the above Shares will represent approximately 29.0% of the Share capital on issue following Completion of the Offer.</td><td>Section 6.4.3</td></tr>
<tr><td>What escrow arrangements are in place?</td><td>In total, assuming no Oversubscriptions, approximately 51.8% of the Shares on issue on Completion of the Offer will be subject to ASX mandatory escrow arrangements, for varying periods.
A further proportion of Shares may also be subject to voluntary escrow arrangements.</td><td>Section 7.7</td></tr>
</table>

Question	Answer	Location in this Prospectus
What related party transactions and other benefits for other parties exist?	Other than the usual contractual arrangements, including a contract with Jayne Shaw as Executive Chair, appointment letters for the other Directors, and deeds of indemnity, there are currently no material agreements between BCAL and its Directors, or other related parties. Advisors and other service providers are entitled to fees for services rendered in relation to the Offer as set out in this Prospectus. At successful Completion of the Offer, the Lead Manager will be given the right to subscribe for fully paid ordinary shares equivalent in value to 3.25% of the post-money fully diluted valuation of the Company at the time of the Offer. The Shares will be issued for $0.0001 per share.	**Sections 6.4.2, 6.5 and 9.12**

2. Industry overview

2. Industry overview

2.1 Introduction

BCAL is a company focused on the development of a non-invasive blood based *in vitro* diagnostic (**IVD**) technology to detect breast cancer. BCAL's initial focus is to achieve Australian regulatory approval for its diagnostic product to be employed alongside traditional mammography. Using sequential trials, BCAL intends to then expand the range of proven uses for its test product. Depending on the outcome of these trials, BCAL aims, as far as possible, to improve international breast cancer diagnosis and management for every woman, everywhere.

BCAL's approach focuses on confirming a "fingerprint" of lipid biomarkers extracted from extracellular vesicles preparations enriched from a patient's blood sample, as a means to diagnose the presence of breast cancer cells in a patient's body.

The Company is developing this new diagnostic approach, seeking to:

- improve the accuracy of breast cancer detection; and
- reduce the rate of false positives and false negatives.

If BCAL is able to demonstrate successful use of its product as a test alongside mammography, it will seek additional regulatory approvals so its technology can offer an alternative test to mammography that is accessible to all women, including those who:

- elect not to attend screening using mammography;
- are under the usual age for mammography screening;
- are in rural regions or areas that do not provide mammography services; or
- are in demographics where mammography is less culturally acceptable (accounting for ~50% in some parts of Australia and significantly higher in other regions).

Key drivers for BCAL will be the accuracy, ease of use, potential breadth of application, and cost of its product as against other technologies available now or in the future.

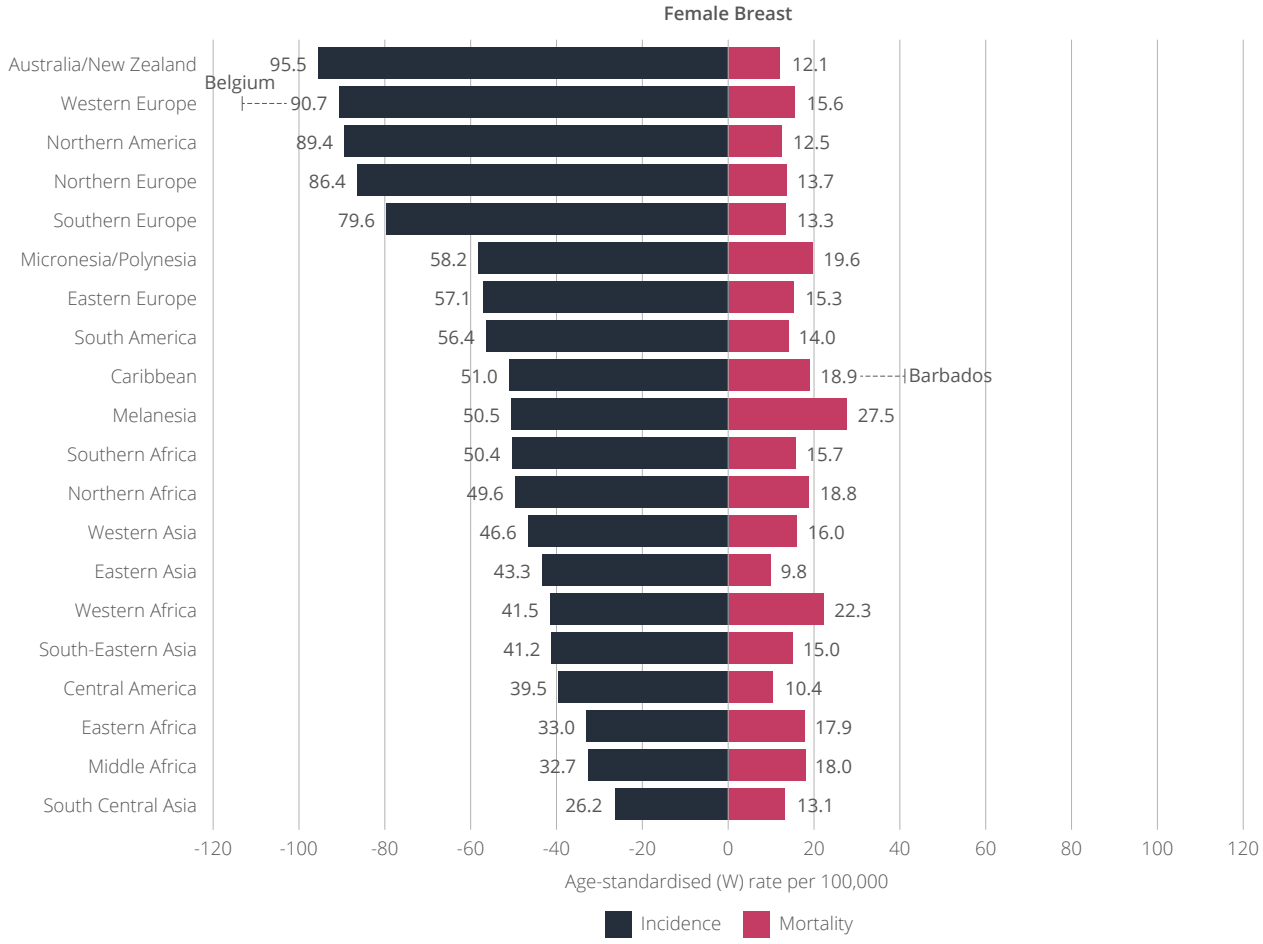
2.2 Breast cancer testing products globally

Breast cancer is the most common cancer among women globally according to the World Cancer Research Fund International, with more than 2 million new cases of breast cancer registered annually (approximately 20,000 in Australia and 250,000 in the USA), with ~627,000 resulting deaths (3,000 in Australia and 40,000 in the USA).

Globally, breast cancer accounts for 25% of all cancer cases and 15% of all cancer deaths in women. In developing economies, breast cancer accounts for approximately 55.6% of all cancer cases and 62.1% of cancer deaths. Breast cancer incidence rates vary substantially by world region, as set out in Figure 1 below. Access to early screening, diagnosis, and management, together with improved treatments, may explain the international disparities in breast cancer mortality trends. Later diagnosis and poorer outcomes for breast cancer patients in developing countries is thought to be due to the lack of access to mammography, availability and quality of primary healthcare facilities, and the psychological and social impacts of treatments, particularly mastectomy.

2. Industry overview continued

Figure 1: Breast cancer incidence and mortality by geographic region



Source: Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, Sung et al., 4 February 2021, available at https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21660

2.3 The growing demand for breast cancer testing products

The American Cancer Society estimates[3] breast cancer to be the most common type of cancer in the USA, with approximately 281,550 cases in 2021, leading to 43,600 deaths that year. While the USA has the world's highest demand for diagnostics in this area, the high costs associated with current breast cancer screening technology has tended to limit growth. Demand for North American breast cancer screening was valued at over US$2 billion in 2019 and is projected to reach US$2.8 billion by 2027; with a compound annual growth rate (**CAGR**) of 5.1% from 2020 to 2027. This increase is attributed to the growing prevalence of breast cancer, investments in rapid technological advancements, and well-established diagnostic infrastructure and initiatives for breast cancer management.

High patient awareness is also driving requests for testing to increase early detection and help reduce cancer mortality rates. Medical professionals, market players and government authorities are implementing new diagnostic and treatment facilities, and breast cancer screening plays a significant role in determining suitable procedures and required pace of treatment.

3. American Cancer Society, How Common Is Breast Cancer? available at: https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html

Global demand for breast cancer diagnostics was valued at just under US$5 billion in 2019 and is anticipated to expand at a CAGR of 7.3%, reaching an estimated size of US$8.7 billion by 2027[4]. The Asia Pacific region is projected to see the biggest increase in demand for diagnostics over the next five to ten years due to unmet clinical needs for a large population. Rapidly improving healthcare infrastructure and awareness regarding early diagnosis are expected to drive the demand for diagnostics.

The drivers of growth include (but are not limited to):

- significantly, technological advancements anticipated to enable diagnostics' enhanced accuracy, cost-effectiveness and portability;
- a significant increase in detection of breast cancer, due to growing awareness among healthcare professionals and patients regarding early detection, and differentiation of particular groups of women carrying identified risk factors;
- the growing insurance coverage and reimbursement for breast cancer diagnostics in Western countries such as Australia, the USA and in Europe.

Improvements in therapeutic approaches and patient awareness have emphasised the importance of early detection for effective treatment with a corresponding growth in global breast cancer diagnostics. Demand continues to grow in developing economies for cost effective diagnostic tools that are easier to use.

In 2019, the risk of a woman being diagnosed with breast cancer by their 85th birthday was estimated to be one in seven. Breast cancer is female centric, but one in 675 males may also develop the disease.[5] Overall, each woman's individual breast cancer risk depends upon several factors, including family history, obesity, genetics and age of first menstruation.[6]

As risk factors are confirmed, they identify particular groups being targeted for new screening and evaluation testing tools. An example is the development of deoxyribonucleic acid (**DNA**) testing to identify women carrying one of the breast cancer (**BRCA**) gene mutations which predispose them to developing breast cancer. This test identifies a group of women who require more frequent breast cancer screening.

While various screening procedures detect breast cancer at an early stage, imaging can pose certain risk factors. Risks include excessive administration of barium and fluorescent contrast agents and radiation exposure in endoscopic and imaging procedures, which may cause numerous adverse effects such as diarrhoea and nausea as well as longer term damage from radiation. The cost of traditional breast cancer diagnostics is also quite high when compared with technologies focused on population-based screening such as prostate specific antigen for prostate cancer, or faecal occult blood test for bowel cancer. Consequently, there is opportunity to develop cost competitive early detection technologies that may be used across all economies.

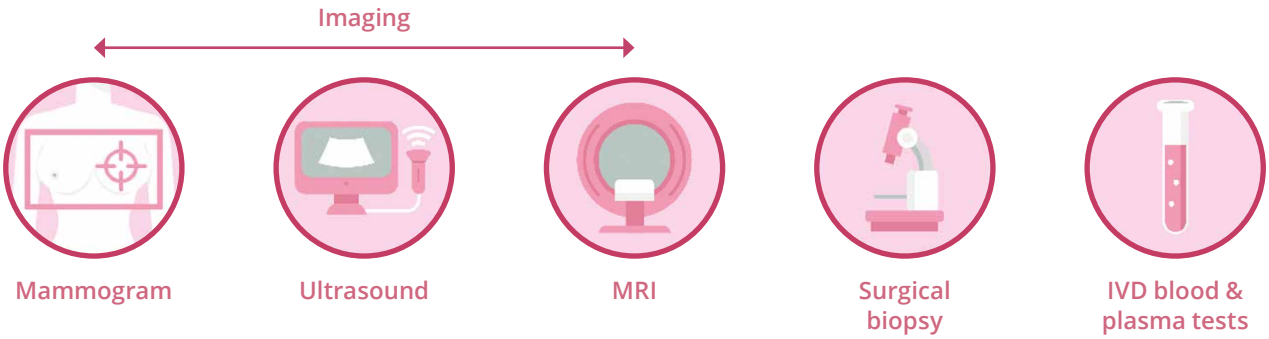
4. Breast Cancer Diagnostics Market Size, Share & Analysis, 25 November 2020, available at: https://www.reportsanddata.com/report-detail/breast-cancer-diagnostics-market
5. Breast Cancer Network Australia, Current breast cancer statistics in Australia, 1 January 2019, available at: https://www.bcna.org.au/media/7111/bcna-2019-current-breast-cancer-statistics-in-australia-11jan2019.pdf
6. Menarche, menopause, and breast cancer risk: individual participant meta-analysis, including 118 964 women with breast cancer from 117 epidemiological studies, The Lancet Oncology, November 2012, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3488186/

2. Industry overview continued

2.4 Different classes of breast cancer testing

There are two types of breast cancer diagnostics: the screening evaluation (for early detection and to indicate the presence of disease, such as traditional mammogram screening), and the diagnostic evaluation (definitive diagnosis, such as biopsy). These can be further divided, according to the technology used, into the following segments:

- imaging, including ionizing breast imaging technologies and non-ionizing imaging technologies;
- surgical biopsy;
- IVD blood or plasma tests.



2.4.1 Current approaches using imaging technology

Currently, imaging using mammography is the primary screening method for breast cancer. Breast ultrasonography and MRI imaging techniques are also used as supportive tests to mammography, along with other genetic and laboratory tests to determine the severity and location of the disease, as well as assisting in the selection of a suitable treatment regimen.

It is estimated that around 70% of women older than 45 years in the USA have mammograms periodically. While it is not uncommon for a mammogram to require additional follow up, fewer than 10% of those called back for further testing are found to have cancer. The only way to make a definitive cancer diagnosis is by breast biopsy. However, in some cases, such as high-risk lesions, pathologists may not be able to make a definitive diagnosis of cancer based on the initial biopsy alone. Of those referred for biopsy, approximately 80% of lesions detected by imaging are shown to be benign.

Not only does mammography yield many false positive results, but it is estimated that approximately 20% of breast cancers are missed at the time of screening. These false negative results tend to be more common in women who have dense breast tissue, particularly women under the age of 40.

While mammography is the current gold standard for routine screening, it has a number of disadvantages including that it is:

- uncomfortable and often painful, which contributes to low participation rates. In Australia approximately 50% of eligible women self-exclude from screening, and this is higher in other countries and within some cultural demographics;
- subjective (mammograms often requiring a “double read” to increase accuracy);
- unavailable in remote locations; and
- dependent on some level of x-ray radiation, limiting the frequency with which it should be used on individuals.

Research has shown that yearly screening detects more early stage cancers with better patient outcomes, but the usual regime for mammography screening is testing every 2 – 3 years.

Mammography is also expensive (particularly for government funded outreach programs) due to the equipment involved, skilled staff required, time taken, and the need for the woman to be physically present for the procedure. Mammography’s reported costs per test vary widely but are typically estimated in the range of US$150-200 per screen, depending on test site. New technologies such as ultrasound and MRI are now also available, and while these can extend the age range of screening to younger women, they remain excessive in cost (US$200-300 per screen) and require specific expertise to operate machinery and interpret the results.

Advantages and disadvantages of different imaging technology currently in use.

Imaging Modality	Advantages	Disadvantages
Mammography: First-line screening tool	Widely accepted method for early detection	Exposure to radiation, operator-dependent, inaccessible in remote areas, high false positive/negative outcomes, intrusive and can also miss cancers such as infiltrative lobular carcinoma
Ultrasound: Complement to Mammography	No radiation, widely available, increased sensitivity* when combined with mammography	Highly operator-dependent, difficult-to-interpret, increased false positives
Tomosynthesis: 3D Mammography	Increased sensitivity*, fewer false positives	More radiation, some cancers obscured in dense breasts, lower sensitivity for detecting microcalcifications
Breast MRI	Increased sensitivity*, ability to evaluate palpable masses not visible on mammogram or ultrasound	Limited specificity** due to enhancing benign breast lesions, increased false positives

* Sensitivity means the ability of a diagnostic test to correctly identify those with the disease (true positive rate).

** Specificity means the ability of a diagnostic test to correctly identify those without the disease (true negative rate).

2.4.2 Current approaches: biopsy

Following positive results from imaging, the next step in breast cancer diagnosis is for a woman to undergo a biopsy. This is a surgical procedure that removes tissue or sometimes fluid from the suspicious area. The removed cells are examined under a microscope and further tested. A biopsy is currently the only diagnostic procedure that can definitively determine if the suspicious area is cancerous.

2.4.3 Emerging approaches: *in vitro* diagnostics (IVDs) for breast cancer

IVDs are used to detect the presence or absence of biomarkers, which can be detected in any substance obtained from the body, preferably blood or plasma, that may indicate something about a person's health. Cancer biomarkers identify the presence and/or status of specific cancers, using information specific to that cancer resulting from the tumour's growth, division, or dissemination.

There are a number of IVDs (using whole blood samples) both in development and in use for breast cancer screening and diagnosis. These include tests identifying DNA, ribonucleic acid (**RNA**), carbohydrates, lipids and proteins, separately, or in combination, to detect changes attributable to breast cancer when compared to a healthy patient sample.

Although there is not yet a definitive blood IVD for breast cancer, there are numerous IVD research studies underway globally by research institutes and other key players.

2. Industry overview continued

There are other companies, based in Australia and internationally, which are seeking to develop IVD cancer diagnostics via blood tests. These companies and their products are at varying stages of development. Based on publicly available information, the Company's main competitors active in the blood test IVD cancer diagnostics are highlighted in the table below:

Name and diagnostic focus	Stage of development	Website
Provista Diagnostics (Breast cancer)	Commercially available in the USA	www.provistadx.com
BARD1 Life Sciences (Multiple cancers, including breast)	Breast cancer product development stage (not yet commercially available)	www.bard1.com
GRAIL (Multiple cancers, including breast)	Commercially available in the USA	www.grail.com
Rhythm Biosciences (Colorectal cancer)	Development stage (not yet commercially available)	www.rhythmbio.com

BCAL's approach differs from the above competitors in that BCAL is focused on the population of lipid molecules in the blood as markers of breast cancer occurrence. Lipids (fats) are organic compounds found in membrane structures, with a multiplicity of roles in cell regulation, growth, and development. There are many different families of lipid types, and each family may be made up of scores of different chemical entities.

Studies in breast cancer have also shown some links between lipids and breast cancer diagnosis and progression. Several studies in this emerging field, providing the basis for work carried out by BCAL, have:

- identified various lipid subtypes (families) that show significant differences in plasma concentration between breast cancer patients and control subjects with benign breast lesions;
- observed the plasma concentrations of phosphatidylcholine (**PC**) and ether-linked PC classes increase in patients with breast cancer; and
- shown that extracellular vesicles, including microvesicles and exosomes, particles that bud from breast cancer cells, are rich in different components including lipids.

BCAL's challenge has been to identify which families and which specific components of the families show a changed (up or down) profile in blood from people with breast cancer, compared with the profile seen in healthy individuals.

BCAL has extended the previous work by identifying a lipid biomarker signature that is present in blood from patients in the early stage of invasive ductal carcinoma (**IDC**) breast cancer, distinguishable from that of a patient without breast cancer. BCAL has further developed a test procedure, by which the lipid-containing vesicles and exosomes in plasma from a blood sample are concentrated, and processed to liberate the lipid components. The profile of lipids in the sample extract is then established following mass spectrometry analysis to determine whether the profile found is characteristic of that from patients with breast cancer, or the different profile seen in subjects without any cancer.

BCAL's progress in identifying an ideal set of blood plasma lipid biomarkers for diagnosing breast cancer is outlined in more detail in Section 3 of this Prospectus.

2.5 The breast cancer testing customer base

2.5.1 By service provider

Breast cancer screening and evaluation diagnostics testing is conducted in laboratories, private or public, with appropriate and often expensive technical equipment, and staffed with trained and qualified personnel to perform the tests. There are two key service providers within breast cancer diagnostics:

- Hospitals dominated breast cancer diagnostics in 2019. Their high percentage share was a result of well-resourced operating and diagnostic rooms, higher purchasing power, access to skilled healthcare professionals including oncologists to perform and evaluate biopsies, and improved health coverage for hospital-based healthcare services under several private and group insurance plans.
- Independent, for-profit and not-for-profit laboratories or diagnostic clinical laboratories are the second largest service provider within breast cancer diagnostics. These facilities provide analytical operations, courier services to and from doctor's offices and other care institutions including hospitals, and return results within short turnaround times. These facilities tend to provide services for patients referred by general practitioners and specialists.

2.5.2 The potential for a diagnostic test for breast cancer, to be used alongside screening mammography

False positive results on screening mammography have multiple patient care and economic consequences, because of the cascade of diagnostic studies that may result. Follow up tests include diagnostic mammography, ultrasound, image guided biopsy, and surgical excisional biopsy. False negative results on screening mammography are also problematic due to the risk of failing to diagnose a cancer. An accurate diagnostic product used for triaging women with suspicious mammographic findings, prior to biopsy, would be an important step in improving breast cancer management for patients, as well as lowering overall health care costs.

With over 65% of USA women over the age of 40 undergoing screening mammography annually, a false positive rate of 10% can amount to over US$1 billion in unnecessary health care treatments. Of these, the largest proportion is attributable to the many breast biopsies performed.[7] While the majority of suspicious lesions identified on imaging are diagnosed by a percutaneous core-needle biopsy (**PCNB**) and do not require further surgical intervention, a sizable percentage of women still require open biopsy or lumpectomy for diagnosis. Analysis indicates that 23.7% of patients with one open procedure and 6.3% of those who underwent re-excision were not ultimately diagnosed with cancer.[8]

Decreasing the number of unnecessary breast biopsies may lead not only to improved patient experience, but also to significant reductions in health care costs.

Health economic modelling indicates that, if used alongside traditional screening mammography, a diagnostic product with 95% sensitivity, 75% specificity, and a cost of US$1,000 or less would eliminate 8,127 unnecessary breast biopsies per million women screened.[9] This analysis indicates this kind of adjunct test, once validated, could also be acceptable for younger women in the mammography screening population (aged 40–49 years). The use of a diagnostic tool by younger women alongside screening mammography would result in many biopsies ultimately revealing benign lesions being avoided, a lower overall burden on health care systems, and a greater focus on effective identification of cancerous lesions after screening mammography[10]. An additional screening approach may also help women in underserved regions and women who choose to self-exclude from mammography.

When developing new adjunct tests, increasing overall specificity in the detection of breast cancer is critical for a corresponding decrease in the health care burden associated with screening and diagnosis. The current USA costs for PCNB and open biopsy or lumpectomy for diagnosis suggest the incremental cost of performing a lumpectomy vs biopsy alone (US$13,190), and the patient out of pocket costs (US$858) would also create significant savings if the initial biopsy could be avoided altogether.[11]

7. Performance Goals for an Adjunct Diagnostic Test to Reduce Unnecessary Biopsies After Screening Mammography: Analysis of Costs, Benefits, and Consequences, Lee et al., Journal of the American College of Radiology 2013; 10: 924-930, available at: http://dx.doi.org/10.1016/j.jacr.2016.09.032
8. The Payer and Patient Cost Burden of Open Breast Conserving Procedures Following Percutaneous Breast Biopsy, Kimball et al., Breast Cancer (Auckl). 2018; 12: 1178223418777766, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5989052/.
9. Performance Goals for an Adjunct Diagnostic Test to Reduce Unnecessary Biopsies After Screening Mammography: Analysis of Costs, Benefits, and Consequences, Lee et al, Journal of the American College of Radiology 2013; 10: 924-930, available at: http://dx.doi.org/10.1016/j.jacr.2016.09.032
10. ibid.
11. The Payer and Patient Cost Burden of Open Breast Conserving Procedures Following Percutaneous Breast Biopsy, Kimball et al., Breast Cancer (Auckl). 2018; 12: 1178223418777766, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5989052/.

2. Industry overview continued

The most desirable profile for an IVD test for screening for breast cancer, to be used alone or in combination with mammography, would be:

- safe, non-invasive and widely accessible;
- as a routine screen, able to identify the presence of breast cancer-related lesions, limited to those that are cancerous only (no false positives);
- useful for monitoring the response to anti-cancer therapy; and
- useful as a routine screen for monitoring any re-emergence of cancer over time – much like the use of the PSA test following treatment for prostate cancer.

2.6 Regulation of breast cancer *in vitro* diagnostics (IVD)

IVDs are clinical tests analysing samples taken from the human body. Patients may receive, or forgo, medical care based on test results, making it critically important that the results are reliable. IVD tests (and any associated learning software or artificial intelligence in their own right) are considered medical devices by international regulatory agencies.[12] They may be reagents, techniques, instruments, or a combination of these, used to examine specimens such as blood, urine, or tissue, with the goal of obtaining a diagnosis from tests in an environment outside a living organism.

2.6.1 Australia

Australia will be the first country in which BCAL will seek regulatory approval for introducing its IVD for breast cancer. BCAL is exploring parallel regulatory approval approaches to accelerate the commercialisation of its test in Australia, with an initial claim (or intended use) for the test to be used as "an adjunct to mammography". The Australian regulatory approval pathways are included in the "Regulatory Pathways for Australia, EU and USA" diagram included at Figure 3 below.

1. BCAL will undertake its sequenced feasibility (analytical performance) study followed by a pivotal clinical performance study to prove the test's intended use. This will determine the accuracy, sensitivity and specificity of the test and its clinical utility as an adjunct to mammography.
2. BCAL intends to work on co-development with one or more clinical laboratory networks in Australia for an in-house *in vitro* diagnostic test (also known in Australia as an in-house IVD, and in the USA as a laboratory developed test, or **LDT**). This pathway uses the selected laboratory to validate the test on behalf of BCAL according to the National Pathology Accreditation Advisory Council (**NPAAC**) guidelines. Once validated, it is approved by the National Association of Testing Authorities (**NATA**) and then the test may be used only within that laboratory network. Supplementary real-world data and any revenue from the LDT pathway will also contribute to the sequenced clinical study program (analytical performance then pivotal) described above.

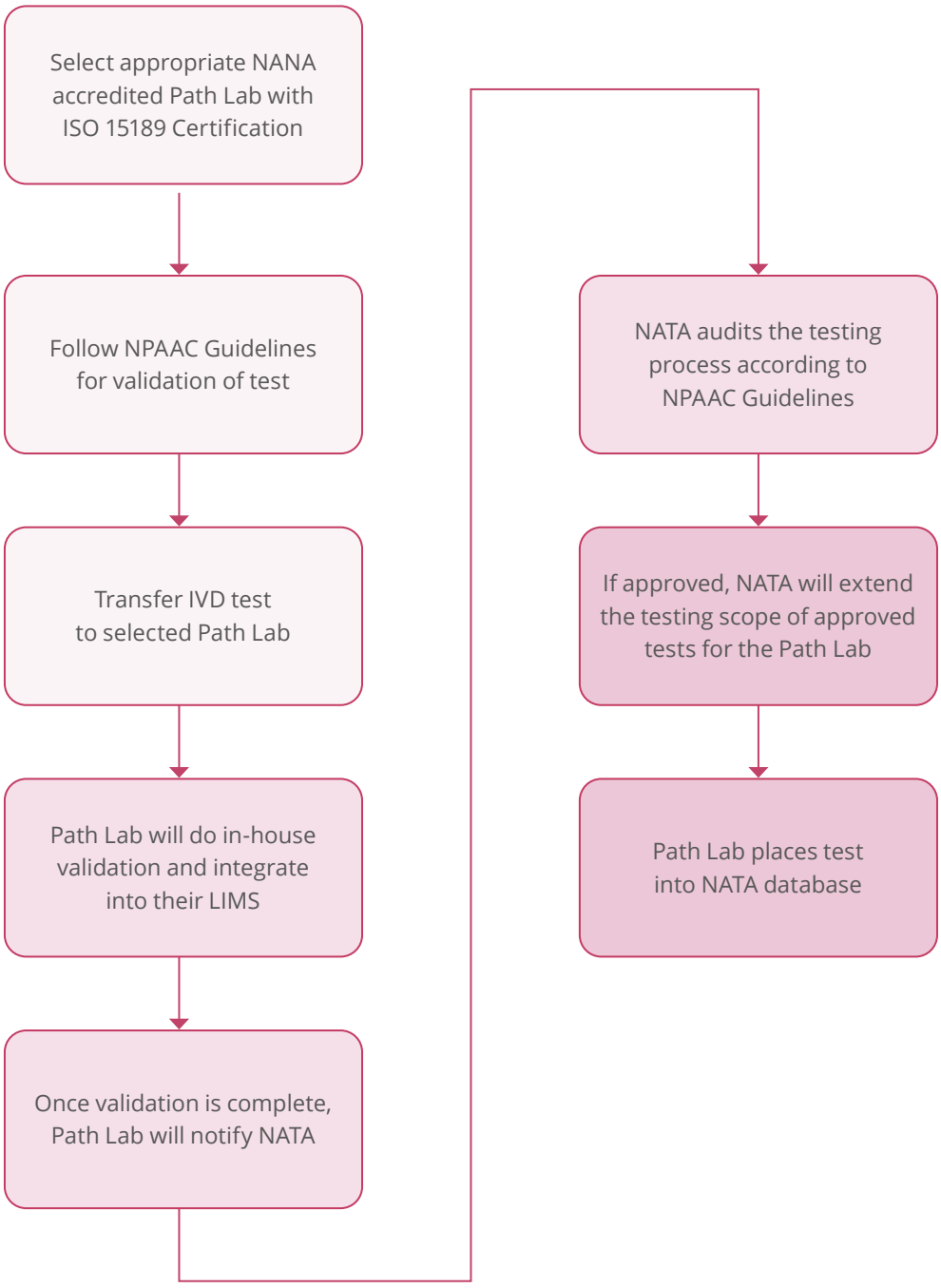
Once the clinical study has ended, the data is analysed and undergoes what is referred to as a conformity assessment. The IVD will need to comply with the TGA's set of "Essential Principles".

The TGA would then review BCAL's Technical File (a combination of analytical and clinical performance data) and the IVD's compliance to a set of 'Essential Principles of Safety and Performance' that, when met, provide assurance that the IVD medical device is safe and performs as intended.

Any TGA applicant such as BCAL must also implement and maintain its QMS in compliance with ISO 13485 (an International Standard that is mandatory for the development and manufacturing of medical devices and IVDs). As part of its TGA application process, BCAL intends to seek approval utilising the TGA's priority review designation pathway.

12. See references in section below by jurisdiction.

Figure 2: Flowchart of the NATA pathway



2. Industry overview continued

2.6.2 United States of America (USA)

2.6.2.1 USA regulation by FDA

While BCAL's first approvals will be sought in Australia, the largest potential demand for breast cancer IVD diagnostics is in the USA.

- To enter the USA market, BCAL will have to determine if there is a predicate for the product, which on the information currently available is unlikely. If there were a predicate on the market, BCAL could submit what is referred to as a 510(k) application, along with Medical Device Single Audit Program (**MDSAP**) certification provided by a Notified Body to get into the US Market.
- To seek clarity on whether a predicate on the market exists, BCAL could submit an FDA 513 (g)* application. If a predicate is found, BCAL would then submit a 510(k) application along with the MDSAP certification to enter the US market.
- If there are no predicates on the market, BCAL could submit an FDA De Novo** application. If the De Novo application is accepted, BCAL can submit a 510(k) application along with MDSAP certification for FDA approval. If the De Novo application is rejected, BCAL would be required to put forward a Pre-Market Approval (**PMA**)*** application, along with the MDSAP certification to receive FDA approval.

* Device manufacturers typically submit a 513(g) request to determine whether the regulations pertain to a product and whether a device is subject to the 510(k) regulations.

** The De Novo pathway for device marketing rights was added to address novel devices of low to moderate risk that do not have a valid predicate device. Upon successful review of a de novo submission, FDA creates a classification for the device, a regulation if necessary, and identifies any special controls required for future premarket submissions of substantially equivalent devices.

***PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III IVDs, and the most stringent of the IVD marketing applications.

2.6.2.1 USA regulation by CMS under CLIA[13]

An alternate pathway for the USA is via regulation under the Center for Medicare & Medicaid Services (**CMS**), which administers the *Clinical Laboratory Improvement Amendments of 1988* (**CLIA**)[14] program. The CLIA program regulates laboratories that perform testing on patient specimens in order to ensure accurate and reliable test results.

Under the CLIA regime, a laboratory which uses a test that has not received FDA clearance or approval (such as an LDT) must also itself be CLIA approved. It is possible for applicants to seek approval from the FDA and under the CMS CLIA regime simultaneously.

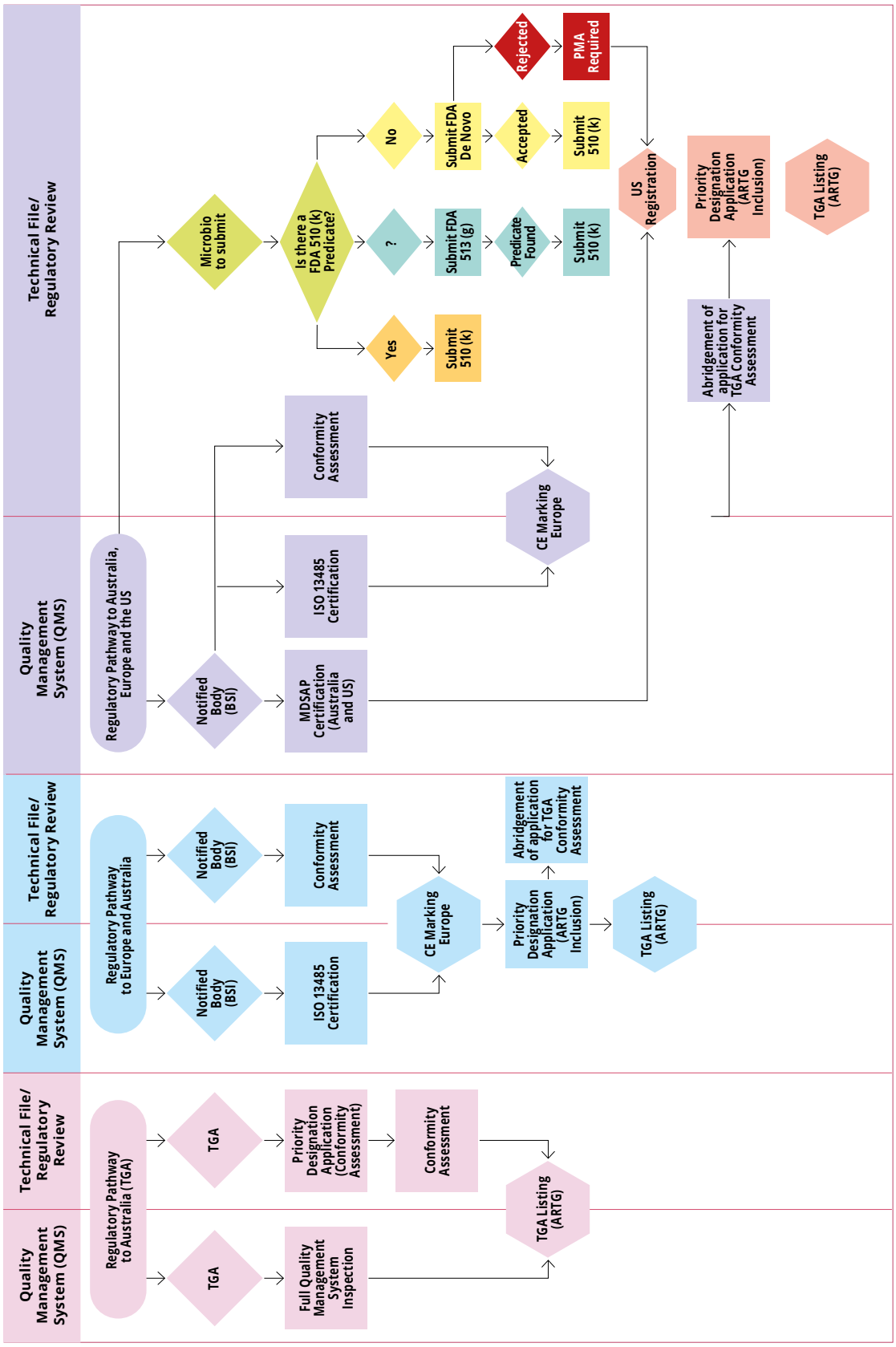
2.6.3 Europe

CE Marking approval is required for all IVDs sold in Europe. CE Marking indicates that an IVD complies with Europe's new *In Vitro* Diagnostic Regulation (IVDR 2017/746) (**IVDR**) to be legally sold in the EU. A separate application for approval in the UK (utilising the same data as for the EU application) will also be required. To seek CE Marking approval, the process for conformity assessment and approval would be:

- for an applicant such as BCAL, to select an EU Notified Body (for example, BSI) to carry out an audit of BCAL's Quality Management System, which will provide BCAL with ISO 13485 certification;
- that Notified Body will carry out an audit and review BCAL's Technical File (a combination of analytical and clinical performance data and the IVD's compliance to a set of 'Essential Principles of Safety and Performance' (**Principles**) that, when met, provide assurance from the manufacturer that a medical device and IVD medical device is safe and performs as intended. These Principles provide broad, high-level, criteria for design, production, and postproduction throughout the life cycle of all medical devices and IVD medical devices, ensuring safety and performance. Compliance with the Principles, via the use of applicable standards throughout a product's lifecycle, (including, where appropriate, a pre-market review), is the approach for applying controls relative to a device's safety and performance.

13. US Food and Drug Administration, Overview of IVD Regulation, available at: https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation#2
14. Mark Burrows AO is to be appointed as an independent, Non-Executive Director on and from BCAL's listing on the ASX.

Figure 3: Flowchart comparison of regulatory pathways for Australia, USA and EU



3. Company overview

3. Company overview

3.1 Company history and overview

The core BCAL technology has evolved from extensive research and investment over ten years by independent groups based in the USA and Australia.

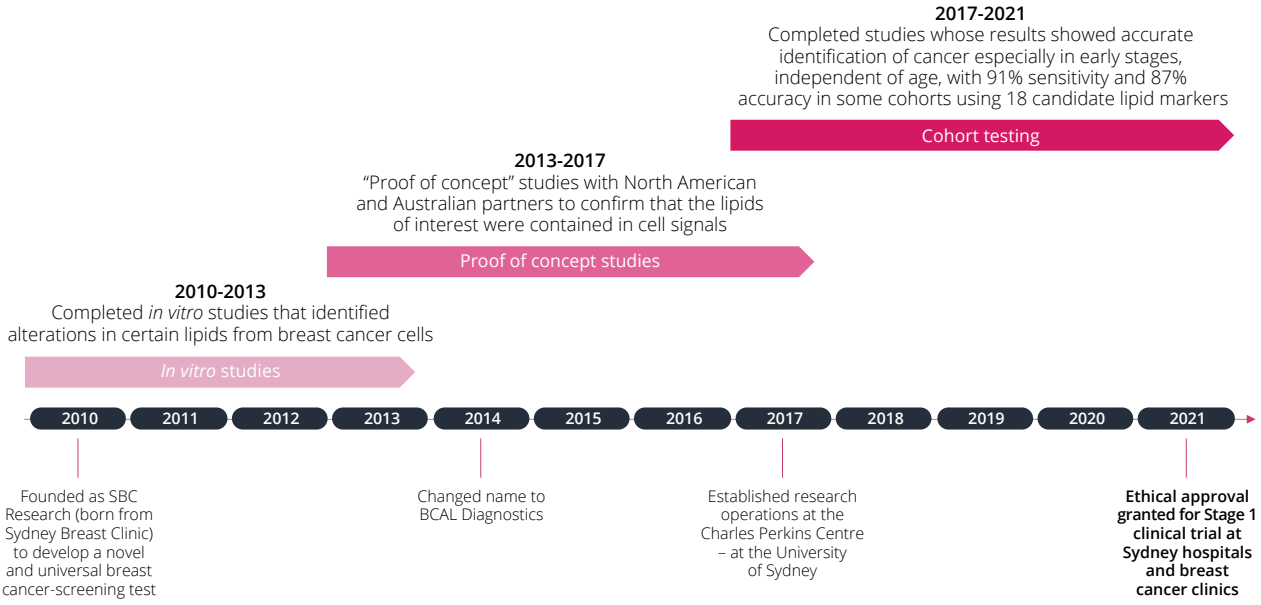
Researchers from the University of Louisville Research Foundation, Inc (**ULRF**) were able to show that breast cancer patient samples contain significantly different phospholipid profiles from those of both healthy volunteers and lung cancer patients using a defined methodology. In 2011 ULRF filed a patent application using this data. Working independently in Sydney, BCAL's science team observed a similar trend in their own research, and as a result the Company decided in 2013 to license the technology the subject of patent applications from ULRF (**License Agreement**).

BCAL is developing a non-invasive laboratory blood test for the detection of breast cancer. The Company was established in Australia in 2010 by a group of private investors to develop and commercialise a novel and universal breast cancer-screening test. At that time the Company was called SBC Research Pty Limited, changing its name in 2014.

From 2010 to 2013, BCAL completed a series of *in vitro* studies that identified alterations in the amount of certain specific lipids produced by cells of an aggressive breast cancer cell line grown in the laboratory, compared to a less aggressive control cell line. The lipids could be measured from the liquid medium in which the cells were grown. The cell culture derived data suggested that there might be a biological change involving lipid profile that may be associated with breast cancer.

From 2013 to 2017, BCAL undertook a series of "proof of concept" studies with USA and Australian partners to confirm that the lipids of interest were contained in extracellular vesicles (**EVs**) preparations including exosomes, which bud from the surface of cells. Using mass spectrometry analysis, some altered lipids could be detected in blood samples, suggesting that this approach could be used as a method for diagnosis of breast cancer (and possibly other cancers).

Later in 2017 BCAL established research operations at the Charles Perkins Centre at the University of Sydney, where subsequent research studies have been carried out.



These studies have led to BCAL's current program for diagnostic product development as described in this Prospectus. The program is based on the following key points:

- the hypothesis that cancerous cells in the breast release higher amounts of EVs into the blood stream than normal breast cells, based on previous published work showing that the number of EVs is elevated in cancer patients;
- EVs found in the blood are reported to originate from a variety of cells including, where present, breast cancer cells and cells of the surrounding tissue, and are rich in biological cargo that can be used as disease biomarkers;

3. Company overview continued

- BCAL has developed a core technology process involving:
  - collection of the plasma portion of the blood, within which EVs of interest are found;
  - enrichment of the EVs and extraction of the lipids;
  - analysis of the lipids by mass spectrometry;
  - identification of sets of lipids which differ between blood samples taken from breast cancer (specifically, IDC) patients compared with samples from healthy individuals in case/control studies conducted by BCAL.

Once validated in further studies, it is expected that these unique lipid profiles will form the basis of a blood-based diagnostic test that may be utilised in many aspects of breast cancer detection and management.

The characteristics of the ideal breast cancer diagnostic product for which BCAL is aiming are outlined in Section 2.5.2 above.

The purpose of the Offer is to raise funds to support the Company in completing the next steps needed to advance development of this product and achieve an approved and marketed test.

BCAL collaborates closely with leading clinicians in Australia, and as set out below, funds from the Offer will support the Company's ongoing clinical development plans including the necessary collection of several thousand samples from representative patient cohorts. The sample sizes will be calculated to provide the credible statistics required for initial and future product approvals.

See Section 3.11 for further information in relation to the Company's proposed use of funds from the Offer.

3.2 Development of BCAL's lead product to date

Since late 2017, BCAL has been executing a multi-stage plan in Australia designed to confirm and expand on the proof of concept studies and to develop a reliable, robust, reproducible protocol testing for lipid biomarkers as a detection tool for breast cancer.

Three studies have been undertaken to demonstrate the potential of analysis of EV-derived lipids (lipid biomarkers) as a tool for identifying breast cancer:

	Breast Cancer Disease Segment	Study Design (n = number of samples evaluated)		Lipid markers identified
Cohort 1:	Focused on IDC, which accounts for 70-80% of diagnosed breast cancer cases	n = 88 freshly collected samples	Control: 44 negative controls	392 lipid markers assessed Derived 25 meaningful markers showing differentiation between control and cancer
Cohort 2:	Focused on IDC early Stage 1 and Stage 2	N = 200 freshly collected samples Analysed as: Set 2 n= 99 Set 3 n= 101	Set 2: 36 negative controls Set 3: 64 negative controls	450 lipid markers detected, several differentiating between control and cancer 12 lipid markers defined Algorithm development increased to 18 markers
Cohort 3	Focused on IDC early Stage 1 and Stage 2	201 freshly collected samples Analysed as: Set 4: samples 1-93; n=93 Set 5: samples 94-201; n=108	Set 4: 45 negative controls Set 5: 55 negative controls	800+ lipid markers detected, several differentiating between control and cancer Reproducible in cohorts 2 & 3 narrowed this to 450 18 from cohort 2 + "improved 18" using cohorts 2 and 3

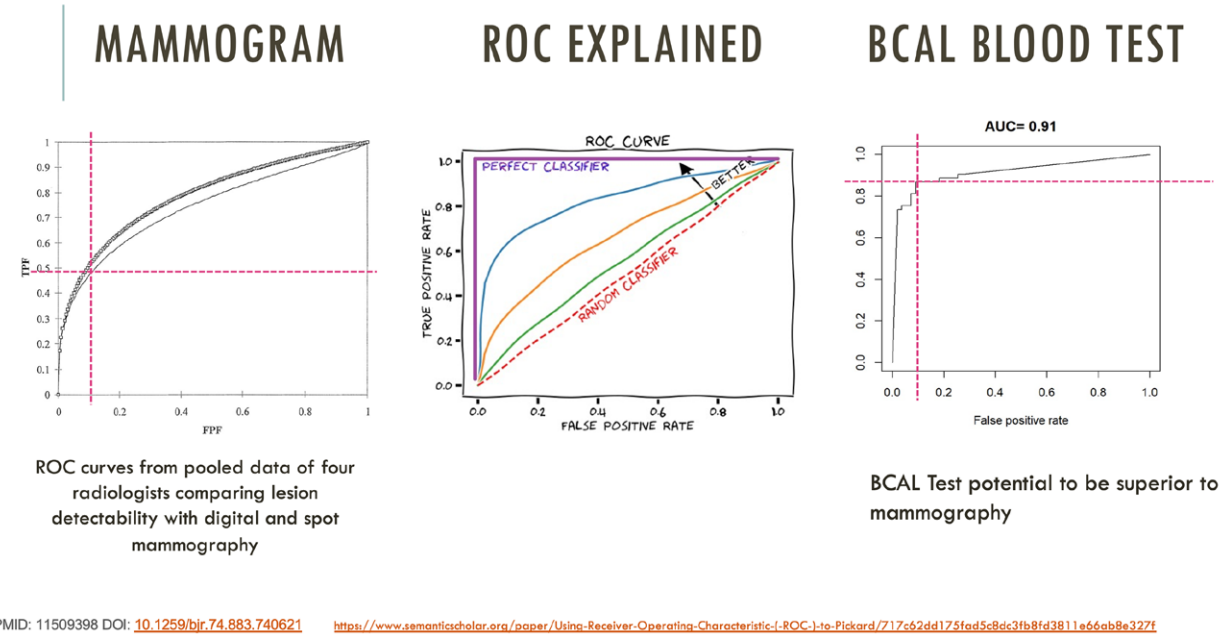
Analysis of the initial marker discovery patient cohorts has demonstrated an initial accuracy of 83% between controls and all IDC stages.

The Cohort 1 data, using an early version of the marker set, supports the ability of the BCAL diagnostic test to differentiate between control and early IDC (Stage 1 and 2) with an initial accuracy of 80% and sensitivity of 83%. The Cohort 2 data reduced a preferred marker set number to 12 candidate markers (with some overlap against the first 25 markers) and 2 clinical variables and differentiated between control and early IDC with an initial accuracy of 85% and sensitivity of 91%.

Cohort 3 was used for validation of the identified markers with minimal further change, and it supported previous studies with accuracy, sensitivity and specificity of 87%, 83% and 91% in the best subset (set 5) and 82%, 81% and 82% in the whole cohort respectively. The area under the curve (AUC) has been as high as 91% for Set 5 and for control vs Stage 2 comparison in Study 3).

As is well known, accuracy when undertaking blinded studies can be initially reduced. This is anticipated to be improved with additional validation using a larger sample set, supporting finalisation of the ideal biomarker panel and processing algorithm.

Figure 4



PMID: 11509398 DOI: 10.1259/bjr.74.883.740621 https://www.semanticscholar.org/paper/Using-Receiver-Operating-Characteristic-(-ROC-)-to-Pickard/717c62dd175fad5c8dc3fb8fd3811e66abBe327f

Figure 4 above provides a comparison of the diagnostic power of mammography in some studies, compared with the potential from the BCAL test in case/control studies. Plotting of the data in a way which highlights the numbers of false positives and false negatives (called a ROC curve – receiver operating characteristic curve) allows for calculation of the effectiveness of the test. The larger the area under the curve, the more effective the test. The central box shows possible variations in a plot of this type where the straight diagonal (red) line would be the result in a test which has zero effectiveness while the purple lines show a test with 100% effectiveness. The results from mammography can be better or worse in different situations and can also depend on equipment available, as well as other variables.

3. Company overview continued

3.3 Introduction and outline of commercialisation – product aims

The overall focus of the products' development life cycle will be to demonstrate analytical performance, clinical performance, and clinical utility of the test against several sequential intended uses (**claims**). Each step is planned to provide the data necessary for progressive stages of regulatory approval and marketing of the test in Australia, and subsequently in other countries. All analytical and clinical performance evaluations (clinical studies) aim to confirm that the BCAL test will be able to deliver the necessary safety and performance characteristics (e.g. sensitivity, specificity, reproducibility and accuracy) to meet all clinical and regulatory requirements.

The future clinical validation of the BCAL assay reflects a cascading product development model under which different claims will be confirmed through clinical trials undertaken to support each individual claim. This approach, with sequential sets of confirmatory results, will seek to ultimately deliver a data set that confirms the safety and accuracy of the BCAL IVD as a comprehensive breast cancer screening for all patients.

BCAL plans, through the IVD development lifecycle, to deliver several iterations of their IVD which will, over time, have the following intended uses:

(1) as "an adjunct to mammography" to provide physicians with an increase in the sensitivity of breast cancer detection;

(2) to monitor breast cancer patients through the disease lifecycle;

(3) to routinely monitor early occurrence and reoccurrence of breast cancer in women who carry the BRCA1 and BRCA2 gene mutations and consequently other groups at high risk of breast cancer; and

(4) ultimately, for comprehensive routine breast cancer screening for every woman, everywhere.

Early detection of curable cancers has been shown to save lives. If successful, the ultimate incarnation of the BCAL test will contribute positively to achieving such early detection, even before a mammogram is undertaken. In particular, the BCAL test will be aimed at providing physicians with further insights at the pre-screening, screening, and post-screening of the mammography stages, helping to confirm those patients that should undergo exploratory biopsies or invasive surgery for the removal of the identified cancer or the associated tissue. If successful, the BCAL test could support setting schedules for further or repeat testing in women potentially at risk, to prevent cancers going undetected in new patients or reoccurring cases. This could be of particular value where mammography results are inconclusive, for women who elect not to attend traditional screening, or for those where traditional screening is inaccessible.

3.3.1 Intended use 1: The BCAL test as an adjunct to traditional mammogram screening

BCAL's first intended use for its test is as a non-invasive test for breast cancer detection as a tool to be used alongside or subsequent to traditional mammography, which aims to improve the accuracy of diagnosis and support patient care following mammography results.

Mammography, the current gold standard for screening to detect breast cancer, has variable sensitivity and specificity, which can be as low as 65% for younger women where breast cancer tends to be more aggressive. The BCAL test results from cohorts so far, as outlined in Section 3.2 above, have returned encouraging results for the accurate identification of IDC, especially in its early stages, without age discriminatory analysis.

The impact of current false negative mammography results indicate a clear need for tests that can work alongside mammograms to improve clinical outcomes and reduce economic burden on the healthcare system.

3.3.2 Intended use 2: BCAL test used to monitor breast cancer patients through the disease lifecycle

BCAL aims to conduct clinical studies designed to establish evidence of lipid biomarkers' function as a monitoring tool. The study will establish a baseline of the lipid profile at the point of diagnosis and monitor for fluctuations after surgery, during and after treatment, and through analysis of the lipid profile from a sequential blood collection at defined time points. The study aims at developing a tool to assist the clinician in monitoring for cancer recurrence, and in 2020, ethics approval was granted.

3.3.3 Intended use 3: BCAL test used to routinely monitor early occurrence of breast cancer in women who carry the BRCA1 and BRCA2 gene mutations and consequently other groups at high risk of breast cancer

Subject to successful clinical results with intended uses 1 and 2 (above) BCAL will look to assess whether the test can be used as an early warning tool for patients with BRCA1 and BRCA2 mutations. BRCA1 and BRCA2 mutations increase the risk of carriers developing breast cancer. If successful, this opens the way for developing the use of the BCAL test as a routine screen, which can be used more frequently and safely than mammography in any group of patients that are at higher risk of disease.

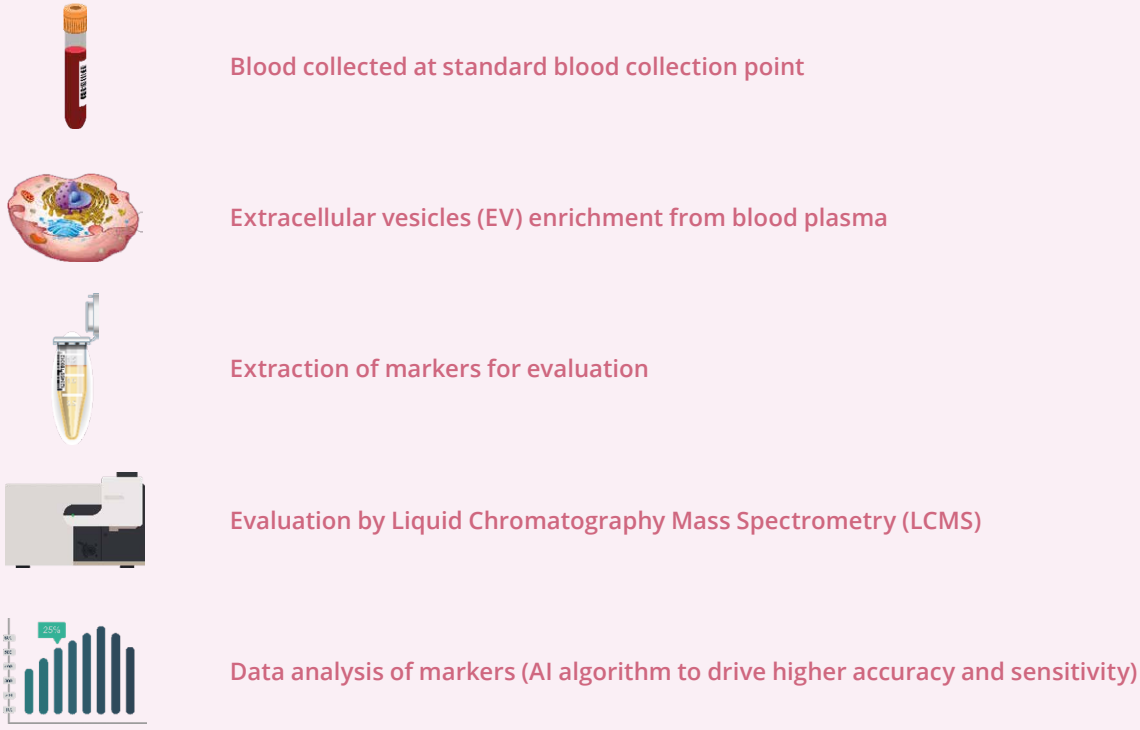
3.3.4 Intended use 4: Comprehensive breast cancer screening for all patients

Subject to successful registration of the intended uses above, BCAL will design further clinical performance evaluations for this intended use: a comprehensive breast cancer screening test for all patients.

The overall aim for this more comprehensive study will be to position BCAL's product as a highly effective "best in class" test for breast cancer detection.

3.4 Assay development and workflow optimisation

BCAL is working to develop a streamlined approach to significantly increase the speed and scalability of the clinical test process, with the expectation that the test product will be launched through pathology laboratories. The following schematic diagram outlines the BCAL test workflow:



Version 1.0:

Current process: extracellular vesicles (**EVs**) are enriched, markers extracted and analysed using BCAL's in-house developed process. This process will be used to validate the fingerprint of the 18 candidate markers and improve the algorithm (see Section 3.5 below).

Version 2.0:

In conjunction with results from the analytical and clinical performance studies, BCAL's research group will work to increase the speed and scalability of the testing process. A final approved product is planned to be used via mass spectrometry accessible to pathology providers.

3. Company overview continued

3.5 Development of the BCAL algorithm

BCAL is developing a machine learning algorithm to better harness the power of artificial intelligence to improve the fingerprint analyses. As study sample numbers increase, so can the ability to learn from the lipidomics data to develop a more accurate breast cancer diagnostic, with the goal of BCAL's test delivering a comprehensive and more advanced diagnostic.

3.6 Product launch in Australia

BCAL is exploring parallel regulatory approval pathways in Australia, as an IVD approved by the TGA and as an in-house IVD (LDT), as described above in Section 2.6.1.

The Australian product launch strategy will look to confirm demand assumptions and could generate first revenues for BCAL, however, revenue generation is not certain. It will also allow BCAL to work with pathology providers in a commercial pathology lab setting.

3.7 Lipid markers as a pipeline to future cancer diagnostic products

BCAL has a License Agreement with ULRF for the use of intellectual property covering the founding technology of its test in breast cancer and lung cancer (Section 9.5.1 below summarises the License Agreement).

A strong body of work also supports the applicability of lipid markers for detection of other cancers. Upon proving the concept in breast cancer, BCAL may pursue lipid biomarker identification for lung cancer in the first instance. Thereafter, new cancer indications such as pancreatic, brain, prostate, ovarian and bladder may be pursued by the Company as line extensions to the lead breast cancer product.

3.8 BCAL's partners in development

BCAL collaborates with key stakeholders in the breast cancer diagnostic market in Australia and internationally. A key differentiator for BCAL is its level of engagement with clinicians. Since BCAL's incorporation, working with clinicians has been crucial to access to opportunities for success in developing a breast cancer diagnostic with clinical utility. The ongoing collaborations supporting BCAL's development are reflected in the table below:

3.9 BCAL's clinical studies

BCAL will initially perform its first analytical performance and clinical evaluations at three specialist sites in NSW. Additional sites within NSW and in other States are planned depending on study participant recruitment rates in order to facilitate the fastest collection of clinical data and time to market.

BCAL is collaborating in relation to these upcoming clinical studies with:

(a) Lead breast care surgeons and clinicians at NSW BreastScreen at Royal Prince Alfred Hospital (**RPAH**) in the Sydney Local Health District (**SLHD**);

(b) Chris O'Brien Lifehouse;

(c) Sydney Breast Clinic; and

(d) the state-of-the-art NSW Health Statewide Biobank.

Key clinical advisors:

(a) A/Prof Sanjay Warrier, breast surgeon

(b) Dr Mary Rickard, radiologist

(c) A/Prof Cindy Mak, breast surgeon

Ethics approval for the upcoming study protocol has already been granted through RPAH's ethics committee at SLHD, and following governance approval, will commence sample collection.

3.10 BCAL's Intellectual Property

BCAL's assets in the form of intellectual property take three forms:

- knowhow and trade secrets;
- patents and patent applications in the patent family licensed by BCAL under the License Agreement as described in the IP Report which forms part of this prospectus as Appendix B; and
- new patent applications which are a part of BCAL's IP planning, but have yet to be filed.

3.10.1 Knowhow and trade secrets

BCAL has accumulated knowhow which includes, but is not limited to:

- the processes and associated documentation for isolating lipid-bearing vesicles from plasma and determining the lipid content of these vesicles;
- statistical processes to differentiate the lipid markers providing the best discrimination between vesicles from breast cancer patients and normal subjects;
- information on the lipid markers that make up the preferred set for such discrimination; and
- approaches for rapid analysis of lipid profiles in plasma samples obtained in a clinical setting.

Knowhow is protected by confidentiality requirements with employees and consultants and may in the future form part of documents submitted for regulatory approval of BCAL's product, patent applications and/or scientific publications, while some will be maintained as trade secrets of BCAL.

3.10.2 Patents and patent applications in the patent family licenced by BCAL from ULRF

Granted patents and pending patent applications in the licensed patent family are as described in Appendix B of this Prospectus. Information in the IP Report included in Appendix B includes the claims granted in each jurisdiction where examination of the patent has been completed. With more data having been generated on BCAL's test subsequent to the original patent filing, allowing for a more exact definition of the test's characteristics, BCAL is in a position to file divisional patent applications in this licensed patent family in some jurisdictions to seek further patent protection in addition to that provided by the granted patents.

A plan for such divisional filings has been developed and applications are currently expected to be submitted in the near term, focussing on the USA and Europe. The Company has appointed advisors to implement this plan.

Investors are reminded that granted patents will not always provide full protection for the BCAL test under development See Section 5.3 for a discussion of the Company's IP risks.

3.10.3 Potential new patent applications

It is expected that one or more new patent applications may be filed in the future based on information accrued during further development of BCAL's product and processes.

3. Company overview continued

3.11 Overview of the Company's Development Program – proposed use of funds

The purpose of the Offer is to raise funds to support the Company in:

- concluding and optimising laboratory/analytical evaluation to optimise test performance;
- establishment of its mandatory QMS;
- completing its pivotal clinical trial program for its initial intended use as "an adjunct to mammography";
- Health Technology Assessment (HTA) and reimbursement strategy;
- developing its test for scalability and ease of use;
- establishing its software tool for result analysis in a user-friendly manner;
- positioning itself for further clinical trial data to:
  - broaden the use case for its technology domestically; and
  - explore pathways to regulatory approval in international jurisdictions, and
- meeting ongoing administration and corporate overhead expenses, including Offer expenses.

Following the successful close of the Offer and with the application of existing funds, the Company will have sufficient working capital to meet its stated objectives as set out in the application of funds table for the next 24 months. Funds from the Offer are intended to be used as follows:

Intended use of Funds from the Offer*	Minimum Subscription Amount: $8 million				Oversubscription: $12 million			
	Year 1		Year 2		Year 1		Year 2	
Clinical development*	$1,500,000	36%	$1,900,000	49%	$3,000,000	48%	$3,400,000	59%
Commercial and product development	$400,000	10%	$600,000	16%	$800,000	13%	$1,000,000	17%
Algorithm Development and Validation	$200,000	5%	$100,000	3%	$200,000	3%	$100,000	2%
Regulatory and Intellectual Property management	$250,000	6%	$250,000	6%	$250,000	4%	$250,000	4%
Working capital	$1,000,000	24%	$1,000,000	26%	$1,000,000	16%	$1,000,000	17%
Expenses of the Offer	$800,000	19%	$0	0%	$1,000,000	16%	$0	0%
Total	**$4,150,000**		**$3,850,000**		**$6,250,000**		**$5,750,000**	

* Clinical development refers to studies undertaken in Australia but designed to support future regulatory approvals in other jurisdictions.

This table is a statement of current intentions as at the date of this Prospectus. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or other development expenses. The Board may alter the way funds are applied in the future.

4. Financial information

4. Financial information

4.1 Introduction

Section 4 contains a summary of the historical financial information prepared by the Directors of BCAL for the financial years ended 30 June 2018 (**FY18**), 30 June 2019 (**FY19**) and 30 June 2020 (**FY20**), and the six months ended 31 December 2020 (**1H21**) as set out below:

- The historical financial information for BCAL comprising:
  - Statutory historical statements of profit or loss for FY18, FY19, FY20 and 1H21 (the **Historical Results**);
  - Statutory historical statements of cash flows for FY18, FY19, FY20 and 1H21 (the **Historical Statements of Cash Flow**);
  - Statutory historical statement of financial position as at 31 December 2020 (the **Historical Statement of Financial Position**);

(together, the **Historical Financial Information**);

- The pro forma historical financial information for BCAL comprising pro forma historical statement of financial position as at 31 December 2020 (the **Pro Forma Historical Statement of Financial Position**), and supporting notes which includes the pro forma transactions, material subsequent events and capital raising.

The statutory and pro forma historical financial information is referred to in this Section 4 collectively as **Financial Information**.

Also summarised in this Section 4 are:

- the basis of preparation and presentation of the Financial Information (Section 4.2);
- the application of new accounting standards to the Financial Information and areas of critical judgements and estimates (Sections 4.10 and 4.11);
- information regarding certain non-IFRS measures (Section 4.4);
- a description of the pro forma adjustments to the Historical Statement of Financial Position, and reconciliations to the Pro Forma Historical Statement of Financial Position (Section 4.7);
- commentary on the liquidity of, and the sources of capital available to BCAL (Section 4.8);
- management's discussion and analysis of the Historical Financial Information (Section 4.9); and
- details of BCAL's proposed dividend policy (Section 4.12).

The information in this Section 4 should be read in conjunction with the Company Overview set out in Section 3, Risk Factors set out in Section 5 and other information contained in this Prospectus.

All amounts disclosed in the tables are presented in Australian dollars and, unless otherwise noted, are rounded to the nearest $1,000. Rounding of figures provided in the Financial Information may result in some immaterial differences between the sum of components and the totals outlined within tables and percentage calculations.

4.2 Basis of preparation and presentation of the Financial Information

The Financial Information included in this Prospectus is intended to present potential investors with information to assist them in understanding the underlying historical financial performance, cash flows and financial position of BCAL. The Directors of BCAL are responsible for the preparation and presentation of the Financial Information.

The Historical Financial Information has been prepared and presented in accordance with the recognition and measurement principles of Australian Accounting Standards (**AAS**) issued by the Australian Accounting Standards Board (**AASB**), which are consistent with International Financial Reporting Standards (**IFRS**) and interpretations issued by the International Accounting Standards Board (**IASB**).

The Pro Forma Historical Statement of Financial Position has been prepared in accordance with the recognition and measurement principles of AAS, other than that it includes certain adjustments which have been prepared in a manner consistent with AAS in order to illustrate their effect as if they had occurred on or before 31 December 2020.

The Financial Information is presented in an abbreviated format and does not contain all of the disclosures required by the AAS and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act.

Forecast financial information

The Directors have considered the requirements of ASIC Regulatory Guide 170 *Prospective financial information* (RG170) to determine if prospective financial information should be included in this Prospectus. The Directors have determined that, as at the date of this Prospectus, BCAL does not have reasonable basis to reliably forecast future earnings and accordingly forecast financial information is not included in this Prospectus. There is uncertainty in relation to the quantum and timing of BCAL's future revenue given the status of its research, resulting in a level of unpredictability in the timing, quantum and recognition of future results.

Independent Limited Assurance Report

The Financial Information presented in this Prospectus has been reviewed by Pitcher Partners as the Investigating Accountant in accordance with the *Australian Standard on Assurance Engagements ASAE 3450 Assurance Engagements involving Corporate Fundraising and/or Prospective Financial Information* as stated in its Independent Limited Assurance Report set out in Section 8. Investors should note the scope and limitations of the Independent Limited Assurance Report.

4.3 Preparation of Historical Financial Information

The Historical Financial Information has been extracted from the audited financial statements of BCAL for FY18, FY19 and FY20, and the reviewed financial statements of BCAL for the six months ended 1H21.

The financial statements of the Company for FY18, FY19 and FY20 were audited and the financial statements for 1H21 reviewed by Pitcher Partners Sydney Partnership in accordance with Australian Auditing Standards. The audit opinion issued for FY18, FY19 and FY20 and the review opinion issued for 1H21 were unmodified.

The Pro Forma Historical Statement of Financial Position has been prepared for the purpose of inclusion in this Prospectus. The Pro Forma Historical Statement of Financial Position has been derived from the Historical Financial Information, with pro forma adjustments being made to reflect:

- the impact of the Pre-IPO Capital Raising;
- the impact the Offer;
- the impact of Oversubscriptions if accepted; and
- issue of shares to the Lead Manager as if they had occurred as at 31 December 2020.

Refer to Section 4.7 for a reconciliation between the Historical Statement of Financial Position and the Pro Forma Historical Statement of Financial Position.

In preparing the Financial Information, the Company's accounting policies have been consistently applied throughout the periods presented.

Investors should note that past results are not a guarantee of future performance.

Going concern

The Financial Information for FY18, FY19, FY20 and 1H21 has been prepared on a going concern basis, which contemplates continuity of normal business activities and realisation of assets and discharge of liabilities in the normal course of business.

The Directors believe that there are reasonable grounds that the Company will be able to continue as a going concern as a result of the proceeds raised from the Offer.

4. Financial information continued

4.4 Explanation of certain non-IFRS financial measures

BCAL uses certain measures to manage and report on its business that are not recognised under AAS, nor under IFRS. These measures are collectively referred in this Section 4 and under ASIC Regulatory Guide 230 *Disclosing Non-IFRS Financial Information* published by ASIC as "non-IFRS financial measures". The principal ones used in this Prospectus are as follows:

- EBITDA is earnings before interest, taxation, depreciation, and amortisation;
- Operating cash flow is calculated as EBITDA, less non-cash items in EBITDA (e.g. share based payment expenses), plus or minus changes in working capital; and
- Working capital is the aggregate of receivables less trade and other payables, and employee benefits.

Certain financial data included in Section 4 is also non-IFRS financial information.

4.5 Historical Results

4.5.1 Statutory Historical Results

Table 4.1 below sets out the Historical Results for FY18, FY19, FY20 and 1H21. Investors are referred to Section 4.9 which provides a description and management discussion of the profit and loss categories and a discussion of the general factors affecting the historical operations and relative financial performance of BCAL.

Table 4.1: Historical Results For FY18, FY19, FY20 and 1H21.

		Historical Statutory Results			
$'000	**Notes**	**FY18**	**FY19**	**FY20**	**1H21**
Revenue from continuing operations					
Income	Note 1	242	258	442	75
Expenses					
Research and development		(252)	(205)	(467)	(16)
Personnel costs		(268)	(304)	(285)	(153)
Superannuation		(24)	(33)	(25)	(14)
Marketing		(2)	–	(34)	–
Consulting fees		(68)	(75)	(69)	(8)
Legal fees		(12)	(4)	(16)	–
General and administration		(65)	(58)	(91)	(91)
Depreciation		(14)	(4)	(8)	–
Borrowing costs		(6)	(5)	–	–
Share based payments		–	–	(142)	(38)
Loss before income tax		**(468)**	**(430)**	**(696)**	**(245)**
Income tax		–	–	–	–
Other comprehensive income for the year		–	–	–	–
Total comprehensive loss for the year		**(468)**	**(430)**	**(696)**	**(245)**

Note:

1. Revenue primarily comprises Research and Development tax offset revenue. In addition, BCAL received an ATO cash flow boost (COVID-19 stimulus) in FY20 and 1H21.

4.6 Historical Statements of Cash Flow

4.6.1 Statutory Historical Statements of Cash Flow

Table 4.2 sets out BCAL's Statutory Historical Statements of Cash Flow for FY18, FY19, FY20 and 1H21. Investors are referred to Section 4.9, which provides a management discussion and analysis of the cash flow line items.

Table 4.2: Statutory Historical Statement of Cash Flow

	Historical Statutory Results			
$'000	**FY18**	**FY19**	**FY20**	**1H21**
Cash flows from operating activities				
Payments to suppliers and employees	(710)	(757)	(945)	(281)
Government grants received	–	–	26	58
Research and development tax offset	238	241	257	342
Interest received	1	2	1	–
Interest paid	–	(11)	–	–
Net cash flow from operating activities	**(471)**	**(525)**	**(662)**	**119**
Cash flow from investing activities				
Purchase of plant and equipment	(14)	(7)	(4)	–
Security Deposit	–	–	–	–
Net cash flow from investing activities	**(14)**	**(7)**	**(4)**	**–**
Cash flows from financing activities				
Loans received	500	–	300	–
Proceeds from share issue	–	500	505	260
Net cash flow from financing activities	**500**	**500**	**805**	**260**
Net increase/(decrease) in cash and cash equivalents	**15**	**(32)**	**140**	**379**
Cash and cash equivalents at the beginning of the financial year	294	309	277	416
Cash and cash equivalents at end of the year	**309**	**277**	**416**	**795**

4.7 Statutory and Pro Forma Historical Statement of Financial Position

Table 4.3 below sets out the pro forma adjustments that have been made to the reviewed Historical Statement of Financial Position for BCAL as at 31 December 2020 in order to prepare the Pro Forma Historical Statement of Financial Position for BCAL. These adjustments reflect certain pro forma adjustments including the Offer proceeds, transaction expenses, the conversion of convertible notes into ordinary equity and other material transactions post 31 December 2020, and the impact of the operating and capital structure that will be in place following Completion of the Offer as if it had occurred or were in place as at 31 December 2020.

4. Financial information continued

Table 4.3: Statutory and Pro Forma Historical Consolidated Statements of Financial Position as at 31 December 2020

$'000	Notes	Statutory	Subsequent Events	Pro forma adjustments	Pro forma Offer	Pro forma Over-subscription
Current assets						
Cash and cash equivalents	4.7.2 (a); 4.7.2 (b); 4.7.2 (c); 4.7.3 (c)	795	3,613	7,073	11,481	15,236
Receivables		82	–	–	82	82
Total current assets		**877**	**3,613**	**7,073**	**11,563**	**15,318**
Non-current assets						
Plant and Equipment		–	–	–	–	–
Office/Computer Equipment		–	–	–	–	–
Accumulated Depreciation		–	–	–	–	–
Total non-current assets		**–**	**–**	**–**	**–**	**–**
Total assets		**877**	**3,613**	**7,073**	**11,563**	**15,318**
Current liabilities						
Trade Payables		70	–	–	70	70
Other Payables	4.7.2 (a)	560	(560)	–	–	–
Provisions		15	–	–	15	15
Total current liabilities		**645**	**(560)**	**–**	**85**	**85**
Total liabilities		**645**	**(560)**	**–**	**85**	**85**
Net assets		**232**	**4,173**	**7,073**	**11,478**	**15,233**
Equity						
Share Capital	4.7.2 (a); 4.7.3 (a); 4.7.3 (b); 4.7.3 (c)	4,940	4,659	9,224	18,822	22,700
Reserves		180	–	134	314	314
Accumulated Losses	4.7.2 (b); 4.7.2 (c); 4.7.3 (c); 4.7.3 (d)	(4,888)	(486)	(2,285)	(7,658)	(7,781)
Total Equity		**232**	**4,173**	**7,073**	**11,478**	**15,233**

4.7.1 Subsequent events and Pro Forma Adjustments

Subsequent to 31 December 2020, events have occurred which have changed the number of Shares on issue. These changes have been reflected in the Pro Forma Statement of Financial Position. These transactions are detailed in Section 4.7.2.

With the exception of the subsequent events and pro forma transactions noted below no other material transactions have occurred between 31 December 2020 and the date of this Prospectus which the Directors consider require disclosure.

This Prospectus contemplates transactions subsequent to 31 December 2020 which are to take place on or before the Completion of the Offer. These transactions are reflected in the Pro Forma Statement of Financial Position and are explained in Section 4.7.3.

4.7.2 Subsequent Events

(a) Pre-IPO Capital Raising

The pro forma cash and cash equivalents adjustment of $4.1 million relates to the net proceeds from the capital raise completed in January 2021. Of the $4.7 million total capital raised, $259,995 had been paid in cash prior to the end of1H21 as subscriptions while $300,003 are the proceeds of the conversion of convertible notes to new Shares on 1 December 2020. This total of $559,998 was included in Other Payables in the 31 December 2020 statement of financial position.

(b) Pre-IPO Capital Raising Costs

The total costs incurred after 30 December 2020 associated with the $4.7 million capital raise in January 2021, amounted to $262,539. Those costs which directly related to the issue of new shares totalled $66,486 and have been capitalised, hence netted against the amount of capital raised, while the remaining costs totalling $196,053 have been expensed (against accumulated losses).

(c) 3Q21 Financial Performance

The net loss after tax of BCAL for the quarter ended 31 March 2021 was $289,477, after capitalisation of pre-IPO Capital Raising Costs and IPO related legal fees discussed in sections 4.7.2(b) and 4.7.3(c) respectively. The loss largely relates to professional fees ($44,134), employee benefit expenses ($115,709) and consultancy fees ($54,584). The impact of the 3Q21 financial performance has been adjusted as a subsequent event in the pro forma Statement of Financial Position against cash and cash equivalents ($289,477) and accumulated losses.

(d) Issue of Employee Share Options post-IPO

BCAL intends to issue employee share options to select employees and consultants under its new Equity Incentive Plan following the IPO. It is envisaged that these share options will serve as incentives to new and existing employees. As the terms of these employee share options are yet to be negotiated and seeing as these options will only be issued after the successful completion of the IPO, no pro forma adjustments are considered necessary in this regard.

(e) Enhancement of Board, employees and consultants

Since December, 2020, BCAL has enhanced its Board by the addition of one Director experienced in the areas of BCAL's operations, and the appointment on listing of a second new Director with a substantial business background. In addition, there have been additions to the Company's scientific staff and appointment of consultants devoting significant proportions of their time to drive the clinical, regulatory and commercialisation aspects of the Company's program.

4. Financial information continued

4.7.3 Pro forma transactions

(a) The Offer

The issue of 32,000,000 Shares amounting to $8 million offer proceeds (before acceptance of any Oversubscriptions).

(b) Issue of Shares to Lead Manager

The issue of 6,615,631 Lead Manager Securities, with an issue price of $0.0001, to be issued to the Lead Manager (or its nominees) in relation to the Offer. The fair value of these shares is $1.65 million. Refer to Section 9.3 for further details.

(c) Offer Costs

Total expenses associated with the Offer are estimated to be $2.58 million, consisting of the Lead Manager Securities issued of $1.65 million and $0.927 million of offer costs to be paid in cash. Those costs which directly related to the issue of new shares totalling $430,112 have been capitalised, hence netted against the amount of capital raised, while the remaining costs totalling $2.15 million have been expensed.

(d) Vesting of Directors' Share Options

A total of 5,778,965 share options were issued to the Directors and a consultant of BCAL on 23 November 2020. These options will vest on the successful completion of the IPO of BCAL. The share-based payment expense is expensed over the vesting period in accordance with AAS. Accordingly, the remaining portion of the share-based payment expense of $134,348 (which has not been expensed as at 31 December 2020) will be expensed at the date of vesting (IPO date), and has been included as a pro forma adjustment against accumulated losses and reserves.

(e) Oversubscriptions

The Company has the ability to accept Oversubscriptions of up to an additional $4,000,000 (by issuing a further 16,000,000 Shares). The incremental costs of accepting the maximum oversubscriptions is estimated to be $375,000, consisting of additional Lead Manager Securities issued of $130,000 and $245,000 of offer costs to be paid in cash. Accordingly, the estimated net proceeds of accepting the maximum oversubscriptions that will increase pro forma cash by $3.755 million, share capital by $3.878 million and accumulated losses by $123,034.

4.7.4 Pro forma cash and cash equivalents

The reviewed pro forma cash and cash equivalents have been set out below:

$'000	Reference	Pro Forma $	
Statutory cash and cash equivalents at 31 December 2020			**795**
Subsequent Events			
Pre-IPO capital raising	4.7.2 (a)	4,165	
Payment of costs relating to the pre-IPO capital raising	4.7.2 (b)	(263)	
3Q21 Financial Performance	4.7.2 (c)	(289)	**3,613**
Pro forma transactions			
Proceeds from Shares issued under the Offer	4.7.3 (a)	8,000	
Payment of the costs relating to the Offer	4.7.3 (b)	(927)	**7,073**
Pro forma cash and cash equivalents *(Offer before Oversubscriptions)*			**11,481**
Proceeds from Shares issued on accepting Oversubscriptions	4.7.3(e)	4,000	
Payment of the incremental costs relating to the Oversubscription	4.7.3(e)	(245)	**3,755**
Pro forma cash and cash equivalents *(Offer with Oversubscriptions)*	Note 1		**15,236**

Note 1 – Reflects pro forma cash and cash equivalents should maximum oversubscriptions be accepted.

The pro forma as at 31 December 2020 does not reflect the change in cash position between 31 December 2020 and Completion, which will occur as a result of ongoing research and development spend and other cash requirements of the business over this period.

4.7.5 Share Capital

The reviewed pro forma share capital has been set out below:

	Reference		Pro Forma $	Issued shares No.
Audited share capital at 31 December 2020			**4,939,580**	**4,423,173**
Subsequent Events				
Conversion of Convertible Notes	4.7.2 (a)	300,003		200,002
Pre-IPO capital raising	4.7.2 (a)	4,424,995		1,499,998
Less Pre-IPO capital raising costs	4.7.2(c)	(66,486)	4,658,512	–
Pro forma share capital before share split			**9,598,092**	**6,123,173**
Pro forma transactions				
Share split	Note 1	–		160,000,002
Shares issued pursuant to the Offer	4.7.3 (a)	8,000,000		32,000,000
Less capital raising costs	4.7.3 (b)	(430,112)		–
Shares issued to Lead Manager	4.7.3 (c)	1,653,908	9,223,796	6,615,631
Pro forma share capital *(Offer before Oversubscriptions)*			18,821,888	198,615,633
Shares issued on accepting Oversubscriptions	4.7.3(e)	4,000,000		16,000,000
Less incremental costs relating to the Oversubscription	4.7.3(e)	(245,000)		–
Lead Manager Securities issued	4.7.3(e)	130,000	3,885,000	520,000
Pro forma share capital *(Offer with Oversubscriptions)*			**22,706,888**	**215,135,633**

Note 1 – BCAL approved a share split on 26 April 2021 at a ratio of 1:26.13024326.

4.8 Liquidity and Capital Resources

Following Completion, BCAL's principal sources of funds are expected to be cash on hand. Until commercialisation is achieved, BCAL's operating cash flows are expected to be negative (outflows). Net cash raised from the Offer will be used to fund working capital, including clinical development, intellectual property management and regulatory management (refer to Section 3.11). Following Completion, BCAL expects that it will have sufficient cash to meet its operational and working capital requirements and stated business objectives for at least the next 12 months.

4. Financial information continued

4.9 Management discussion and analysis

4.9.1 General factors affecting the operating results of Historical Financial Information

This section discusses the general factors that affected BCAL's operations and relative financial performance in FY18, FY19, FY20 and 1H21 and which BCAL expects may continue to affect it in the future.

The discussion of these general factors is intended to provide a summary only and does not detail all factors that affected BCAL's historical operating and financial performance, nor everything that may affect BCAL's operations and financial performance in the future.

Unless otherwise stated, all metrics and financial information presented in this section, and the related commentary are on a pro forma basis.

FY18

BCAL's total revenue was $242,288, consisting almost entirely of research and development tax offsets.

Research and development expenditure represented $251,901 (35%) of the operating cost base, consulting and legal fees represented $79,743 (11%), employee benefits expense was $292,449 (41%), and administration and other costs amounted to $156,461 (13%).

Net loss after income tax expense totalled $467,632.

The net increase in cash and cash equivalents of $15,070 is a combination of operating losses for the year, and the receipt of convertible notes in the amount of $500,000. The notes were converted into equity in the 2019 year. Each note had a face value of $1.00 and carried an interest rate of 12% and was secured by a general charge over the assets of the Company.

FY19

BCAL's total revenue was $258,224, consisting almost entirely of research and development tax offsets.

Research and development expenditure represented $205,385 (35%) of the operating cost base, consulting and legal fees represented $78,723 (11%), employee benefits expense was $337,255 (49%) and administration and other costs amounted to $66,838 (5%).

Net loss after income tax expense totalled $429,957.

The net decrease in cash and cash equivalents of $32,483 is a combination of operating losses for the year net of proceeds of a capital raise of $500,000.

FY20

BCAL's total revenue was $442,096, comprising research and development tax offsets of $341,982, an ATO cash flow boost receipt of $99,610 and interest income of $504.

Research expenditure represented $466,773 (41%) of the operating cost base, consulting and legal fees represented $85,743 (8%), whilst employee benefits expense was $310,943 (27%). Operating costs in FY20 also included a share-based payment expense of $142,044 relating to employee share options issued during the financial year. Share-based payment expenses are expensed over the vesting period in accordance with AAS.

Net loss after income tax expense totalled $696,360.

The net increase in cash and cash equivalents of $139,582 is a combination of operating losses for the year, a capital raising of $505,037 and convertible note received of $300,003. The notes were converted to equity in 1H21. Each note had a face value of $1.50, an interest rate of 5% and was secured by a general charge over assets of the Company.

1H21

BCAL's total revenue was $75,083, comprising an estimate of an expected research and development tax offset receipt.

The research and development receivable is calculated at 43.5% of research and development expenses which comprises primarily personnel costs.

Operating costs include a share-based payment expense of $37,825 relating to employee share options issued in FY20, as well as options issued to Directors and a consultant of BCAL in November 2020. Share-based payment expenses are expensed over the vesting period in accordance with AAS.

Net loss after income tax expense totalled $244,687.

The net increase in cash and cash equivalents of $378,980 is a combination of research and development claims and ATO cash flow boost payments exceeding payments to suppliers and employees during the six months, and the early receipt of $259,995 for the capital raise which closed in January 2021.

Second half 2021 (2H21)

In January 2021 the Company issued 1,499,998 shares at $2.95 per share in a placement raising $4,424,995 including subscription monies totalling $259,995 received before 31 December 2020. In addition, 200,002 shares for the conversion price of $300,003 were issued on conversion of convertible notes. The amount received before 31 December 2020 and the amount received in respect of the conversion of convertible notes are shown in Other Payables at 31 December 2020. The Company converted from a private company to an unlisted public company on 5 February 2021.

4.10 Application of new accounting standards to the Financial Information

The significant accounting policies applied consistently in the preparation of the Financial Information are set out in Appendix A. BCAL adopted AASB 9 *Financial Instruments* and AASB 15 *Revenue from Contracts with Customers* from 1 July 2018, and AASB 16 Leases from 1 July 2019.

The adoption of AASB 9, AASB 15 and AASB 16 did not materially impact BCAL's financial performance or cash flows, and accordingly no pro forma adjustments have been retrospectively applied to reflect these standards.

4.11 Critical accounting judgements and estimates

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities (refer to the respective notes) within the next financial year are discussed below.

(i) Research and development expenditure

The entity has expensed research and development expenditure incurred during the year, where applicable, as the costs relate to the initial expenditure for research and development of products for medical use where generation of future economic benefits is not considered certain. It was considered appropriate to expense these research and development costs as they did not meet the criteria to be capitalised under AASB 138 Intangible assets.

(ii) Share based payment transactions

The entity measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using the Black-Scholes model taking into account the terms and conditions upon which the instruments are granted. The accounting estimates and assumptions relating to equity-settled shares-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity. Judgement is required in relation to the non-market vesting conditions.

4. Financial information continued

4.12 Dividend policy

BCAL is currently in the development phase of operations and therefore is not expected to be in a position to declare a dividend in the short to medium term. Accordingly, no dividends are expected to be paid in the near to medium term following the Company's listing on the ASX.

The payment of a dividend by BCAL, if any, is at the discretion of the Directors and will be a function of a number of factors (many of which are outside the control of the Directors), including the general business environment, the operating results, cash flows and the financial condition of BCAL, future funding requirements, capital management initiatives, taxation considerations (including the level of franking credits available), any contractual, legal or regulatory restrictions on the payment of dividends by BCAL, and any other factors the Directors may consider relevant. The Directors do not provide any assurance of the future level of dividends paid by the Company.

5. Risks

5. Risks

5.1 Introduction

BCAL is subject to various risk factors. Some of these are specific to the Company's business activities. Others are of a more general nature. Individually, or in combination, these risk factors may affect the future operating and financial performance of BCAL, its investment returns and the value of an investment in the Shares. Each of the risks set out in this Section, if they eventuate, could have a material adverse impact on the Company's business, financial condition and results of operations.

Investors should be aware that this Section does not purport to list every risk that may be associated with an investment in the Shares or the industry in which BCAL operates now or in the future. The occurrence or consequences of some of the risks described in this Section are partially or completely outside of the control of BCAL, its Directors and its management team. This Section should be read in conjunction with other information disclosed in this Prospectus. There can be no guarantee that BCAL will achieve its stated objectives or that any forward looking statements will be realised or otherwise eventuate.

The selection of risks has been based on a number of factors, including the probability of the risk occurring, the ability to mitigate the risk and the impact of the risk if it did occur. That assessment is based on the knowledge of the Directors at the Prospectus Date, but there is no guarantee or assurance that the importance of different risks will not change or that other risks will not emerge.

Before applying for Shares, investors should satisfy themselves that they have a sufficient understanding of these matters and should consider whether Shares are a suitable investment for them, having regard to their own investment objectives, financial circumstances and taxation position. If investors are unclear in relation to any of the risks outlined in this Section or are uncertain as to whether BCAL is a suitable investment for them, they should seek professional guidance from their solicitor, stockbroker, accountant or other independent and qualified professional adviser before deciding whether to invest.

5.2 Business risks associated with the Company

5.2.1 Sufficiency of funding

BCAL has finite financial resources and will need to raise additional funds from time to time to finance the complete development and commercialisation of its products and its other longer-term objectives. If Shareholders at that time do not participate in the fundraising, they will be diluted.

The Company's product development activities may never generate revenues and the Company may never achieve profitability.

The Company's ability to raise additional funds will be subject to, among other things, factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, if at all. If for any reason BCAL was unable to raise future funding, its ability to achieve the milestones outlined in this Prospectus or continue future development of its products and technology would be significantly affected.

5.2.2 Competition

The medical device and diagnostic industries are highly competitive, and include companies with significantly greater financial, technical, human, research and development, and marketing resources than the Company. There are companies that compete with the Company's efforts to discover, validate and commercialise diagnostic products or product candidates. The Company's competitors may discover and develop products in advance of the Company and/or products that are more effective than those developed by the Company. As a consequence, the Company's current and future technologies and products may become obsolete or uncompetitive, resulting in adverse effects on revenue, margins and profitability.

5.2.3 Healthcare insurers and reimbursement

In both domestic and foreign markets, sales of BCAL's products are likely to depend in part upon the availability and amounts of reimbursement from third party healthcare payer organisations, including government agencies, private health care insurers and other health care payers such as health maintenance organisations and self-insured employee plans. There is considerable public policy and government pressure to reduce healthcare costs and government and other third party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products.

No assurance can be given that reimbursement will be provided by these parties at all or without substantial delay, or, if reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable the Company to sell its products on a profitable basis.

5.2.4 Reliance on key personnel

The Company currently employs a number of key management and scientific personnel, and the Company's future depends on retaining and attracting suitably qualified personnel. The Company operates an equity incentive scheme which aims to assist in the attraction and retention of personnel. The Company has also established contractual mechanisms through employment and consultancy contracts to limit the ability of key personnel to join a competitor or compete directly with the Company.

Despite these measures, however, there is no guarantee that the Company will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the business, operating results and financial prospects.

5.2.5 Expenditure program

BCAL has not yet entered into contracts for some of the material items expected to be covered by its expenditure program, nor does it have binding quotations in relation to those items. Rather, the Directors have determined that following the successful close of the Offer, BCAL will be well positioned to negotiate the exact terms for those contracts. BCAL has, however, obtained indicative quotations for many of the major expenditure items. The Directors and executive team and their consultants have extensive experience and have prepared the anticipated expenditure described in this Prospectus based on discussions with potential suppliers of those services and their own experience of the likely costs for those expenditure items. While the Directors are confident BCAL will be able to source suitable suppliers, there is a risk that BCAL may not be able to source those suppliers at the estimated expenditure.

5.2.6 Innovative technological development – clinical and product development

The Company's product candidates are at a relatively early clinical stage and further clinical study using varied patient populations and larger sample sizes is necessary. No guarantee can be provided that the proposed clinical work will be successful or result in an approved product.

It will be necessary for the Company to undertake further development of its clinical findings to progress its diagnostic test(s) into a format that can be readily utilised by appropriate testing parties. There is no guarantee that this work will be successful in presenting its test(s) in a format that is accessible and acceptable to the market.

5.2.7 Clinical trials – regulatory requirements

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory and legal requirements. In addition, trial design can change as further knowledge is gained, which may have adverse impact on cost and time of the Company's proposed clinical trials. Clinical trials of the Company's products may take several years to complete to obtain information to support registration for the different indications outlined in this Prospectus. There is a risk that the relevant regulators may not approve BCAL's proposed applications for registration and this would require BCAL to undertake more trials and cause a delay in BCAL's commercialisation program.

Clinical development of the Company's products may fail for a number of other reasons, including lack of sensitivity or specificity. Failure can occur at any stage of the trials, requiring the Company to abandon or repeat clinical trials. The Company and/or the relevant regulatory authorities, human research ethics committees and institutions where the clinical trials are conducted, may cause the Company to suspend one or more of the Company's clinical trials at any time if it appears that the trials are not demonstrating diagnostic efficacy, or are thought to be exposing the trial participants and/or the staff involved in conducting the clinical trial to unacceptable health risks.

Alternatively, there is the risk that despite completing a relevant clinical trial in compliance with regulatory requirements, the results of the trial do not support any further development of the product for the associated indication or may result in a rejection by the relevant regulator. As a result, BCAL may fail to commercialise or out-license one or more of its proposed products.

Any changes to the laws and regulations in relation to the regulatory approval and sale of therapeutic goods (including the laws and regulations of the TGA or FDA) could also adversely affect the Company's clinical trials and commercialisation.

5.2.8 Disruption of business operations

The Company is exposed to a large range of operational risks relating to both current and future operations. These operational risks include but are not limited to fraud/dishonesty by its employees or service providers, industrial action or disputes and natural disasters. While the Company endeavours to take appropriate action to mitigate these operational risks and, where the Directors consider it practicable, insure against them, the Company cannot remove all possible risks of disruption to its business operations. A disruption in the Company's operations/service access may have an adverse impact on the Company's growth prospects, operating results and financial performance.

5.2.9 Dependence on service providers

The Company intends to undertake a significant amount of its key clinical activities through a series of contractual relationships with independent contractors and suppliers and depending on the advice of various consultants The Company relies on and will continue to rely on a number of its contractors for their expertise in clinical development.

All of the Company's contractual relations (including with consultants) carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations. That failure can lead to termination and/or significant delay or damage to the Company's product development efforts.

5.2.10 Laboratory distribution channel

One of the possible regulatory pathways for the Company's product is to distribute the product via LDT in Australia, or in the USA via CLIA approved laboratories. There is no assurance that these laboratories will agree to sell the product, or that their customer base will purchase the product.

5.2.11 Product liability

As with all new diagnostic products, even after the granting of regulatory approval, there is no assurance that unforeseen adverse events or manufacturing defects will not arise. Adverse events could expose the Company to product liability claims or litigation, resulting in the removal of the regulatory approval for the relevant products and/or monetary damages being awarded against the Company. In that event, the Company's liability may exceed the insurance coverage the Company might hold (if any) at the time.

5.2.12 Currency risk

Revenue and expenditures in overseas jurisdictions are subject to the risk of fluctuations in foreign exchange markets. The Company's payment obligations under many of its material contracts are in foreign currencies (in particular, US$). Accordingly, payment will be made in US$, € and other currencies, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the Australian dollar. The Company has no plans at this stage to hedge its foreign currency payments.

5.2.13 Contractual and counterparty risks

As a party to many contracts, the Company will have various contractual rights in the event of non-compliance by a contracting party. However, no assurance can be given that all contracts will be fully performed by all contracting parties and that the Company will be successful in securing compliance with the terms of each contract by the counterparties to its contracts.

The Company's material contracts contain provisions providing for early termination of the contracts, on giving notice and paying a termination amount (which varies between the contracts). The early termination of any of these contracts, for any reason, may mean that the Company will not realise the full value of the contract, which is likely to adversely affect the growth prospects, operating results and financial performance of the Company.

5.3 The Company's IP

5.3.1 Intellectual property

There is no guarantee that the Company's intellectual property comprises all of the rights that the Company may require to freely commercialise its product candidates. The Company's existing intellectual property includes its licensing rights under a licensing agreement between BCAL and ULRF.

The Company has, under the License Agreement, acquired the rights to various patent applications (as detailed in Section 3.10) relating to its lead product. No assurance is given that the Company's current and future patent applications, derived from the original patent licensed from ULRF, will result in granted patents or that such patents collectively will fully protect all aspects of the BCAL product.

The License Agreement provides that BCAL must use reasonable efforts to achieve the commercial goals outlined in its development plan, and must have relevant products ready for commercial sale by 31 July 2023 unless otherwise extended. Following the first commercial sale, BCAL must reasonably fill market demand for the products during the term of the ULRF License Agreement. If BCAL fails to comply, ULRF may convert the License into a non-exclusive license. BCAL and ULRF have amended the License Agreement on three separate occasions to (amongst other things) extend the commercial sale date. There is, however, a risk that BCAL will not have the relevant products ready for commercial sale by 31 July 2023 and may be unable to secure a further extension of the commercial sale date.

Even though some of the patent applications arising from the patent that is the subject of the License Agreement have already been successful (resulting in granted patents) investors should note that a competitor may at any time challenge granted patents and a court may find that although a patent has been granted it is invalid or unenforceable or revoked. It is possible a court may find that the Company's entitlement is subsequently revealed not to have existed, may not have any exclusive patent rights or any patent rights at all and/or may be prevented from developing and/or commercialising its products by the existence of competing patents. If the Company's intellectual property rights are ever challenged it may also not have the funds to oppose the challenge.

Subject to national patent term adjustments and extensions, the patents the subject of the License Agreement have a maximum term, such that they expire on 22 June 2031. The Company's ability to exclusively exploit the patented technology under the License Agreement will therefore cease after that date, and there is a risk that BCAL's competitors will be able to use the technology currently subject of the License Agreement, to compete with BCAL from the time of that patent expiry. The License Agreement is summarised below at Section 9.5.1 and further details are provided in the IP Report in Appendix B.

As development of its product continues, the Company is in discussions with its advisers in relation to its ability to file additional patents (**New Patents**) where possible, including to protect any aspects of its intellectual property that fall outside the License Agreement. However, there is no guarantee that filing of New Patents will be successful and will proceed to grant.

5.3.2 Trade secrets

The Company relies on trade secrets, which include information relating to the content, manufacture, development and use of its diagnostic products. The protective measures employed may not provide adequate protection for those trade secrets. This could erode the Company's competitive advantage and materially harm its business. The Company cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology.

5.3.3 Infringement of third party IP

If a third party accuses the Company of infringing its intellectual property rights or if a third party commences litigation against the Company for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending such action, whether or not it ultimately prevails. Costs that the Company incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time. In the event of a successful claim of infringement against the Company, it may be required to pay damages and obtain one or more licences from the prevailing third party. If it is not able to obtain these licences at a reasonable cost, if at all, it could encounter delays in product introductions and loss of substantial resources while it attempts to develop alternative products.

5. Risks continued

5.4 General risks

In addition to the specific risks outlined above, the operating results and profitability of the Company are sensitive to a number of general risk factors including those set out below.

Many of the general risks discussed below are outside the control of the Company and the Directors and cannot be mitigated.

The list of risk factors below should be carefully considered, together with the information contained elsewhere in this Prospectus, before deciding to apply for Shares.

5.4.1 Market for Shares

Prior to the Offer there has been no public market for the Shares. Once the Shares are quoted on ASX, their price might rise or fall and they might trade at prices below or above the Offer Price. No assurance can be given that an active market will develop in the Shares or that the Shares will trade at or above the Offer Price in the future.

5.4.2 General economic conditions

The general economic climate may affect the performance of the Company. These factors include the general level of international and domestic economic activity, inflation and interest rates. These factors are beyond the control of the Company and their impact cannot be predicted.

Further, share market conditions may affect the value of BCAL's quoted securities regardless of the Company's operating performance. Share market conditions can be affected by many market factors including:

- general economic outlook;
- interest rates and inflation rates;
- currency fluctuations;
- changes in investor sentiment towards equities or particular market sectors;
- political instability;
- short selling and other trading activities;
- the demand for, and supply of, capital; and
- force majeure events.

The market price of the Shares can fall as well as rise and may be subject to varied and unpredictable influences on the share market. The trading price of the Shares at any given time may be higher or lower than the price paid under the Offer. Further, you may be unable to sell or realise your investment because the market for Shares may be illiquid.

5.4.3 Taxation

There are tax implications arising from buying and selling Shares, the receipt of dividends (both franked and unfranked) (if any) from the Company and participation in any on-market Share buy-back. The tax treatment of an investment in Shares will differ depending on each investor's personal circumstances. Investors should seek their own independent taxation advice before applying for Shares.

The Company currently benefits from a tax rebate or refund of expenditure, through a scheme managed by the Australian Tax Office, in relation to expenditure incurred through its research and development programs. There is no guarantee that this scheme will continue to operate at current levels or at all. Any reduction in or cancellation of the scheme would increase the effective cost of research and development carried out by the Company and may result in delays to or failures of its scientific and/or clinical programs, with accompanying impact on product commercialisation.

5.4.4 Insurance risks

Although the Company maintains insurance, no assurance can be given that this insurance will cover every eventuality, or that adequate insurance will continue to be available to the Company in the future on commercially acceptable terms.

5.4.5 Government actions and other events

The impact of actions by domestic and international governments may affect the Company's activities, including in relation to its infrastructure, compliance with environmental regulations, export, taxation and royalties.

BCAL operates in a market which is subject to significant regulation which may change or be increased by governmental or other regulatory authorities in the future. Changes to the regulatory framework could impact on BCAL and the industry in which it operates generally and could result in an adverse impact on the financial position, performance, assets and operations of the Company.

Events may occur within or outside Australia that could impact on the world economy, the market for the Company's product candidates, the Company's operations and the price of the Shares. These events include war, acts of terrorism, civil disturbance, political intervention and natural disasters. The Company has only a limited ability to insure against some of these risks.

5.4.6 Unforeseen expenses

The proposed expenditure on the Company's projects may be adversely affected by any unforeseen expenses which arise in the future and which have not been considered in this Prospectus.

5.4.7 Impact of COVID-19

The global impact of the COVID-19 pandemic, and the advice and responses from health and regulatory authorities, is continuously developing. The global economic outlook is facing uncertainty due to the COVID-19 pandemic which has had and may continue to have a significant impact on capital markets and share prices. The Company's Directors are monitoring the situation and considering the impact on the Company's business from both a financial and operational perspective.

To date, COVID-19 has affected equity markets, governmental action, regulatory policy, quarantining, self-isolations and travel restrictions. These impacts are creating risks for the Company's business and operations in the short to medium term.

5.4.8 Litigation

The Company is not currently involved in any material contractual disputes or litigation, arbitration or government prosecution matters. There is a risk that the Company may in the future have disputes with third parties (including payment disputes) and this may have an adverse impact on the Company's growth prospects, operating results and financial performance.

5.5 Prospective information

No assurance as to future profitability or dividends can be given as they are dependent on successful product development, future earnings and the working capital requirements of the Company.

There can be no guarantee that the assumptions on which the financial forecasts and development strategies of the Board, or those upon which the Company bases its decisions to proceed, will ultimately prove to be valid or accurate. The forecasts and development strategies depend on various factors many of which are outside the control of the Company.

Changes in interest rates, exchange rates, government budgetary measures, relevant taxation and other legal regimes and Government policies may adversely affect the Company.

The Directors expect that the funds raised under the Offer will provide sufficient capital resources to enable the Company to achieve its immediate business objectives. The Directors can give no assurance, however, that these and longer term objectives can be met without future financing or, if future financing is necessary, that it can be obtained on favourable terms.

5. Risks continued

5.6 Concluding comment

The above list of risk factors ought not to be taken as exhaustive in setting out the risks faced by the Company or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of the Company and the value of the Shares. Therefore, the Shares to be issued under this Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares.

Investment in the Company must be regarded as highly speculative and neither the Company nor any of its Directors or any other party associated with the preparation of this Prospectus guarantees that any specific objectives of the Company will be achieved or that any particular performance of the Company or of the Shares, including those offered by this Prospectus, will be achieved.

6. Key people, interests and benefits

6. Key people, interests and benefits

6.1 Board of Directors

Jayne Shaw – Executive Chair

Trained as a Registered Nurse in the UK, on arrival in Australia Jayne became a Director of Nursing and Chief Executive Officer of two private hospitals. Following this, she established an Australian and international consulting business which was sold to Healthsouth, a large USA Healthcare company. Jayne then became the Co-founder of Vision Group, an Opthalmic Doctor equity consolidation model that was successfully listed on the ASX.

Jayne joined a number of private healthcare boards involved with specialist consolidation including Cardiology, Orthopaedics, and Women's Health, and continued to work with private equity firms on local and international healthcare transactions. Jayne, together with Ron Phillips, was a co-owner of Sydney Breast Clinic and a co-founder of BCAL. Current board positions are The Woolcock Research Institute, Corum Group (ASX: COO) and Mable Technologies.

The Hon Ron Phillips AO – Non-Executive Director

Following 15 years in the NSW Parliament which included serving as Minister for Health and Deputy Leader of the Opposition, Ron developed a successful consulting business in the Health and Aged Care Industry.

His business interests included co-owner and Managing Director of Sydney Breast Clinic which he sold to Healthscope. He recently retired as Chair of the Sydney Local Health District and as Director of Westmead IVF.

Jonathan Trollip – Independent Non-Executive Director

Professional non-executive director. Jonathan is a globally experienced Director with over 30 years of commercial, corporate, governance and legal and transactional expertise. He is currently non-executive Chairman of ASX listed Global Value Fund Limited, Future Generation Investment Company Limited, Antipodes Global Investment Company Limited, Plato Income Maximser Limited, and Spheria Emerging Companies Limited and a non-executive director of ASX listed Propel Funeral Partners Limited and LSE listed Kore Potash PLC. Jonathan has postgraduate degrees in economics and law and is a Fellow of the Australian Institute of Company Directors. He has a keen interest in the not-for-profit sector.

Merilyn Sleigh, PhD – Independent Non-Executive Director

Dr. Sleigh has over 30 years of experience as a senior executive and non-executive director in Australia's biotechnology sector. She was, from its foundation, Chief Executive Officer and Managing Director of EvoGenix Limited, a biotech startup company that expanded internationally and listed on the ASX before acquisition by a larger company.

She was 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. She has held non-executive director positions with Mimetica Pty Ltd and Adalta Ltd as well as with ASX listed companies Clover Corporation, and Tyrian Diagnostics Ltd. Other director roles have been with government and not-for-profit organisations, including the Rural Industries Research and Development Corporation and Relationships Australia. She has acted as an adviser and consultant to companies, government, research institutes and investors on technology commercialisation. She holds a BSc, Doctorate in Philosophy and Diploma in Corporate Management and is a Fellow of the Australian Institute of Company Directors.

Mark Burrows AO, Independent Non-Executive Director – Director (to be appointed on listing)

Mark Burrows AO will be joining the BCAL Board on a pro-bono basis, as he is an advocate for early diagnosis of breast cancer and other cancers. He has enjoyed a long and distinguished career in investment banking both in Australia and the UK. Mark co-founded Baring Brothers Burrows & Co in Australia in the early 80s. In 1999 he was appointed the Managing Director/ Deputy Chairman of ING Barings in London. In 2004, Mark joined Lazard as a Managing Partner and in 2006 returned to Australia and was appointed Lazard Australia's inaugural Chairman. Mark returned to investment banking in 2011 as Vice Chairman of Credit Suisse's Global Investment Bank.

During his extensive investment banking career, Mark has been the principal financial advisor to some of the most significant and transformative corporate and government transactions in Australia. Mark has served as a non-executive director on several Australasian and UK public companies including Chairman and Deputy Chair of Brambles, Fairfax Media and Telstra.

Since the Rio Earth Summit in 1992, Mark has also been an advocate of global financial institutions' Private Sector involvement in sustainable development. Over this period, Mark has retained a number of roles advising United Nations, G20 and corporates on climate initiatives relating to the financial sector. From 2017 to 2020, Mark was a Senior Advisor to Macquarie Bank, on climate finance and renewable energy. Mark currently retains a role as a senior advisor to UNEP, UNDP, The Green Finance Initiative in London and is on the Asian Council of The Nature Conservancy. He is also a Senior Advisor to the G20 Sustainability Group.

6.2 Management

Guy Robertson, CFO (Integrated CFO Solutions) – Chief Financial Officer and Company Secretary

Prior to establishing Integrated CFO Solutions Pty Ltd, Guy has been a Finance Director/Chief Financial Officer for a number of companies.

Over the last seventeen years Guy has provided CFO consulting services to many large corporations and SMEs. Guy has been 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. Guy is Company Secretary for Bioxyne Limited, Artemis Resources Limited and Truscreen Group Limited.

Dr. Amani Batarseh – Chief Scientist

Dr Amani Batarseh is BCAL Diagnostics' Chief Scientist. She graduated magna cum laude from La Roche University in Pennsylvania where she had a Pacem in Terris scholarship for academic excellence. Later, Amani received a fellowship to pursue her PhD at Georgetown University, Washington, DC in Biochemistry and Molecular & Cellular Biology. Amani completed post-doctoral studies at Harvard University, McGill University and Wollongong University.

During her time in Canada, Amani managed and co-established two mass spectrometry laboratories at the Research Institute of McGill University Hospital and The Glen Hospital in Montreal, respectively. Her versatile profile of expertise combines over 18 years of research experience with lipidomics and mass spectrometry to answer biological questions. She is an affiliate at the University of Sydney Knowledge Hub.

6. Key people, interests and benefits continued

Jane Ryan, PhD, Product Development Advisor

Dr Jane Ryan has over 30 years of international experience in the pharmaceutical and biotechnology industries where she has held executive roles in management of research and development programs as well as business development and alliance management. Jane has worked in Australia, the USA and UK with companies including Peptech, Cambridge Antibody Technology and Biota Holdings. Throughout her career, she has led many successful fundraising campaigns and licensing initiatives including the awarding of a $230m USA Government contract.

Jane is a non-executive director of ASX listed companies Anatara Lifesciences and Bionomics Limited. Jane was previously a Board Member of the Victorian Endowment for Science Knowledge and Innovation (veski), Diabetes Victoria and TechInSA.

Alison Cook (formerly Mew), Regulatory and Commercialisation Manager

With management and leadership experience of more than 30 years across the biopharmaceutical, diagnostic and health service sectors, Alison was CEO of Genetic Technologies Ltd, and spent 13 years in senior executive roles at CSL Limited.

Genetic Technologies Ltd is an ASX and NASDAQ listed leading edge genetic testing services business which developed and launched a breast cancer risk assessment test (BREVAGen Plus) in the US. At CSL Limited, Alison served in senior executive positions across the Animal Health, Biosciences and Pharmaceutical Divisions – managing veterinary and human vaccines, antivenoms and diagnostics.

Alison has 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.

She has worked internationally and in senior executive roles in Manufacturing, Engineering/ Maintenance, Quality, Logistics, Sales and Marketing and Product Development.

6.3 Scientific Advisory Board

Kim Ekroos, PhD – Lipidomics Scientific Advisor

Dr Kim Ekroos is the founder and CEO of Lipidomics Consulting Ltd., a consulting business providing unique services for customers globally in the field of Lipidomics. He received his Ph.D. in biology from the Technical University in Dresden, Germany, in 2003. 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.

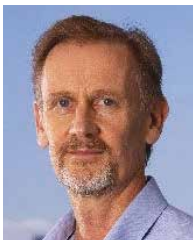
Kim is a globally experienced independent consultant for Lipidomics. He has over 20 years of expertise in the field, ranging from academics to industry. He has several patents for biomarker discovery, numerous peer-reviewed publications and is an editor of a widely read Lipidomics book. He is the current president of the newly founded International Lipidomics Society (ILS) to which the Lipidomics Standards Initiative (LSI) belongs that focuses on standardisation of Lipidomics studies.

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

Craig is a medical oncologist and cancer researcher. He works for people with melanoma, brain, prostate, bladder and kidney cancers at the Calvary Mater Newcastle, and is the Director of the HMRI Clinical Trials Unit.

His research focuses on complexity and heterogeneity in cancer – why are cancers different between different people; why are cancers cells different to each other; what does this mean for each person's treatment? This challenging problem spans projects across the research spectrum, from patient experience, through clinical trials, translational biomarkers and questions in basic science.

Craig is privileged to lead several national cancer clinical trials for the ANZUP and COGNO cancer trials groups, chairs the ANZUP Renal Cancer Subcommittee, and is a member of the Mark Hughes Scientific Advisory Committee, HNEHLD Clinical Trials Ethics Subcommittee, COGNO Scientific Advisory Committee and ANZUP Cancer Trials Scientific Advisory Committee.



Professor Peter Meikle

Professor Peter Meikle is the Head of the Systems Biology Domain, Co-Lead of the Obesity and Lipids Program and is Head of the Metabolomics Laboratory at the Baker Heart and Diabetes Institute. He is Editor in Chief of Metabolites, the official Journal of the International Metabolomics Society. His research has a focus on the dysregulation of lipid metabolism associated with metabolic diseases including obesity, diabetes, cardiovascular and Alzheimer's disease and its relationship to the pathogenesis of these disease states. This work is leading to new approaches to early diagnosis and risk assessment, and to the development of new lipid modulating therapies for chronic disease.

6.4 Directors' shareholding qualifications, remuneration and interests

Directors are not required under the Company's Constitution to hold any Shares.

Except as disclosed in the Prospectus, no Director or proposed Director of the Company, or firm in which a Director or proposed Director is a partner, has any interest, nor has had any interest for registration, or has received or is entitled to receive any sum for services rendered by either them or the firm to induce them to become or qualify them as a Director, or otherwise in connection with the promotion or formation of the Company or in the property proposed to be acquired by the Company in connection with its promotion or formation.

6.4.1 Directors' remuneration

Shareholders have resolved that the total aggregate amount to be paid to the Directors (excluding any Executive Director) is $500,000. Under the ASX Listing Rules, any increase to that aggregate annual amount will need to be approved by the Shareholders. The Company does not utilise that full amount based on its current Board of Directors.

The annual remuneration of the Board of Directors to be paid by the Company following admission to the ASX is as follows:

Director	Annual board fees inclusive of serving on any committee
Jayne Shaw, Chairman and Executive Director	$180,000
The Hon Ron Phillips AO, Non-Executive Director	$50,000
Jonathan Trollip, Non-Executive Director	$50,000
Merilyn Sleigh, Non-Executive Director	$50,000
Mark Burrows AO, Non-Executive Director	Nil

In addition to their annual remuneration, the Directors may also be reimbursed for expenses properly incurred by the Directors in connection with the affairs of the Company including travel and other expenses. There are no retirement benefit schemes for Non-Executive Directors.

6. Key people, interests and benefits continued

6.4.2 Directors' deeds of indemnity

The Company has entered into deeds of indemnity with each Director (the **Deeds**). In accordance with the Constitution, under the Deeds the Company indemnifies each Director on a full indemnity basis against:

(a) any liability incurred by the Director as a director of a group company (being the Company and its related bodies corporate); and

(b) all Liabilities incurred by the Director in relation to a claim by the Director against third parties in order to protect the Director's interests or reputation. This indemnity includes a liability for reasonable legal costs.

Subject to the terms of the Deed, the Company must also pay or indemnify the Director on a full indemnity basis for any defence costs.

The Directors are indemnified under the Deeds for the entirety of their term as Director and for 7 years from the date of the Director's retirement or removal or ceasing to hold office.

Under the Constitution, the Company may purchase and maintain insurance, or pay or agree to pay a premium for insurance, for any person who is or has been a director, secretary or executive officer of the Company or its related bodies corporate against any liability incurred by that person as such an officer, including, but not limited to, a liability for negligence and for legal costs.

6.4.3 Directors' interests in securities

Set out below are details of the interests of the Directors in the Shares and other securities of the Company immediately prior to lodgement of the Prospectus with the ASIC. Interests include those held directly by Directors in their own names and indirectly by their associates and/or entities that they control.

Name	Position	Annual Remuneration	Shares	Options	Option exercise price
Jayne Shaw	Executive Chairman	$180,000	27,569,602	2,022,638	$0.0574
The Hon Ron Phillips AO	Non-Executive Director	$50,000	26,514,567	2,022,638	$0.0574
Jonathan Trollip	Non-Executive Director	$50,000	3,147,649	1,155,793	$0.0574
Merilyn Sleigh	Non-Executive Director	$50,000	Nil	Nil	–
Mark Burrows AO	Non-Executive Director	Nil	442,908	Nil	–

Notes:

1. Jayne Shaw has a relevant interest in Shares through Nabelle Pty Ltd and OPSC Pty Limited, entities that she controls.
2. The Hon Ron Phillips AO has a relevant interest in Shares held in his own name, in the names of family members and through Rapcor Pty Limited, an entity that he controls.
3. Jonathan Trollip has a relevant interest in Shares through Piaster Pty Ltd, an entity that he controls.
4. Mark Burrows AO has a relevant interest in Shares through Permore Pty Ltd, an entity that he controls.

6.5 Interests of advisers

On successful completion of the Offer, the Lead Manager will be given the right to subscribe for fully paid ordinary shares equivalent in value to 3.25% of the post-money fully diluted valuation of the Company at the time of the Offer (**Lead Manager Securities**). The Shares will be issued for $0.0001 per Share.

Other than as disclosed in this Prospectus, no other person named in this Prospectus as providing professional or advisory services in connection with the preparation of this Prospectus or any firm in which any such person is a partner:

- has or had at any time during the two years preceding the date of the Prospectus, any interest in the formation or promotion of the Company, or in any property acquired or proposed to be acquired by the Company or the Offer; or
- has been paid or agreed to be paid any amount or given or agreed to be given any other benefit for services.

6.6 Related party transactions

Other than as set out below or elsewhere in this Prospectus, there are no existing agreements or arrangements nor any currently proposed transactions in which the Company was, or is to be, a participant and in which any related party of the Company has or will have a direct or indirect material interest in the Company or the Offer:

- the compensation arrangements with Directors and executive officers which are described in Section 6.4.1; and
- the indemnification arrangements with Directors and executive officers which are described in Section 6.4.2.

The Company's Audit and Risk Committee is responsible for reviewing, monitoring and making recommendations to the Board in relation to decisions on related party transactions and investments involving BCAL and its Directors and senior executives. If a Director considers that they may be in a position where there is a reasonable possibility of a conflict of interest, they must fully and frankly inform the Board and abstain from voting and absent from deliberations relating to the matter, unless the Board otherwise determines.

The Board will only approve those related party transactions that are determined to be in, or are not inconsistent with, the best interests of the Company and its Shareholders, after taking into account all available facts and circumstances as the Board determines in good faith to be necessary. Transactions with related parties will also be subject to Shareholder approval to the extent required by the Corporations Act and the ASX Listing Rules.

6.7 Former Employee Share Option Plan

6.7.1 Background

The BCAL Employee Share Option Plan 2019 (**Former ESOP**) was approved by shareholders in December 2019 to provide ongoing incentives to employees of, consultants to, or directors of, the Company or a person to whom an offer of employment by, or appointment as a consultant to, the Company has been made, who is determined by the Board to be eligible to receive grants of options under the Former ESOP (**Eligible Employees**).

6.7.2 Maximum number of options to be issued

At the time of the Former ESOP's approval by Shareholders, it was resolved that the total share options available for allocation under the Former ESOP would be limited to 10% of the share capital of the Company.

BCAL has applied for a waiver in relation to ASX Listing Rule 1.1 (condition 12) which requires that the Company's options on issue have an exercise price of at least $0.20.

Options issued under the Former ESOP are set out in the table below.

Option holder	Number of options held	Exercise price	Number of options unvested as at listing	Last exercise date
Dharmica Mistry[15]	2,311,560	$0.0574	–	30 January 2030
Amani Batarseh	3,467,353	$0.0574	577,896	20 November 2029
Jayne Shaw	2,022,638	$0.0574	–	23 November 2023
The Hon Ron Phillips AO	2,022,638	$0.0574	–	23 November 2023
Jonathan Trollip	1,155,793	$0.0574	–	23 November 2023
Charlie Lewis[16]	577,896	$0.0574	–	23 November 2023
Total	**11,557,878**			

The options held by Jayne Shaw, The Hon Ron Phillips AO, Jonathan Trollip and Charlie Lewis vest upon listing of the Company on the ASX.

As set out at Section 6.8.1 below, the Former ESOP was terminated on 30 March 2021. At the time of termination, the Directors resolved that the options issued under the Former ESOP that had not been exercised would continue to be governed by the Former ESOP. However, as no new options will be issued under the Former ESOP, the maximum number of equity securities to be issued under the Former ESOP is as set out in the table above.

15. Dharmica Mistry was formerly BCAL's chief scientist.
16. Charlie Lewis is an advisor to BCAL.

6.7.3 Key Terms

The key terms of the Former ESOP are summarised below.

6.7.3.1 Employee Rights

Under the Former ESOP, the Company may offer or issue to Eligible Employees options to acquire a specified number of the Company's shares at an exercise price, granted at the discretion of the Board.

6.7.3.2 Price

Options issued under the Former ESOP may be made on such terms as the Board determines in its absolute discretion. The options' exercise price under the Former ESOP is the market value of the Company's shares on the date the options are issued.

6.7.3.3 Vesting and exercise of Employee Rights

Options will vest in and become exercisable by a participant upon the satisfaction of any conditions specified in the offer. Vesting conditions may be waived at the Board's discretion.

The Company and the participant may agree to satisfy the Company's obligations in respect of exercised options in cash rather than shares.

6.7.3.4 Exit

On the proposal of an exit, including a sale of all shares on issue, an initial public offering and admission to the official list or a similar sale process, the Board may determine that unvested options will vest, notwithstanding some or all of the vesting conditions have not been satisfied and any restrictions on disposal will be waived.

6.7.3.5 Disposal restrictions

The Board may determine that a restriction period or other conditions apply to some or all of the options or shares and determine the terms and conditions applying to that restriction period or other conditions.

6.7.3.6 Forfeiture

If a participant ceases to be an employee, and at that time the participant's options have not yet vested or the options have vested but have not been exercised, the participant will forfeit all their options and all rights in respect of the options will cease unless the Board determines otherwise.

The Former ESOP also includes provision for 'bad leavers' which provides that the options held by a bad leaver are forfeited, unless the Board determines otherwise.

6.7.3.7 Variation of Share capital

In the event of any merger, reorganisation, consolidation, recapitalisation, separation, liquidation or any other change in the structure of the capital of the Company, the number and type of options and/or option shares issued will be adjusted accordingly such that the proportion and value of options and/or option shares issued in accordance with the Former ESOP will be substantially the same or similar to the proportion and value of options and/or option shares as at the date of issue and the terms of each issue will be varied accordingly.

6.8 Current Equity Incentive Plan

6.8.1 Background

On 30 March 2021, in accordance with the Constitution, the Board resolved to terminate the Former ESOP with effect from the date of the resolution, and has now adopted a new Equity Incentive Plan (**Equity Incentive Plan**).

The Company has adopted the Equity Incentive Plan in order to assist in the attraction, motivation and retention of current and prospective Company employees, Directors and advisors, consultants and contractors. The Equity Incentive Plan is designed to align the interests of eligible participants more closely with the interests of the Company by providing an opportunity for eligible participants to receive an equity interest in the Company. Under the Equity Incentive Plan, eligible participants may be offered rights, options, performance share awards or share awards, which may be subject to vesting and exercise conditions set by the Board.

The Equity Incentive Plan applies to eligible participants who are any permanent full time or part time employee of the Company, a Director, or an employee, consultant, advisor or contractor who works a pro-rata equivalent of at least 40% of a comparable full time position (**Eligible Participants**). Currently, Directors do not participate in the Equity Incentive Plan, and it is not at this time proposed that they would do so.

6.8.2 Key Terms

The key terms of BCAL's current Equity Incentive Plan (which replaces the Former ESOP) are summarised below. Capitalised terms are as defined in the Equity Incentive Plan, unless the context otherwise requires.

6.8.2.1 Employee Awards

Under the Equity Incentive Plan, the Company may, at the Board's discretion, offer or issue to Eligible Participants, the following awards:

- Options: a right to acquire a share upon satisfaction of any applicable performance hurdles, service conditions and exercise conditions (including payment of the exercise price, if any) in accordance with the terms set out in the Equity Incentive Plan and the Invitation;
- Performance Share Award: a Share granted under the Equity Incentive Plan, which is subject to performance hurdles and/or service conditions and/or exercise conditions in accordance with the terms set out in the Equity Incentive Plan and the invitation;
- Share Award: being –
  - an exempt share award: a Share issued for no consideration or at a purchase price which is a discount to the then market price of the Share with the intention that up to $1,000 (or such other amount which is exempted from tax under the *Income Tax Assessment Act 1997* (Cth) and any other applicable law) of the total value or discount received by each participant and which is taxed upfront will be exempt from tax;
  - a salary sacrifice share award; or
  - a Directors' fee sacrifice share award;
- Right: a right to acquire a Share upon satisfaction of any applicable performance hurdles, service conditions and exercise conditions (other than the payment of an exercise price) in accordance with the terms set out in the Equity Incentive Plan and the invitation.

6.8.2.2 Price

The exercise price for a Right is nil, unless otherwise determined by the Board. For an Option, the exercise price is the amount payable (if any) as specified in the Invitation.

6.8.2.3 Vesting and exercise of Awards

Awards will vest in that Participant upon the satisfaction of any performance hurdles and/or service conditions specified and become exercisable upon the satisfaction of any exercise conditions specified and before the last exercise date. performance hurdles, service conditions and exercise conditions may be waived at the discretion of the Board.

6.8.2.4 Ranking

Each Participant's Share issued will rank equally in all respects with all existing Shares from the date of issue.

6.8.2.5 Change of control

Where:

(a) a takeover bid is made for the Company and the Board recommends acceptance of that bid by the Company's shareholders;

(b) a Court orders that a meeting of shareholders of the Company be held to consider a scheme of arrangement between the Company and its shareholders; or

(c) the Board determines that some other transaction has occurred, or is likely to occur, which involves a change of control of the Company,

the Board may determine that any Right, Option or Performance Share Award that has not vested will vest on, and may be exercised on and from, the date determined by the Board.

6.8.2.6 Holding lock

Any security granted to a participant may be subject to a holding lock up to a maximum of 15 years from the grant date, at the Board's absolute discretion. A holding lock prevents the participant from dealing with or transferring their Shares or creating a security interest over their Shares. The holding lock may be removed at the Board's discretion in certain circumstances.

6.8.2.7 Lapsing and forfeiture

Participants are subject to lapsing and forfeiture events, unless the Board determines otherwise in its absolute discretion. These events include Rights, Performance Share Awards and/or Options held by a Participant which have not vested by the last vesting date and in the case of breach, fraud or dishonesty.

6.8.2.8 Clawback

The Board may take action to adjust or recover/clawback unvested 'at risk' remuneration where there is reasonable evidence that a Participant has materially contributed to, or been materially responsible for, the need for the restatement of financial results.

6.8.2.9 Variation of Share capital

In the event of a reorganisation of the Company's share capital, the Board will review and modify the terms of the awards if required by, and in accordance with, the ASX Listing Rules.

6.9 Director disclosures

6.9.1 No legal or disciplinary action

No Director (or company that the Director was a director of at the relevant time) has, in the 10 year period ending on the date of this Prospectus, had any legal or disciplinary action against the Director that is relevant to the Director's role in the Company and a potential investor's decision to apply for Shares.

6.9.2 Insolvent companies

No Director has been an officer of a company that entered into a form of external administration because of insolvency while the Director was an officer of the company or within 12 months of the Director ceasing to be an officer of the company.

6.10 Corporate Governance

The Directors are responsible for the strategic direction of the Company, the identification and implementation of corporate policies and goals, and monitoring of the business and affairs of the Company on behalf of its members.

6.11 Compliance with ASX corporate governance principles and recommendations

BCAL is seeking to list on the ASX. The ASX Corporate Governance Council has developed and released its Corporate Governance Principles and Recommendations (4th Edition) (**ASX Recommendations**) for entities listed on the ASX in order to promote investor confidence and to assist companies to meet shareholders' expectations.

The ASX Recommendations are not mandatory, but guidelines. However, under the ASX Listing Rules, the Company will be required to provide a statement in its annual report or on its website and also in an Appendix 4G that it must lodge with the ASX at the time it lodges its annual report, disclosing the extent to which it has followed the ASX Recommendations. The Company must identify the recommendations that have not been followed and give reasons for not following them.

The Directors have assessed BCAL's current practice against the ASX Recommendations and outlines its assessment below:

Principles and Recommendations	Compliance	Comply
Principle 1 – Lay solid foundations for management and oversight		
1.1 A listed entity should have and disclose a board charter setting out: (a) the respective roles and responsibilities of its board and management; and (b) those matters expressly reserved to the board and those delegated to management.	The Board is responsible for the overall corporate governance and decision-making of the Company. The Board has adopted a Board charter that formalises its roles and responsibilities and defines the matters that are reserved for Board approval and specific matters that are delegated to management. The members of the Board and their qualifications and experience are disclosed on the Company's website. The Board Charter is also available on the website.	Complies
1.2 A listed entity should: (a) undertake appropriate checks before appointing a director or senior executive or putting someone forward for election as a director; and (b) provide security holders with all material information in its possession relevant to a decision on whether or not to elect or re-elect a director.	The Remuneration and Nominations Committee, being a sub-committee of the Board, will monitor that character and background checks of proposed Directors are undertaken prior to putting a person forward for election as a Director. The Remuneration and Nominations Committee will identify and assess the skills, knowledge, experience, diversity, independence and time commitment of proposed directors, before recommending suitable candidates to the Board. The Company will conduct police checks, solvency and banned director searches in relation to all prospective Directors or senior executives. The Company will also make appropriate inquiries into the experience and education of prospective directors and senior executives. The Remuneration and Nominations Committee will provide security holders with all material information in the Company's possession relevant to the decision on whether to elect or re-elect a Director. This includes biographical details, other directorships held, Board statement of support and reasons why, and for new Directors, confirmation and detail of appropriate background checks, conflicts of interest and level of independence, and for re-elected Directors, current term of office and level of independence.	Complies

6. Key people, interests and benefits continued

Principles and Recommendations	Compliance	Comply
1.3 A listed entity should have a written agreement with each director and senior executive setting out the terms of their appointment.	The Company has written agreements with each Director and senior executive setting out the terms of their appointment. The Board is responsible for ensuring that the Company enters into written employment or consultancy agreements with Directors and senior executives. Each executive Director enters into a service contract with the Company setting out their duties, responsibilities, rights and termination conditions. Each Non-executive Director will be engaged by a letter of appointment setting out the terms and conditions of their appointment.	Complies
1.4 The company secretary of a listed entity should be accountable directly to the board, through the chair, on all matters to do with the proper functioning of the board.	Under the Board Charter, the company secretary is responsible for all matters to do with the proper functioning of the Board and is accountable directly to the Board through the Chair. The company secretary's responsibilities include all of those included in recommendation 1.4. Specifically, they are required to help organise and facilitate the induction and professional development of Directors as the secretary of the Remuneration and Nominations Committee. The Board approves the appointment of the company secretary. The company secretary is responsible for ensuring each director has access to the company secretary.	Complies

Principles and Recommendations	Compliance	Comply
1.5 A listed entity should: (a) have and disclose a diversity policy; (b) through its board or a committee of the board set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally; and (c) disclose in relation to each reporting period: (1) the measurable objectives set for that period to achieve gender diversity; (2) the entity's progress towards achieving those objectives; and (3) either: (A) the respective proportions of men and women on the board, in senior executive positions and across the whole workforce (including how the entity has defined "senior executive" for these purposes); or (B) if the entity is a "relevant employer" under the Workplace Gender Equality Act, the entity's most recent "Gender Equality Indicators", as defined in and published under that Act.	The Company has a Diversity and Inclusion Policy, which is publicly disclosed on its website. The Board and Remuneration and Nominations Committee are jointly responsible under that Policy to set measurable objectives for achieving diversity in the composition of the Board, senior executives and the workforce generally. These objectives are reviewed on an annual basis. Progress against the objectives, including against benchmarks where applicable, are assessed and reported on an annual basis. The measurable objectives, progress and respective proportion of female and male employees, senior executives and Directors will be disclosed in the Company's annual report. Due to the size and structure of the Company, the Board and Remuneration and Nominations Committee have not yet determined a fixed percentage target of women at any given level within the Company, so no measurable objectives have been set at this time. The Company expects to be able to set more specific, numerical targets once its human resources grow to a number that allows these targets to be set. The Board considers that the current proportion of women in the Company is appropriate in light of the size and structure of the organisation. The Company will regularly review the proportion as the Company grows and will regularly check for unjustifiable gender pay gaps across all levels of the workforce. The Company is not required to comply with the 'Gender Equality Indicators' as it does not qualify as a 'relevant employer' under the Workplace Gender Equality Act, since it is not likely to have 100 or more employees in Australia. As and when it does qualify as a 'relevant employer', it will have regard to those requirements under that Act. In accordance with recommendation 1.5, the Company's Diversity and Inclusion Policy seeks to consider gender as well as other facets of diversity.	Partially complies

6. Key people, interests and benefits continued

Principles and Recommendations	Compliance	Comply
1.6 A listed entity should: (a) have and disclose a process for periodically evaluating the performance of the board, its committees and individual directors; and (b) disclose for each reporting period whether a performance evaluation has been undertaken in accordance with that process during or in respect of that period.	Under the Board Charter, the Board, with assistance from the Remuneration and Nominations Committee, is responsible for annually evaluating the performance of the Board, its committees and individual Directors. The Chair has responsibility to assess each Director standing for re-election following mandatory retirement in accordance with the Company's constitution and the ASX Listing Rules. The Board (aside from the Director involved) will then determine whether to recommend the re-election of that Director to the shareholders. Under the Board Charter, the Board is required to disclose in the Company's annual report whether a performance evaluation has been taken in respect of any particular Director during the relevant period.	Complies

Principles and Recommendations	Compliance	Comply
Principle 2 – Structure the board to be effective and add value		
2.1 The board of a listed entity should: (a) have a nomination committee which: (1) has at least three members, a majority of whom are independent directors; and (2) is chaired by an independent director, and disclose: (3) the charter of the committee; (4) the members of the committee; and (5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or (6) if it does not have a nomination committee, disclose that fact and the processes it employs to address board succession issues and to ensure that the board has the appropriate balance of skills, knowledge, experience, independence and diversity to enable it to discharge its duties and responsibilities effectively.	The Board has a combined Remuneration and Nominations Committee established with its own charter. The members are: • Merilyn Sleigh, Chair • Jonathan Trollip • Ron Phillips AO Under the Remuneration and Nominations Committee Charter, the Committee must have at least three members with at least one Director being an independent Director. The requirement for at least on independent director rather than a majority is due to the size of the Company, which has only five Directors as at listing, so it is impractical at present to require a majority of independent Directors and to be chaired by an independent Director. See more on the Board's composition at item 2.4 below. The members of the Remuneration and Nominations Committee and their qualifications and experience are disclosed on the Company's website. The charter of the committee is also available on that website. The number of times the committee meets during a given reporting period and individual attendances of the members at those meetings will be included in the annual reports provided to investors. The Remuneration and Nominations Committee is also responsible for developing succession plans for the Board to ensure an appropriate mix of skills, knowledge, experience, independence and diversity within the Board, and for overseeing the ongoing process of succession planning for the role of the Chair and CEO (if one is appointed).	Partially complies

6. Key people, interests and benefits continued

Principles and Recommendations	Compliance	Comply
2.2 A listed entity should have and disclose a board skills matrix setting out the mix of skills that the board currently has or is looking to achieve in its membership.	The Remuneration and Nominations Committee is required to maintain and disclose a board skills matrix updated on a regular basis, setting out the appropriate mix of skills, knowledge, experience, diversity and independence that the Board and its committees are seeking to achieve, and the time commitment required from non-Executive Directors.	Complies
2.3 A listed entity should disclose: (a) the names of the directors considered by the board to be independent directors; (b) if a director has an interest, position or relationship of the type described in Box 2.3 but the board is of the opinion that it does not compromise the independence of the director, the nature of the interest, position or relationship in question and an explanation of why the board is of that opinion; and (c) the length of service of each director.	The Board considers Jayne Shaw (appointed 15 February 2010), an Executive Director, to not be independent, as she is a founding and substantial shareholder of the Company. The Board considers the Hon Ron Phillips AO (appointed 15 February 2010), a Non-Executive Director, not to be independent as he is a founding and substantial shareholder of the Company. The Board considers Jonathan Trollip (appointed 23 December 2020), a Non-Executive Director, to be independent. The Board considers Dr Merilyn Sleigh (appointed 30 March 2021), a Non-Executive Director, to be independent. The Board considers Mark Burrows AO (to be appointed on and from listing), a Non-Executive Director, to be independent.	Complies
2.4 A majority of the board of a listed entity should be independent directors.	On listing, three of the five Directors are independent, making the Board majority independent. The Board considers its present composition to be appropriate, given the small size of the Board reflects the size of the Company's operations, and takes into account the degree of contribution of the two non-independent directors to date. However, the Board will monitor this composition and, if deemed appropriate, recruit another independent Non-Executive Director.	Complies

Principles and Recommendations	Compliance	Comply
2.5 The chair of the board of a listed entity should be an independent director and, in particular, should not be the same person as the CEO of the entity.	The Chair of the Board is Jayne Shaw, who is not an independent Director. Because of her support of and engagement with the Company, both in terms of time and financial commitment, the Board unanimously views Ms Shaw as the most suitable person to provide the best corporate governance and leadership at this point in time. Ms Shaw is not, however, the CEO of the entity. On listing, the Company will not have appointed a CEO.	Does not comply
2.6 A listed entity should have a program for inducting new directors and for periodically reviewing whether there is a need for existing directors to undertake professional development to maintain the skills and knowledge needed to perform their role as directors effectively.	Under the Board Charter, new Directors are expected to participate in induction or orientation programs. Directors are expected to participate in any continuing education or training arranged at the Company's expense. The Remuneration and Nominations Committee is responsible for assisting the Board in relation to director induction and continuing professional development. The induction program must sufficiently allow new Directors to gain an understanding of the Company, its operations and values, financial, strategic and risk management, and the rights, duties and responsibilities of the Board, its committees and senior executive management team. The Remuneration and Nominations Committee must ensure the Directors have access to professional development at the Company's expense to the extent that the Committee considers it necessary and appropriate, assessing against the board skills matrix that it is required to maintain.	Complies

Principles and Recommendations	Compliance	Comply
Principle 3 – Instil a culture of acting lawfully, ethically and responsibly		
3.1 A listed entity should articulate and disclose its values.	The Company is committed to acting lawfully, ethically and responsibly, which is reflected in its Code of Conduct. The Code of Conduct is designed to be followed by all officers, employees and contractors – in short, anyone who can be seen to be a representative of the Company. The Code of Conduct includes a statement of the Company's values, which include a number of the suggestions for the content of a code of conduct in Box 3.2 of the ASX Recommendations.	Complies
3.2 A listed entity should: (a) have and disclose a code of conduct for its directors, senior executives and employees; and (b) ensure that the board or a committee of the board is informed of any material breaches of that code.	The Company has adopted the Code of Conduct which applies to all Directors, senior executives and employees. The Code sets out the Company's values as a framework for the Company's representatives to follow in the performance of their duties and responsibilities. The Code ensures a set of behavioural standards is made known and followed by representatives, in pursuit of best practice corporate governance. Any breaches of the Code are to be reported to the Chair, and any material breaches of the Code will be directly reported to the Board to ensure proper accountability and action. The Code of Conduct is disclosed to the public on the Company's website.	Complies

Principles and Recommendations	Compliance	Comply
3.3 A listed entity should: (a) have and disclose a whistleblower policy; and (b) ensure that the board or a committee of the board is informed of any material incidents reported under that policy.	The Company has adopted a Whistleblower Policy which encourages the reporting of any suspected unethical, illegal, fraudulent or undesirable conduct involving the Company's businesses, and specifies the processes and protections available to those reporting. The Whistleblower Policy has been prepared on the basis of ASIC Regulatory Guide 270 and section 1317AI of the Corporations Act and is consistent with Box 3.3 'Suggestions for the content of a whistleblower policy' of the ASX Recommendations. The Eligible Recipients of whistleblower incident reports (as identified under the *Corporations Act 2001* (Cth) and *Taxation Administration Act 1953* (Cth)) must report at least annually to the Board on the number and type of reports (with anonymity preserved). The Board will receive copies of all whistleblower reports (anonymised) and Eligible Recipients must consider immediately referring serious or material Disclosable Matters to the Chair. The Whistleblower Policy is disclosed to the public on the Company's website.	Complies
3.4 A listed entity should: (a) have and disclose an anti-bribery and corruption policy; and (b) ensure that the board or a committee of the board is informed of any material breaches of that policy.	The Company has adopted an Anti-Bribery and Corruption Policy. The Anti-Bribery and Corruption Policy complies with Box 3.4 'Suggestions for the content of an anti-bribery and corruption policy' of the ASX Recommendations. All material breaches of the Anti-Bribery and Corruption Policy are to be reported to the Board. The CEO (and if one is not appointed, the chief operating officer or Executive Chair) has primary and day-to-day responsibility for implementing the policy. The Board will monitor the effectiveness and review the implementation of the policy by periodically considering its suitability, adequacy and effectiveness.	Complies

Principles and Recommendations	Compliance	Comply
Principle 4 – Safeguard the integrity of corporate reports		
4.1 The board of a listed entity should: (a) have an audit committee which: (1) has at least three members, all of whom are non-executive directors and a majority of whom are independent directors; and (2) is chaired by an independent director, who is not the chair of the board, and disclose: (3) the charter of the committee; (4) the relevant qualifications and experience of the members of the committee; and (5) in relation to each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or (6) if it does not have an audit committee, disclose that fact and the processes it employs that independently verify and safeguard the integrity of its corporate reporting, including the processes for the appointment and removal of the external auditor and the rotation of the audit engagement partner.	The Company has established a combined Audit and Risk Management Committee operating in accordance with its own charter. The members are: • Jonathan Trollip (Chair) • Merilyn Sleigh • Ron Phillips AO Under its Charter, the Audit and Risk Management Committee must comprise at least three members, all of whom must be Non-Executive Directors and a majority of whom must be independent. The Chair of the committee is a Non-Executive Director who is independent. If the independent Non-Executive Directors are not eligible or available to serve as chair, a Non-Executive Director who is not independent will be appointed as the Chair. This is due to the size of the Board and the practicality of having an appropriate appointee as chair. The members of the Audit and Risk Management Committee and their qualifications and experience are disclosed on the Company's website. The charter of the committee is also available on the website. The number of times the committee met during a given reporting period and individual attendances of the members at those meetings will be included in the annual reports provided to investors.	Complies
4.2 The board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.	Under the Audit and Risk Management Committee Charter, the Audit and Risk Management Committee will, prior to providing approval of financial statements for a financial period, receive from the CEO (if one is appointed) and CFO a declaration in accordance with this recommendation 4.2.	Complies

Principles and Recommendations	Compliance	Comply
4.3 A listed entity should disclose its process to verify the integrity of any periodic corporate report it releases to the market that is not audited or reviewed by an external auditor.	The Audit and Risk Management Committee Charter sets out the process to verify the integrity of periodic corporate reports released to market that are not audited or review by an external auditor, namely, that the Audit and Risk Management Committee must first review the draft report in accordance with the standards in its charter and once it is comfortable with it, present it to the Board for consideration and approval prior to release to market.	Complies
Principle 5 – Make timely and balanced disclosure		
5.1 A listed entity should have and disclose a written policy for complying with its continuous disclosure obligations under listing rule 3.1.	The Company has adopted a Continuous Disclosure Policy to ensure prompt and complete disclosure of price sensitive information in compliance with listing rule 3.1.	Complies
5.2 A listed entity should ensure that its board receives copies of all material market announcements promptly after they have been made.	Under the Continuous Disclosure Policy, each member of the Board must receive a copy of all material market announcements promptly after their release.	Complies
5.3 A listed entity that gives a new and substantive investor or analyst presentation should release a copy of the presentation materials on the ASX Market Announcements Platform ahead of the presentation.	All new investor and analyst presentations must be approved by the Disclosure Committee (which is established under the Continuous Disclosure Policy). A copy of the presentation materials, once approved by the Disclosure Committee, are released on the ASX Market Announcements Platform ahead of the presentation.	Complies
Principle 6 – Respect the rights of security holders		
6.1 A listed entity should provide information about itself and its governance to investors via its website.	Under the Shareholder Communications Policy, the Company will use its website https://www.bcaldiagnostics.com/ to communicate with investors. The 'Investor Centre' section of the BCAL website contains all information relevant to shareholders and stakeholders, including statements lodged with the ASX, Board and committee charters and corporate governance policies and other material relevant to shareholders.	Complies

6. Key people, interests and benefits continued

Principles and Recommendations	Compliance	Comply
6.2 A listed entity should have an investor relations program that facilitates effective two-way communication with investors.	The Company's Continuous Disclosure Policy and Shareholder Communications Policy provide that the Company will use its website, half year and annual reports, market announcements and media disclosures to communicate with its shareholders, as well as encourage participation at general meetings. The policies also allow for briefings for analysts and institutional investors to engage existing and potential investors.	Complies
6.3 A listed entity should disclose how it facilitates and encourages participation at meetings of security holders.	Under the Shareholder Communications Policy, shareholders are encouraged to express to the Company's representatives at the AGM any matters of concern or interest to the shareholder group. Shareholders who are unable to attend the AGM are given the opportunity to provide questions or comments beforehand and where appropriate, these questions or comments are addressed at the AGM. The Company may also facilitate participation in the AGM via technology to ensure participation and voting in the meeting.	Complies
6.4 A listed entity should ensure that all substantive resolutions at a meeting of security holders are decided by a poll rather than by a show of hands.	The Shareholder Communications Policy provides that all substantive resolutions at a meeting of shareholders are decided by poll rather than by a show of hands, to enable the chair of the meeting to ascertain the true will and voting of the shareholders attending, whether in person, electronically, by proxy or other representative.	Complies
6.5 A listed entity should give security holders the option to receive communications from, and send communications to, the entity and its security registry electronically.	Under the Shareholder Communications Policy, the Company encourages shareholders to receive information and communications from, and send communications to, the Company and its share registry, electronically. The policy sets out the specific process, being that shareholders may elect to send and receive communications electronically by registering their email addresses online with the Company's share registry. Shareholders are directed to the share registry to obtain further information about this process.	Complies

Principles and Recommendations	Compliance	Comply
Principle 7 – Recognise and manage risk		
7.1 The board of a listed entity should: (a) have a committee or committees to oversee risk, each of which: (1) has at least three members, a majority of whom are independent directors; and (2) is chaired by an independent director, and disclose: (3) the charter of the committee; (4) the members of the committee; and (5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or (6) if it does not have a risk committee or committees that satisfy (a) above, disclose that fact and the processes it employs for overseeing the entity's risk management framework.	The Company has a combined Audit and Risk Management Committee. See 4.1 above.	Complies
7.2 The board or a committee of the board should: (a) review the entity's risk management framework at least annually to satisfy itself that it continues to be sound and that the entity is operating with due regard to the risk appetite set by the board; and (b) disclose, in relation to each reporting period, whether such a review has taken place.	In accordance with the Audit and Risk Management Committee Charter, the committee must review the Company's risk management framework at least annually and report the results to the Board. The risk management review is with reference to the risk appetite of the Company as set by the Board and includes assessment of the management's performance against the risk management framework, examines new and emerging sources and risk and mitigation processes of existing and new risks. The Company is required to disclose in each reporting period whether the above reviews have taken place.	Complies

6. Key people, interests and benefits continued

Principles and Recommendations	Compliance	Comply
7.3 A listed entity should disclose: (a) if it has an internal audit function, how the function is structured and what role it performs; or (b) if it does not have an internal audit function, that fact and the processes it employs for evaluating and continually improving the effectiveness of its governance, risk management and internal control processes.	The Company does not have an internal audit function as at the date of the Prospectus. This is disclosed in the Audit and Risk Management Committee Charter. Therefore, section 4.4 of the charter applies to specify the processes employed for the committee to review and report to the Board on the overall adequacy and effectiveness of internal control systems, controls and processes, legal and ethical compliance and insurance coverage. As a part of this process, the committee will review and report to the Board on any material threatened or actual claims or issues in relation to tax or legal matters, recommendations to changes to be made to the risk management framework or risk appetite, and any material incidents involving non-compliance with internal controls or breakdown of risk controls and 'lessons learned'. Minutes of each committee meeting will be circulated to all members of the Board to ensure proper communication of matters. For completeness, section 4.3 of the Audit and Risk Management Committee Charter sets out the responsibilities of the committee with respect to an internal auditor should they be engaged at any time.	Complies
7.4 A listed entity should disclose whether it has any material exposure to environmental or social risks and, if it does, how it manages or intends to manage those risks.	The Board does not believe that the Company has material exposure to any such risks. Under the Audit and Risk Management Committee Charter, the committee will consider, at least annually, whether the Company has any material exposure to environmental or social risks and provide a report to the Board on how it intends to manage those risks.	Complies

Principles and Recommendations	Compliance	Comply
Principle 8 – Remunerate fairly and responsibly		
8.1 The board of a listed entity should: (a) have a remuneration committee which: (1) has at least three members, a majority of whom are independent directors; and (2) is chaired by an independent director, and disclose: (3) the charter of the committee; (4) the members of the committee; and (5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or (6) if it does not have a remuneration committee, disclose that fact and the processes it employs for setting the level and composition of remuneration for directors and senior executives and ensuring that such remuneration is appropriate and not excessive.	The Company has a combined Remuneration and Nominations Committee operating in accordance with its own charter. The members are: • Merilyn Sleigh, Chair • Jonathan Trollip • Ron Phillips AO Under its Charter, the Remuneration and Nominations Committee must comprise at least three members with at least one Director being an independent Non-Executive Director. While the majority of Directors are independent, requiring a majority of independent Directors at present is not practical due to the small size of the Board, but the Company intends to move towards a required majority when the Board size increases. The Chair is an independent Non-Executive Director. The charter of the committee is available on the website. The number of times the committee met during a given reporting period and individual attendances of the members at those meetings will be included in the annual reports provided to investors.	Partially complies
8.2 A listed entity should separately disclose its policies and practices regarding the remuneration of non-executive directors and the remuneration of executive directors and other senior executives.	The Company discloses its policies and practices of Non-Executive Directors, and remuneration of Executive Directors and other senior executives in the Prospectus and will continue to do so on an ongoing basis in remuneration reports forming part of the annual reports provided to investors.	Complies
8.3 A listed entity which has an equity-based remuneration scheme should: (a) have a policy on whether participants are permitted to enter into transactions (whether through the use of derivatives or otherwise) which limit the economic risk of participating in the scheme; and (b) disclose that policy or a summary of it.	In accordance with the Securities Trading Policy, the Company has the policy that participants in an equity-based remuneration scheme are only permitted to enter into transactions (whether through the use of derivatives or otherwise) which limit the economic risk of their participation in that scheme after they have received approval through the general trading clearance process specified in the Securities Trading Policy.	Complies

Principles and Recommendations	Compliance	Comply
Additional compliance requirements from the ASX Listing Rules		
Listing Rule 1.1 Condition 13 requires a listed entity to appoint a person responsible for communication with ASX on Listing Rule matters.	Under the Board Charter, the company secretary is responsible for ensuring compliance with the ASX Listing Rules and communication with the ASX on Listing Rule matters and generally.	Complies
Listing Rule 12.9 requires a listed entity to have a trading policy covering its directors and other key management personnel and regulating trading in its securities during certain "prohibited periods".	The Securities Trading Policy applies to all Directors, employees, contractors and anyone with access to confidential information about the Company, and sets out prohibitions on insider trading as well as the restrictions on trading during certain prohibited periods (which are in relation to the release of quarterly, half year and full year results, or any other periods that the Board may set).	Complies
Listing rule 4.10.3 requires a listed entity to include in its annual report either a corporate governance statement that meets the requirements of that rule, or the URL of the page on its website where such a statement is located. "Corporate governance statement" is defined in listing rule 19.12 to mean the statement referred to in listing rule 4.10.3 which discloses the extent to which an entity has followed the recommendations set by the ASX Corporate Governance Council during a particular reporting period. Listing rule 4.7.4 provides that if an entity's corporate governance statement is not included in its annual report, the entity must also give ASX a copy of its corporate governance statement at the same time as it gives its annual report to ASX.	In the Board Charter, the Company has stated that it will include in its annual report a corporate governance statement that complies with the requirements of the ASX Listing Rules.	Complies

7. Details of the Offer

7. Details of the Offer

7.1 The Offer

The Company is undertaking an Offer of 32,000,000 Shares at $0.25 per Share to raise $8,000,000 before costs, with the ability to accept Oversubscriptions for up to an additional $4,000,000. The Shares issued under this Prospectus will represent approximately 16.1% of Shares on issue upon Completion of the Offer (without Oversubscriptions).

Based on the offer price, the market capitalisation after the Offer will be approximately $49,653,908, or if the Offer is fully Oversubscribed, approximately $53,653,908.

The Offer is made subject to the terms and conditions set out in this Prospectus. All Shares will rank equally with each other.

Please refer to the Key Offer Information section for the Opening Date and Closing Date for the Offer and refer to Section 7.4 for details on how to apply for Shares pursuant to the Offer.

7.2 Structure of the Offer

The Offer consists of a Broker Firm Offer.

The allocation of Shares will be determined by agreement between the Company and the Lead Manager, having regard to the allocation policy outlined in Section 7.3 below.

7.3 Terms and Conditions of the Offer

Topic	Summary
What is the type of security being offered?	Shares in BCAL Diagnostics Limited.
What is the consideration payable for the Shares?	The Offer Price is $0.25 per Share.
What is the Offer period?	The key dates are set out in the Key Offer details section.
What are the cash proceeds to be raised?	$8,000,000, with the ability to accept Oversubscriptions for an additional $4,000,000.
What are the conditions to the Offer?	The Offer is conditional on the Company raising the Minimum Subscription Amount and being granted conditional approval to list on the ASX. There is no guarantee that ASX will grant this approval. If these conditions are not met the Offer will not proceed and investors' Application Monies will be returned (without interest).
What is the minimum and maximum Application size under the Offer?	The minimum Application size under the Offer is $2,000, being an Application for 8,000 Shares. There is no maximum Application size under the Offer.

Topic	Summary
What is the allocation policy?	The Company reserves the right to authorise the issue of a lesser number of Shares than those for which Application has been made or to reject any Application. Where no issue or allocation is made or the number of Shares issued is less than the number applied for, surplus Application money will be refunded without interest. If an Application Form is not completed correctly, or if the accompanying payment is for the wrong amount, it may still be treated as valid. The Company's decision as to whether to treat an Application as valid, and how to construe, amend or complete it, will be final. The Company's decision on the number of Shares to be allocated to an Applicant will also be final.
When will I receive confirmation whether my Application has been successful?	It is expected that initial holding statements will be mailed by standard post on or about 8 July 2021.
Will the Shares be quoted?	The Company will apply for admission to the Official List of the ASX and quotation of Shares on ASX under the code "BDX". Completion of the Offer is conditional on the ASX approving this application. If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all Application Monies received will be refunded without interest as soon as practicable. The Company will be required to comply with the ASX Listing Rules, subject to any waivers obtained by the Company from time to time. ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that ASX may admit the Company to the Official List is not to be taken as an indication of the merits of the Company or the Shares offered for subscription.
When are the Shares expected to commence trading?	It is expected that trading of the Shares on the ASX will commence on or around 16 July 2021. It is the responsibility of each Applicant to confirm their holding before trading in Shares. Applicants who sell Shares before they receive an initial statement of holding do so at their own risk. The Company, the Share Registry and the Lead Manager disclaim all liability, whether in negligence or otherwise, to persons who sell Shares before receiving their initial statement of holding, even if such person received confirmation of allocation from the Share Registry, by a broker or otherwise.
Is the Offer underwritten?	No.
Are there any escrow arrangements?	Yes. Details are provided in Section 7.7 below.
Are there any taxation considerations?	Yes. Please refer to Section 9.17 regarding Australian tax considerations and note it is recommended that all potential investors consult their own independent tax advisers regarding the income tax (including capital gains tax), stamp duty and GST consequences of acquiring, owning and disposing of Shares, having regard to their specific circumstances.

7. Details of the Offer continued

Topic	Summary
Are there any brokerage, commission or stamp duty considerations?	No brokerage, commission or stamp duty is payable by Applicants on acquisition of Shares under the Offer.
Where can I get more information about this Prospectus or the Offer?	Enquiries in relation to this Prospectus may be directed to the Share Registry on 1300 288 664 (toll free within Australia) or +61 2 9698 5414 (outside Australia) from 9am until 5pm (Sydney time) Monday to Friday. Enquiries in relation to the Broker Firm Offer should be directed to your broker. If you are unclear in relation to any matter or are uncertain as to whether the Company is a suitable investment for you, you should seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

7.4 How to apply

Applications for new Shares offered under the Offer may only be made on the appropriate Application Form attached to and forming part of this Prospectus. Please read the instructions on the Application Form carefully before completing it.

If you are an investor applying under the Broker Firm Offer, you should complete and lodge your Application Form and Application Monies with the broker from whom you received your firm allocation of Shares. Applications under the Broker Firm Offer must not be sent to the Share Registry.

Applications for Shares under the Offer must be for a minimum of 8,000 Shares and thereafter in multiples of 4,000 Shares and payment for the Shares must be made in full at the issue price of $0.25 per Share. The Company and Lead Manager reserve the right to aggregate any Applications which they believe are multiple applications from the same person, or to reject or scale back any Applications.

A completed Application Form is an offer by an Applicant to the Company to apply for the amount of Shares specified in the Application Form on the terms and conditions set out in this Prospectus (including any supplementary or replacement document) and the Application Form. To the extent permitted by law, an Application by an Applicant is irrevocable.

The Company reserves the right to decline any Application and all Applications in whole or in part, without giving any reason. Applicants under the Offer whose Applications are not accepted, or who are allocated a lesser number of Shares than the amount applied for, will receive a refund of all or part of their Application Monies, as applicable. Interest will not be paid on any monies refunded. Acceptance of an Application will give rise to a binding contract.

Completed Application Forms (and accompanying cheques) must be mailed or delivered to the address set out on the Application Form by no later than the Closing Date. The Company and the Lead Manager may elect to extend the Offer or any part of it, or to accept late Applications in particular cases or generally. The Offer, or any part of it, may be closed at an earlier date or time without notice, or your broker may impose an earlier closing date.

Applicants are therefore encouraged to submit their Application Forms as soon as possible. Please contact your broker for instructions.

7.5 How to pay

If you are an investor applying under the Broker Firm Offer, you should complete and lodge your Application Form and Application Monies with the broker from whom you received your firm allocation of Shares. Applications under the Broker Firm Offer must not be sent to the Share Registry. If payment is being made by cheque, the cheque must accompany the completed Application Form. The Company and the Lead Manager may elect to extend the Offer or any part of it, or to accept late Applications in particular cases or generally. The Offer, or any part of it, may be closed at an earlier date or time without notice, or your broker may impose an earlier closing date. Applicants are therefore encouraged to submit their Application Forms as soon as possible. Please contact your broker for instructions.

You should be aware that your financial institution may implement earlier cut off times with regard to electronic payment and you should take this into consideration when making payment. None of the Company, the Lead Manager or the Share Registry takes any responsibility for any failure to receive Applications Monies or payment before the Offer closes arising as a result of, among other things, delays in processing of payments by financial institutions.

7.6 Application Monies

Application Monies received under the Offer will be held in a special purpose account until Shares are issued or transferred to successful Applicants. Applicants under the Offer whose Applications are not accepted, or who are allocated a lesser amount of Shares than the amount applied and paid for, will be provided with a refund of the relevant portion of their Application Monies. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any Application Monies refunded and any interest earned on Application Monies pending the allocation or refund will be retained by the Company.

7.7 Escrow arrangements

The Directors of the Company have agreed with ASX not to dispose of, create any security interest in or transfer effective ownership or control of the Shares or options that they currently hold (directly or indirectly) amounting to 57,674,726 Shares and 5,201,069 options for a period of 24 months from Official Quotation.

Further Shares and options to be held under the ASX restriction agreements (assuming the Offer raises $8 million) are as follows:

	Escrow for 12 months	Escrow for 24 months	% of issued capital on listing
Directors and Management	–	58,648,234 Shares 8,668,422 options	32.03%
Lead Manager Securities	–	6,615,631	3.15%
Other Shareholders	21,841,589 Shares	15,730,293 Shares	17.88%
Total	**21,841,589**	**80,993,993 Shares 8,668,422 options**	**53.05%**

Further Shares may be subject to voluntary escrow under the terms of escrow deeds preventing Shareholders from disposing of their respective escrowed Shares until 6 months from the date of Official Quotation. The restriction on "disposing" is broadly defined and includes, among other things, selling, assigning, transferring or otherwise disposing of any interest in the Shares, encumbering or granting a security interest over the Shares, doing, or omitting to do, any act if the act or omission would have the effect of transferring effective ownership or control of any of the Shares or agreeing to do any of those things.

7. Details of the Offer continued

7.8 ASX Listing

An application will be made to ASX not later than seven days after the date of this Prospectus for the Company to be admitted to ASX, and for Official Quotation of the Shares. Acceptance of the application by ASX is not a representation by ASX about the merits of the Company or the Shares. Official Quotation of Shares, if granted, commences as soon as practicable after the issue of initial shareholding statements to successful Applicants.

It is expected that trading of the Shares on ASX will commence on or about 16 July 2021.

If permission is not granted for Official Quotation of the Shares on ASX within three months of the date of this Prospectus, or any longer period permitted by law, all Application Money received is refunded without interest as soon as practicable under the requirements of the Corporations Act. ASX takes no responsibility for the contents of this Prospectus.

Assuming 32,000,000 Shares are issued under the Offer, the expected free float of the Company on Completion of the Offer will be approximately 48.2%, based on 198,615,633 Shares being on issue less 102,835,747 Shares subject to mandatory escrow and assuming no voluntary escrow agreements are entered into.

7.9 CHESS and issuer sponsored holdings

The Company will apply for the Shares to participate in CHESS. Applicants who are issued Shares under this Offer will receive shareholding statements in lieu of share certificates. They set out the number of Shares issued to each successful Applicant.

The shareholding statement also provides details of the Shareholder's HIN (in the case of a holding on the CHESS sub-register) or SRN (in the case of a holding on the issuer sponsored sub-register).

In future, Shareholders need to quote their HIN or SRN, as applicable, in all dealings with a stockbroker or the Share Registry. Further statements are given to Shareholders showing changes in their shareholding during a particular month. Additional statements may be requested at any time, although the Company reserves the right to charge a fee for them.

7.10 Restrictions on distribution

No action has been taken to register or qualify this Prospectus, the Shares or the Offer or otherwise to permit a public offering of the Shares in any jurisdiction outside Australia. This Prospectus does not constitute an offer or invitation to subscribe for Shares in any jurisdiction in which, or to any person to whom, it would not be lawful to make such an offer or invitation or issue under this Prospectus.

Accordingly, neither this Prospectus nor any advertisement may be distributed or published in any other jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. This Prospectus may not be released or distributed in the USA and may only be distributed to persons outside the USA to whom the Offer may lawfully be made in accordance with the laws of any applicable jurisdiction. This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the USA. The Shares have not been, and will not be, registered under the US Securities Act or the securities laws of any state of the USA and may not be offered or sold, directly or indirectly, in the US except in accordance with an exemption from, or in a transaction not subject to, the registration requirements of the USA Securities Act and applicable USA State securities laws.

Each Applicant in the Offer will be taken to have represented, warranted and agreed the following:

(a) if outside Australia, it is a person to whom the Offer can be lawfully made and Shares lawfully allocated and issued or transferred to without the requirement of any person to prepare, or file with any regulatory authority, a prospectus or other document under the laws applicable to that person or the jurisdiction it is in;

(b) it understands and agrees that the Shares have not been, and will not be, registered under the US Securities Act or the securities law of any state of the USA and may not be offered or sold, directly or indirectly, in the USA, except in accordance with an exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and applicable USA State securities laws, and it agrees not to engage in hedging transactions with regard to such securities except in compliance with the US Securities Act;

(c) it is not in the USA;

(d) it has not sent, and will not send, the Prospectus or any other material relating to the Offer to any person in the USA; and

(e) it will not offer or sell the Shares in any other jurisdiction outside Australia except in transactions exempt from, or not subject to, registration under applicable securities laws and in compliance with all other applicable laws in the jurisdiction in which Shares are offered and sold.

Each Applicant under the Broker Firm Offer will be required to make, or will be deemed to have made, certain representations, warranties and covenants set out in the Application Form attached to or accompanying this Prospectus.

7.11 International offer restrictions

This Prospectus does not constitute an offer of Shares in any jurisdiction in which it would be unlawful. In particular, this Prospectus may not be distributed to any person, and the Shares that are the subject of the Offer may not be offered or sold, in any country outside Australia except to the extent permitted below.

7.11.1 Hong Kong

WARNING: This Prospectus has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the **SFO**).

No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this Prospectus or any documents issued in connection with it. Accordingly, the Shares offered under this Prospectus have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the Shares offered under this Prospectus has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares offered under this Prospectus may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this Prospectus have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offer. If you are in doubt about the contents of this Prospectus, you should obtain independent professional advice.

7.11.2 New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the **FMC Act**). The Shares offered under this Prospectus are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

(a) is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;

(b) meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;

(c) is large within the meaning of clause 39 of Schedule 1 of the FMC Act;

(d) is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or

(e) is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

7. Details of the Offer continued

7.11.3 Singapore

This Prospectus and any other materials relating to the Shares the subject of the Offer have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this Prospectus and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of Shares offered under this Prospectus, may not be issued, circulated or distributed, nor may the Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part XIII of the Securities and Futures Act, Chapter 289 of Singapore (the **SFA**), or as otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

This document has been given to you on the basis that you are (i) an "institutional investor" (as defined in the SFA) or (ii) an "accredited investor" (as defined in the SFA). If you are not an investor falling within one of these categories, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the Shares offered under this Prospectus being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

8. Investigating Accountant's Report

8. Investigating Accountant's Report

4 June 2021

Pitcher Partners Sydney Corporate Finance Pty Ltd

Level 16, Tower 2 Darling Park
201 Sussex Street
Sydney NSW 2000

Postal Address
GPO Box 1615
Sydney NSW 2001

p. +61 2 9221 2099
e. sydneypartners@pitcher.com.au

The Directors
BCAL Diagnostics Limited
1 O'Connell Street
Sydney NSW 2000

Dear Directors,

PART 1: INDEPENDENT LIMITED ASSURANCE REPORT ON BCAL DIAGNOSTICS LIMITED HISTORICAL FINANCIAL INFORMATION AND PRO FORMA HISTORICAL FINANCIAL INFORMATION

8.1 INTRODUCTION

The directors ("*Directors*") of BCAL Diagnostics Limited (the *"Company"*) have engaged Pitcher Partners Sydney Corporate Finance Pty Ltd (*"Pitcher Partners"*) to report on the Historical Financial Information and Pro Forma Historical Financial Information of the Company to be included in the prospectus of the Company (*"Prospectus"*) for the proposed initial public offering of new fully paid ordinary shares in the Company ("*Offer*") and listing on an Australian Securities Exchange (*"ASX"*).

We have prepared this Independent Limited Assurance Report ("*Report"*) to be included in a Prospectus dated on or around 4 June 2021 relating to the Offer.

The Offer is not underwritten.

Under the Offer, there will be no options attached to the Shares.

Unless stated otherwise, expressions defined in the Prospectus (in which this Report is included) have the same meaning in this Report and section references are to sections of the Prospectus.

The nature of this Report is such that it can only be issued by an entity which holds an Australian Financial Services License (*"AFSL"*) under the Corporations Act. Pitcher Partners holds the appropriate AFSL authority under the Corporations Act. Refer to our Financial Services Guide included as Part 2 of this Report.

8.2 SCOPE

This Report deals with the financial information included in Section 4 of the Prospectus ("*Financial Information*"). The Financial Information consists of the Company's:

- historical Statement of Financial Position as at 31 December 2020, historical Statements of Financial Performance, and historical Statements of Cash Flows for the financial years ended 30 June 2018, 30 June 2019, 30 June 2020, and the six months ended 31 December 2020 (*"Historical Financial Information"*);
- pro forma historical Statement of Financial Position as at 31 December 2020 (*"Pro Forma Historical Financial Information"*);
- related notes as set out in Section 4 of the Prospectus.

As described in Section 4.2 of the Prospectus the stated basis of preparation is the recognition and measurement principles contained in Australian Accounting Standards and the Company's adopted accounting policies applied to the Historical Financial Information.

The Historical Financial Information in Section 4 has been prepared for inclusion in the Prospectus and has been derived from the audited financial statements of the Company for the financial years ended 30 June 2018, 30 June 2019 and 30 June 2020, and the reviewed six months ended 31 December 2020 by Pitcher Partners in accordance with Australian Auditing Standards. The three audit opinions and the 31 December 2020 half year review conclusion issued to the members of the Company relating to those financial reports were unmodified.

The Pro Forma Historical Financial Information in Section 4.7 has been prepared to illustrate the financial position of the Company as at completion of the Offer and has been derived from the 31 December 2020 historical Statement of Financial Position and adjusted for the effects of the events to which the pro forma assumptions relate, as described in Sections 4.7.1, 4.7.2 and 4.7.3 of the Prospectus, as if those events had occurred as at 31 December 2020. Due to its nature, the Pro Forma Financial Information does not represent the Company's actual or prospective financial position.

The Financial Information is presented in the Prospectus in an abbreviated form insofar as it does not include all the presentation and disclosures required by Australian Accounting Standards and other mandatory professional reporting requirements applicable to the general purpose financial reports prepared in accordance with the Corporations Act 2001 (Cth).

8.3 DIRECTORS' RESPONSIBILITIES

The Directors of the Company are responsible for the preparation and presentation of the Historical Financial Information and Pro Forma Historical Financial Information, including its basis of preparation and the selection and determination of pro forma adjustments made to the statutory Historical Financial Information and included in the Pro Forma Historical Financial Information.

This includes responsibility for its compliance with applicable laws and regulations and such internal controls as the Directors determine are necessary to enable the preparation of the Financial Information that is free from material misstatement, whether due to fraud or error.

8.4 OUR RESPONSIBILITIES

Our responsibility is to express a limited assurance conclusion on the Financial Information included in Section 4 of the Prospectus based on the procedures performed and the evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagement ASAE 3450 *Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information*.

A review consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the Financial Information of the Company.

Our engagement did not involve updating or re issuing any previously issued audit or review report on any Financial Information used as a source of the Financial Information.

PITCHER PARTNERS

8.5 CONCLUSION

Historical Financial Information

Based on our review, which is not an audit, nothing has come to our attention which causes us to believe that the Historical Financial Information for the financial years ended 30 June 2018, 30 June 2019, 30 June 2020, and the six months ended 31 December 2020 comprising:

- the statutory historical Statement of Financial Position as at 31 December 2020 as set out in Section 4.7 of the Prospectus;
- the statutory historical Statements of Financial Performance for the financial for the financial years ended 30 June 2018, 30 June 2019, 30 June 2020, and the six months ended 31 December 2020 as set out in Section 4.5 of the Prospectus; and
- the statutory historical Statements of Cash Flows for the financial years ended 30 June 2018, 30 June 2019, 30 June 2020, and the six months ended 31 December 2020 as set out in Section 4.6 of the Prospectus,

are not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 4.2 of the Prospectus being the recognition and measurement principles described under Australian Accounting Standards and the Company adopted accounting policies applied to the Historical Financial Information.

Pro Forma Historical Financial Information

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Pro Forma Historical Financial Information, being the pro forma historical Statement of Financial Position as at 31 December 2020 as set out in Section 4.7 is not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 4.2 of the Prospectus, as if those events or transactions had occurred as at the date of the Pro Forma Historical Financial Information.

8.6 RESTRICTION ON USE

Without modifying our conclusions, we draw attention to Section 4.3 of the Prospectus, which describes the purpose of the Financial Information, being for inclusion in the Prospectus. As a result, the Financial Information may not be suitable for use for another purpose.

Investors should consider the risks factors set out in Section 5 of the Prospectus.

8.7 LIABILITY

Pitcher Partners has consented to the inclusion of this Report in the Prospectus in the form and context in which it is included. At the date of this Report, this consent has not been withdrawn.

The liability of Pitcher Partners is limited to the inclusion of this Report in the Prospectus. Pitcher Partners has not authorised the issue of the Prospectus. Accordingly, Pitcher Partners makes no representation regarding, and takes no responsibility for, any other Statements or material in or omissions from, the Prospectus.

8.8 INDEPENDENCE OR DISCLOSURE OF INTEREST

Pitcher Partners has no financial or other interest that could reasonably be regarded as being capable of affecting its ability to give an unbiased conclusion on the matters that are subject of this Report for which normal professional fees will be received.

Pitcher Partner Sydney Partnership is the auditor of the Company and from time to time, associated entities may also provide the Company with certain other professional services (where independence requirements permit) for which normal professional fees are received.

8.9 FINANCIAL SERVICES GUIDE

We have included our Financial Services Guide as Part 2 of this Report. The Financial Services Guide is designed to assist retail investors in their use of any general financial product advice in our Report.

Yours faithfully

Pitcher Partners Sydney Corporate Finance Pty Ltd

Scott Whiddett

Director

PART 2 - FINANCIAL SERVICES GUIDE

1. Pitcher Partners Sydney Corporate Finance Pty Ltd

Pitcher Partners Sydney Corporate Finance Pty Ltd ("Pitcher Partners") is licensed as an Australian Financial Services Licensee, Licence No. 516413.

Pitcher Partners may provide the following financial services to wholesale and retail clients:

- Financial product advice for the following classes of financial products:
  - (i) deposit and payment products including:
    - (a) basic deposit products;
    - (b) deposit products other than basic deposit products; and
    - (c) non-cash payment products;
  - (ii) debentures, stocks or bonds issued or proposed to be issued by a government;
  - (iii) interests in managed investment schemes excluding investor directed portfolio services; and
  - (iv) securities;

  (collectively "Authorised Financial Products") and
- Deal in a financial product by:
  - (i) arranging for another person to issue, acquire, vary or dispose of a financial product in respect of the following classes of financial products:
    - (a) interests in managed investment schemes excluding investor directed portfolio services; and
    - (b) securities; and
  - (ii) applying for, acquiring, varying or disposing of a financial product on behalf of another person in respect of the following classes of products:
    - (a) deposit and payment products including:
      - (1) basic deposit products;
      - (2) deposit products other than basic deposit products; and
      - (3) non-cash payment products;
    - (b) debentures, stocks or bonds issued or proposed to be issued by a government;
    - (c) interests in managed investment schemes excluding investor directed portfolio services; and
    - (d) securities.

2. Financial Services Guide

The Corporations Act 2001 (Cth) requires Pitcher Partners to provide this Financial Services Guide ("FSG") in connection with its provision of an Independent Limited Assurance Report ("Report") which is included in the Prospectus issued by the Company (the "Entity").

3. General Financial Product Advice

The financial product advice provided in our Report is known as "general advice" because it does not take into account your personal objectives, financial situation or needs. You should consider whether the general advice contained in our Report is appropriate for you, having regard to your own personal objectives, financial situation or needs. You may wish to obtain personal financial product advice from the holder of an Australian Financial Services Licence to assist you in this assessment.

4. Remuneration

The fees we charge for preparing reports are usually determined on an hourly basis; however they may be a fixed amount or derived using another basis. We may also seek reimbursement of any out-of pocket expenses incurred in providing the services.

Fee arrangements are agreed and confirmed in a letter of engagement with the party or parties who engage us.

Neither Pitcher Partners, nor its directors or officers, nor any related bodies corporate and their directors and officers, receives any other fees, commissions or other benefits in connection with preparing and providing this report.

All of our employees receive a salary and while eligible for annual salary increases and bonuses based on overall performance they do not receive any commissions or other benefits arising directly as a result of the services provided to you. We do not pay commissions or provide any other benefits to any parties or person for referring customers to us in connection with the reports that we are licensed to provide.

5. Independence

Pitcher Partners is required to be independent of the Entity.

Neither Pitcher Partners, any related entities, any Director thereof, nor any individual involved in the preparation of the Report have any financial interest in the outcome of the Entity's application for renewal of registration, other than a fee in connection with the preparation of our Report for which professional fees in the order of $50,000 (excluding GST) will be received and audit fees agreed from time to time.

No pecuniary or other benefit, direct or indirect, has been received by Pitcher Partners, any related entities, their Directors or employees, or related bodies corporate for or in connection with the preparation of this Report.

6. Complaints Resolution

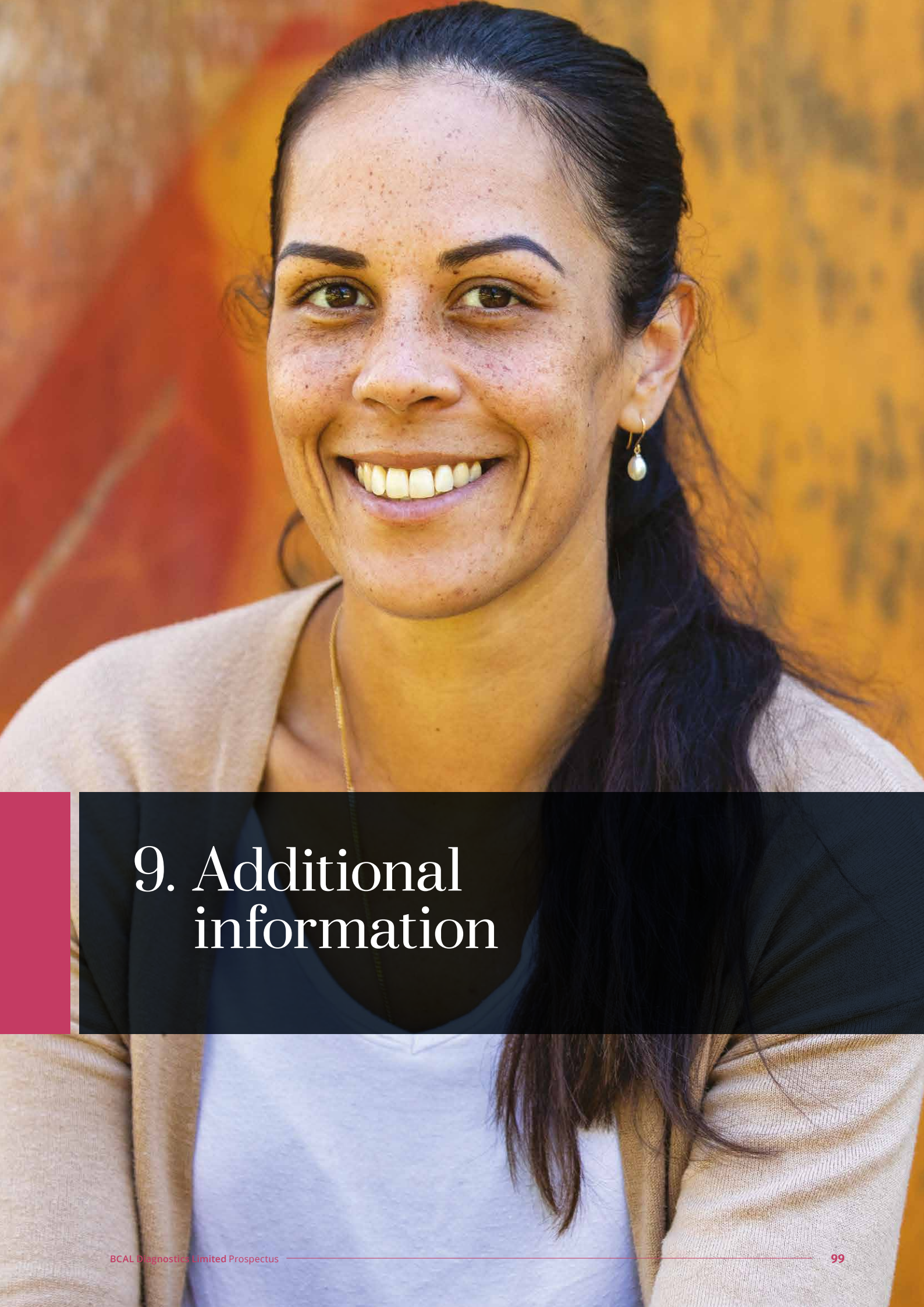
Pitcher Partners is only responsible for its Report and this FSG. Complaints or questions about the Disclosure Statement should not be directed to Pitcher Partners which is not responsible for that document. Pitcher Partners may be contacted as follows:

- By phone: (02) 9221 2099
- By fax: (02) 9223 1762
- By mail: GPO Box 1615 SYDNEY NSW 2001

If you have a complaint about Pitcher Partners' Report or this FSG you should take the following steps:

1. Phone Pitcher Partners on (02) 9221 2099 or send a written complaint to Darling Park, Level 16, Tower 2, 201 Sussex Street, Sydney NSW 2000. We will try to resolve your complaint quickly and fairly.
2. If you still do not get a satisfactory outcome, you have the right to complain to the Australian Financial Complaints Authority at GPO Box 3 Melbourne VIC 3001 or call on 1800 931 678. We are a member of this scheme.
3. The Australian Securities and Investments Commission (ASIC) also has a freecall Infoline on 1300 300 630 which you may use to make a complaint and obtain information about your rights.

5



9. Additional information

9. Additional information

9.1 Company Information

The Company was incorporated on 15 February 2010 under the Corporations Act as a proprietary company limited by shares. On 5 February 2021, the Company converted to a public company limited by shares. The Company will be taxed as a public company and its statutory accounts will be made up to 30 June annually.

9.2 Current Share Capital Structure

The issued capital of the Company at the Prospectus Date is set out below:

	Shares
Ordinary Shares	160,000,002
Options issued under Former ESOP	11,557,878
Total Diluted Share Capital	**171,557,880**

9.3 Capital structure following the Offer – no Oversubscriptions

	Post Completion of Offer		Diluted
	Ordinary Shares	%	%
Directors and management	58,648,234	29.53%	27.90%
Other Shareholders	101,351,768	51.03%	48.22%
New Investors under the Offer	32,000,000	16.11%	15.23%
Lead Manager Securities	6,615,631	3.33%	3.15%
	198,615,633	**100%**	**94.50%**
Options under employee share option plans	11,557,878		5.50%
Total diluted share capital	**210,173,511**		**100%**

9.4 Company's Constitution: rights attaching to Shares

The Shares the subject of the Offer are fully paid ordinary shares in the capital of the Company. A summary of the rights, liabilities and obligations attaching to the Shares, and a description of other material provisions of the Constitution are set out below. This summary is not exhaustive and is qualified by the full terms of the Constitution, which is available from the Company on request free of charge. This summary does not constitute a definitive statement of the rights and liabilities of the Shareholders, which can involve complex questions of law arising from the Constitution's interaction with statutory and common law requirements. Shareholders should seek legal advice in relation to any definitive assessment of the rights and liabilities attached to Shares in any specific circumstances.

9.4.1 Ranking

At the date of this Prospectus, the Company's only class of shares on issue is ordinary shares which rank equally in all respects. From their date of issue, the Shares offered under this Prospectus will rank equally with the Company's existing shares.

9.4.2 General meetings

Shareholders are entitled to be present in person, or by proxy, attorney or representative to attend and vote at general meetings of the Company. Shareholders may requisition general meetings in accordance with the Corporations Act and the Constitution.

9.4.3 Voting

At a general meeting of the Company, every Shareholder present in person, or by proxy, attorney or representative shall on a show of hands have one vote and upon a poll every Shareholder present in person or by proxy, attorney or representative has one vote for every Share held.

9.4.4 Winding up

Shareholders will be entitled in a winding up to share in any surplus assets of the Company in proportion to the capital paid up on the Shares held.

9.4.5 Transfer of Shares

Shares in the Company may be transferred by a written transfer instrument, in any other form approved by the Directors or, at the discretion of the Directors, by a computerised or electronic system for market settlement, securities transfer and registration conducted in accordance with the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules. The Directors may, subject to the ASX Listing Rules and the ASX Settlement Operating Rules, request an ASX approved clearing and settlement facility to apply a holding lock to prevent any transfer of Shares. The Directors may refuse to register a paper based transfer of a Share in particular circumstances.

9.4.6 Variation of class rights

The rights attached to any class of shares may be varied or cancelled with the consent in writing of the holders of shares of that class who are entitled to at least 75% of the votes that may be cast in respect of the shares of that class or by special resolution passed at a meeting of the holders of the shares of that class.

9.4.7 Restricted securities

If the ASX classifies any of the Company's share capital as restricted securities, then the restricted securities must not be disposed of, or agreed to be disposed of, during the escrow period and the Company must refuse to acknowledge a disposal of the restricted securities during the escrow period, except as permitted under the ASX Listing Rules or by the ASX.

9.4.8 Non-marketable parcels

In accordance with the ASX Listing Rules, the Board may sell Shares which constitute less than a marketable parcel by following the procedures set out in the Constitution.

9.4.9 Dividends

If the Directors determine that a final or interim dividend is payable, it is (subject to the terms of issue on any shares or class of shares) paid on all Shares proportionate to the amount paid up on each Share.

The Directors may set aside out of profits such amounts by way of reserves as they think appropriate to pay a dividend.

Subject to the ASX Listing Rules, the Directors may adopt and implement on the terms they think appropriate, one or more dividend reinvestment plans, under which a Shareholder may elect that the dividends payable by the Company be reinvested by a subscription for new Shares.

9. Additional information continued

9.5 Material contracts

The Board considers that certain agreements relating to the Company are significant to the Offer, the operations of the Company or may be relevant to investors. A description of material agreements or arrangements, together with a summary of the more important details of each of these agreements is set out below.

9.5.1 ULRF License Agreement

The Company and the University of Louisville Research Foundation, Inc (**ULRF**) are parties to an exclusive license (US spelling) agreement dated 21 June 2013, as amended (the **ULRF License Agreement**). Under the ULRF License Agreement, the Company has acquired license rights to the intellectual property described in the following patents:

Applicant:	**University of Louisville Research Foundation, Inc**
Inventor:	Fan, Teresa Whei-Mei; Lane, Andrew Nicholas; Higashi, Richard M.; Bousamra, Michael
Title:	Methods for detecting cancer
Priority:	USA61/357,642 (filed 23 July 2010)
PCT:	PCT/US2011/041399 (filed 22 June 2011)
Expiry date:	22 June 2031 (subject to national patent term adjustments/extensions)

Official No	**Country**	**Case status**
2011270968	Australia	Granted (last renewal June 2020)
2803865	Canada	Pending (under exam, last action July 2020)
EP2585833 (2011798823)	Europe	Granted (last renewal July 2020)
JP5944385 (2013516721)	Japan	Granted
JP6092302 (2015109485)	Japan	Granted
13/805352	USA	Pending (under exam, last action Sept 2020)
2016213855	Australia	Granted (last renewal June 2020)
2018236876	Australia	Lapsed (Jan 2019)
EP3206034 (2017163073)	Europe	Granted (last renewal July 2020)
2020176591	Europe	Pending
2016218085	Japan	Refused (Jan 2018)

(the **ULRF Patents and Patent Applications**).

ULRF owns the ULRF Patents and Patent Applications, and the material terms of the ULRF License Agreement, which is governed by the laws of Kentucky, USA, are as follows:

(a) (**exclusivity**) ULRF has granted to BCAL an exclusive license to use and exploit the ULRF Patents and Patent Applications (**License**). The License term is for the longer of 20 years from 21 June 2013 and the period ending when the last valid claim under one of the ULRF Patents and Patent Applications expires (which will be 22 June 2031 for any patents granted).

(b) (**scope of license**) The License extends to all fields for which it may be exploited including commercial detection, diagnosis and treatment of cancer (noting that the ULRF Patents and Patent Applications cover methods of diagnosis rather than treatment per se).

(c) (**sub-licensing**) BCAL has the right to sub-license the rights granted to it, and BCAL must pay to ULRF 20% of any sub-licensing fees.

(d) (**non-commercial purposes**) ULRF retains the right to use the ULRF Patents and Patent Applications for non-commercial research purposes.

(e) (**development plan and commercial sale**) BCAL is required to use reasonable efforts to achieve the commercial goals outlined in its development plan, and must have relevant products ready for commercial sale by 31 July 2023 unless otherwise extended. Following the first commercial sale, BCAL must reasonably fill market demand for the products during the term of the ULRF License Agreement. If BCAL fails to comply, ULRF may convert the License into a non-exclusive license.

(f) (**fees**) BCAL pays royalties to ULRF in respect of net sales revenue derived from sale of products in countries covered by valid claims in the ULRF Patents and Patent Applications by BCAL and any sub-licensees.

(g) (**claims and infringement**) ULRF has the right, but not the obligation, to take action for infringement of any granted patents within the ULRF Patents and Patent Applications, and may join BCAL as a party. ULRF bears all costs if it initiates action, and retains all damages recovered. If ULRF does not initiate proceedings within 30 days, BCAL may initiate proceedings at its sole cost.

(h) (**indemnities**) BCAL indemnifies ULRF from all claims, losses and damage resulting from or arising out of the exercise of the License or any sub-licenses, including in relation to product liability.

(i) (**confidentiality**) Each party is subject to standard obligations in relation to protecting the other party's confidential information.

(j) (**termination**) Either party may terminate if the other party fails to remedy its breach within 30 days' notice. ULRF may terminate immediately if BCAL suffers an insolvency event. Either party may terminate with 30 days' notice if the other party breaches the agreement on three separate occasions within a two year period.

(k) (**change of control/assignment**) Neither party may assign or transfer its rights or obligations without prior written consent of the other party, and a change of control is considered an assignment. To the extent that the Offer might constitute a change of control, ULRF has provided its corresponding consent in writing.

9.5.2 Sydney Local Health District – Clinical Trial Research Agreement

The Company and Sydney Local Health District (**SLHD**) have settled an agreed form Clinical Trial Research Agreement (**CTRA**), governed by the laws of New South Wales. The CTRA sets out the terms governing the study in respect of breast cancer associated lipids found in plasma to be carried out at BreastScreen NSW at the Royal Prince Alfred Hospital (**Study**). While the terms of the CTRA have been agreed, the final signatures for the agreement are not possible until the Study protocols for the Study have received governance approval. The material terms of the CTRA are as follows:

(a) (**roles**) BCAL as sponsor under the CTRA is responsible for initiating, managing and financing the Study. SLHD, through the Principal Investigator (as defined in the CTRA), is responsible for conducting the Study. The Principal Investigator has day-to-day responsibility for conducting the Study, including obtaining ethics sign-off, recruiting 1,000 – 3,000 participants, and reporting. SLHD must make good any Principal Investigator breaches.

(b) (**SLHD obligations**) SLHD must allow BCAL, authorities and ethics committees regular monitoring visits and access to documents and personnel. SLHD must also make available and store blood samples and ensure the Study is subject to ethics committee oversight. SLHD must retain copies of all Study materials for at least 15 years following Study completion.

(a) (**public statements and publications**) press or promotional statements regarding the Study are subject to BCAL's written approval. Procedures are specified under which BCAL, SLHD, the Principal Investigator and other investigators involved may publish the Study's methods, results and conclusions.

(b) (**BCAL obligations**) BCAL must provide all relevant information regarding blood samples, provide required equipment and software, implement quality assurance and control systems, provide advisory personnel, indemnify SLHD and the ethics committee against claims that might arise, and maintain corresponding insurance.

(c) (**payments**) BCAL must pay to SLHD an initial payment of up to $5,000 to reimburse out of pocket initial recruitment expenses and $9,000 for recruitment on 1 July 2021, and then $9,000 on 1 October 2021 and each three-month anniversary of that date for the term of the CTRA, provided up to 125 patients are identified for potential recruitment during each of those three-month periods.

(d) (**confidentiality, and privacy**) Each party is subject to standard obligations in relation to protecting the other's confidential information and the privacy of Study Participants.

(e) (**intellectual property**) Any new intellectual property created during the Study vests in BCAL.

(f) (**term**) The CTRA commences from the date that the agreement is finally signed and terminates on the final payment to SLHD, unless otherwise terminated earlier. The Study participant recruitment period is from 1 March 2021 to 4 November 2025.

(g) (**termination with cause**)

(i) Either party may terminate the CTRA if:

(A) the other party breaches the CTRA or Protocol and fails to remedy the breach within 30 days, is subject to an insolvency event, or assigns the CTRA to a person unsuitable to perform the CTRA.

(B) the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants;

(ii) BCAL may terminate the CTRA if SLHD makes any improper payments to government officials.

(h) (**termination without cause**) BCAL may terminate the CTRA with 30 days' prior written notice and must pay SLHD's reasonable costs.

(i) (**sub-contracting**) BCAL may subcontract its obligations except for those relating to indemnities and insurance. SLHD may also subcontract its obligations. Subcontracting parties remain responsible for all subcontracted obligations and liable for all acts and omissions of subcontractors.

9.5.3 GenesisCare Master Services Agreement

The Company and GenesisCare Clinical CRO Pty Limited (**GenesisCare**) are parties to a Master Services Agreement dated 26 April 2021 (**GenesisCare MSA**), governed by New South Wales law. GenesisCare is a contract research organisation which, under the GenesisCare MSA, will provide services including clinical research and scientific consulting. The GenesisCare MSA sets out the master terms to govern the scientific research services that GenesisCare may provide to the Company. The material terms of the GenesisCare MSA are as follows:

(a) (**work orders**) individual work orders under the GenesisCare MSA will describe, in respect of specific studies, the nature and scope of the services to be provided, the price, fees and payment schedule, and any modification to the GenesisCare MSA that are applicable to that specific study including payment schedules and reporting requirements. The parties must ensure adequate levels of insurance relevant to and as set out in each work order. The parties may amend work orders by written agreement (as they can the GenesisCare MSA) and each work order is incorporated in and becomes part of the GenesisCare MSA.

(b) (**indemnities**) BCAL indemnifies GenesisCare against all claims and losses (including legal costs) arising out of any claim alleging infringement of any personal rights. BCAL also indemnifies GenesisCare and the Human Research Ethics Committee against all claims and losses (including legal costs) arising out of any claim alleging personal injury including death of an individual in connection with the services provided.

(c) (**liability**) The parties' liability to each other is limited to the amount of work order fee payments made, however this limit does not apply to breaches of confidentiality, intellectual property, or death or personal injury caused by a party's negligence or intentional misconduct.

(d) (**confidentiality and privacy**) Each party is subject to standard obligations in relation to protecting the other's confidential information and protecting the privacy of study participants.

(e) (**records and access**) In addition to keeping proper records (and providing BCAL appropriate access to confirm compliance is in order), GenesisCare must retain documents essential to the relevant study, including for at least 15 years after the expiry or termination of the GenesisCare MSA.

(f) (**intellectual property**) Any new intellectual property generated will vest as specified in each work order. Where no party is specified, the new intellectual property vests in BCAL.

(g) (**publications and promotional activities**) Each party must seek the other's prior written consent before releasing any public statements or publications, or using the other's logo, name or trademarks.

(h) (**termination**) Either party may terminate the GenesisCare MSA or a work order where the other party has materially breached the GenesisCare MSA and failed to remedy on 30 days' notice. Either party may terminate where the other party becomes insolvent.

9.6 Other agreements and collaborations

In addition to the material contracts set out above, the Company has also entered into agreements with other collaborators to further support its clinical studies and broader objectives.

9.6.1 Sydney Breast Clinic

BCAL has entered into a clinical study heads of agreement with Sydney Breast Clinic Pty Ltd (ABN 78 139 412 445) (**SBC**) dated 27 May 2021. Under this agreement, SBC will provide support to BCAL in its clinical study by facilitating collection of patient blood samples and providing any other strategic services as agreed between SBC and BCAL.

9.6.2 University of Sydney

The Company and the University of Sydney have entered into a facilities access agreement relating to the period 1 April 2021 to 31 March 2022, for BCAL to have access to and use of Sydney Mass Spectrometry, a core research facility at the University of Sydney. The arrangements include BCAL having access to dedicated laboratory space and storage to complete product development work, and access to and use of multiple mass spectrometers.

9.6.3 NSW Health Statewide Biobank

The Company and NSW Health Pathology (ABN 49 382 586 535) (**NSW Health Pathology**) are currently negotiating a biobank service agreement, under which BCAL will engage NSW Health Pathology to collect, transport and process biospecimen samples for the purpose of carrying out clinical trials.

9.7 Executive service contracts

The Company has entered into:

- an executive service agreement commencing 3 January 2021 with Jayne Shaw, under which Ms Shaw has agreed to act as Executive Chair of the Company. Ms Shaw will be paid $180,000 per annum (exclusive of any GST); and
- an employment agreement dated 17 March 2020 with Dr Amani Batarseh, under which Dr Batarseh confirms her agreement to act as Chief Scientist of the Company. Dr Batarseh will be paid a base salary of $259,000 per annum, inclusive of base salary and superannuation contributions.

The agreements with key executives each contain standard terms and conditions for agreements of this nature, including in relation to confidentiality and intellectual property. The agreements can each be terminated by either party. Both Ms Shaw and Dr Batarseh are eligible to participate in the Company's Equity Incentive Plan, however it is not currently proposed that Ms Shaw participate in the Equity Incentive Plan. The Board expects to issue incentives to Dr Batarseh later in 2021, please see Section 4.7.2(d) for commentary.

9.8 Chief Financial Officer and Company secretarial services

The Company has engaged Integrated CFO Solutions Pty Ltd (**Integrated CFO Solutions**) to provide secretarial and accounting services to the Company pursuant to the terms of a service agreement which commenced on 1 February 2021 (**CFO Service Agreement**). The CFO Service Agreement continues in force until it is terminated in accordance with its terms.

Under the terms of the CFO Service Agreement, Integrated CFO Solutions is to provide support in relation to company secretarial and investor relations, tax and compliance, contract management, ASX reporting, preparation and review of financial reports, insurance arrangements, capital raisings, monthly corporate overhead reporting and development and management of incentive schemes.

Integrated CFO Solutions is to be paid a monthly fee of $5,000 (excluding GST), which is revised to $6,000 per month on the Company's listing.

The CFO Service Agreement contains terms consistent with similar arrangements, including provisions in respect of confidentiality and intellectual property.

9.9 Legal proceedings

There is no litigation of a material nature or threatened which may significantly affect the Company or its activities.

9. Additional information continued

9.10 Directors responsibility statement

The Directors of the Company state that for the purposes of section 731 of the Corporations Act, they have made all enquiries that were reasonable in the circumstances and have reasonable grounds to believe that any statements by them in this Prospectus are true and not misleading or deceptive, and that with respect to any other statements made in this Prospectus by persons other than the Directors, the Directors have made reasonable enquiries and have reasonable grounds to believe that persons making the statement or statements were competent to make such statements, those persons have given the consent required by section 716(2) of the Corporations Act and have not withdrawn that consent before lodgement of this Prospectus with ASIC.

This Prospectus is prepared on the basis that:

- certain matters may be reasonably expected to be known to professional advisers of the kind with whom Applicants may reasonably be expected to consult; and
- information is known to Applicants or their professional advisers by virtue of any legislation or laws of any State or Territory of Australia or the Commonwealth of Australia.

9.11 Consents and disclaimers

Chapter 6D of the Corporations Act imposes a liability regime on the Company (as the offeror of the Shares), the Directors of the Company, persons named in the Prospectus with their consent as proposed Directors of the Company, any underwriters, persons named in the Prospectus with their consent as having made a statement in the Prospectus and persons involved in a contravention in relation to the Prospectus, with regard to misleading or deceptive statements made in the Prospectus. Although the Company bears the primary responsibility for the Prospectus, other parties involved in the preparation of the Prospectus can also be responsible for certain statements made in it.

In light of the above, each of the parties referred to below in this Section 9.11 (each a Consenting Party), to the maximum extent permitted by law, expressly disclaims all liabilities in respect of, makes no representations with regard to, and takes no responsibility for, any statements in or omissions from this Prospectus, other than the reference to its name in the form and context in which it is named and a statement or report included in this Prospectus with its consent as specified below.

PAC Partners has given, and has not withdrawn, its written consent to be named as Lead Manager to the Offer in the form and context in which it is named.

Mills Oakley has given, and has not withdrawn, its written consent to be named as legal adviser to the Company in the form and context in which it is named.

Pitcher Partners has given, and has not withdrawn, its written consent to be named as Investigating Accountant in the form and context in which it is named and to the inclusion of its Investigating Accountant's Report in Section 8 of this Prospectus in the form and context in which it is included.

Pitcher Partners Sydney Partnership has given, and has not withdrawn, its written consent to be named as Independent Auditor of the Company in the form and context in which it is named.

Shelston IP has given, and has not withdrawn, its written consent to the inclusion in this Prospectus of its IP Report in Appendix B and the statements specifically attributed to it in the text of this Prospectus, in the form and context in which they are included in this Prospectus.

Automic has given, and has not withdrawn, its written consent to be named as the Share Registry of the Company in the form and context in which it is named.

Each of the following entities and individuals have given, and not withdrawn, their consent to be named in the Prospectus in the form and context in which they are named: University of Louisville Research Foundation, Inc, University of Louisville, University of Sydney (Charles Perkins Centre), NSW Breastscreen, Sydney Local Health District, Royal Prince Alfred Hospital, Chris O'Brien Lifehouse, Sydney Breast Clinic Pty Ltd, NSW Health Pathology, Thermo Fisher Scientific Australia Pty Ltd, A/Prof Sanjay Warrier, Dr Mary Rickard, A/Prof Cindy Mak, GenesisCare Clinical CRO Pty Limited, Izon Science Ltd, Mark Burrows AO, Guy Robertson, Dr Amani Batarseh, Dr Jane Ryan, Alison Cook, Dr Kim Ekroos, A/Prof Craig Gedye, Professor Peter Meikle and Integrated CFO Solutions Pty Ltd.

9.12 Interests of experts and advisers

PAC Partners has acted as the Lead Manager to the Offer and will be paid a management fee comprising the following:

- a corporate advisory fee of $5,000 per month commencing on 29 October 2020 through to listing of the Company on the ASX; and
- on settlement of the Offer, a fee of 6.0% of the gross proceeds of the Offer,

in addition to the Lead Manager Securities.

Mills Oakley has acted as legal adviser to the Company for the Offer and has undertaken due diligence enquiries and provided legal advice on the Offer. Mills Oakley will be paid an estimated fee of $260,000 for these services.

Pitcher Partners has acted as Investigating Accountant to the Offer and has prepared the Investigating Accountant's Report in Section 8 and performed work on due diligence queries. Pitcher Partners will be paid an estimated fee of $50,000 for these services.

Pitcher Partners Sydney Partnership has acted as the Independent Auditor to the Company and will be paid an estimated fee of $35,000 for the audit of the financial reports for the financial years ending 30 June 2018, 30 June 2019 and 30 June 2020 and the half year ending 31 December 2020.

Shelston IP has prepared the IP Report in Appendix B and will be paid an estimated fee of $29,200 for their services.

9.13 Investor considerations

Before deciding to participate in this Offer, you should consider whether the Shares to be issued are a suitable investment for you. There are general risks associated with any investment in the stock market. The value of Shares listed on the ASX may rise or fall depending on a range of factors beyond the control of the Company. You should carefully read the key risks set out in Section 5. If you are in doubt as to the course you should follow, you should seek advice on the matters contained in this Prospectus from a stockbroker, solicitor, accountant or other professional adviser.

The potential tax effects relating to the Offer will vary between investors. Investors are urged to consider the possible tax consequences of participating in the Offer by consulting a professional tax adviser.

9.14 Substantial Shareholders

Details of Shareholders who hold 5% or more of the Shares on issue as at the date of this Prospectus, and who will hold more than 5% after Completion of the Offer, are set out below.

Shareholder	Shares held at date of Prospectus	% of total Shares at date of Prospectus	% of total Shares after Completion of Offer
Jayne Shaw	27,569,602	17.23%	13.88%
The Hon Ron Phillips AO	26,514,567	16.57%	13.35%
The Trust Company (Australia) Ltd	17,420,171	10.89%	8.77%
Mera Vale No 3 Pty Ltd	9,743,471	6.09%	4.91%

The above assumes no additional participation by these Shareholders in the Offer.

Final holdings of all Substantial Shareholders will be notified to ASX on the Company's listing.

9.15 Expenses of the Offer

The total estimated expenses of the Offer payable by the Company including ASX and ASIC fees, management fees, accounting fees, legal fees, share registry fees, printing costs, public relations costs and other miscellaneous expenses are estimated to be approximately $800,000.

9. Additional information continued

9.16 Electronic Prospectus

This Prospectus is available in electronic form at www.bcaldiagnostics.com. Any person receiving this Prospectus electronically will, on request, be sent a paper copy of the Prospectus by BCAL free of charge until the Closing Date.

Applications must be made by completing a paper copy of an Application Form. BCAL does not accept Application Forms electronically.

An Application Form may only be distributed attached to a complete and unaltered copy of the Prospectus. An Application Form included with this Prospectus contains a declaration that the investor has personally received the complete and unaltered Prospectus before completing the relevant Application Form.

BCAL will not accept a completed Application Form if it has reason to believe that the Applicant has not received a complete paper copy or electronic copy of the Prospectus or if it has reason to believe that the Application Form or electronic copy of the Prospectus has been altered or tampered with in any way.

While BCAL believes that it is extremely unlikely that during the period of the Offer the electronic version of the Prospectus will be altered in any way, BCAL cannot give any absolute assurance that this will not occur. Any investor in doubt about the validity or integrity of an electronic copy of the Prospectus should immediately request a paper copy of the Prospectus directly from BCAL or a financial adviser.

9.17 Australian tax considerations

The comments below provide a general summary of Australian tax issues for Australian tax resident Shareholders who acquire Shares under this Prospectus.

9.17.1 Dividends paid on Shares

Australian resident individuals and complying superannuation entities

Dividends paid by the Company on a Share will constitute assessable income of an Australian tax resident Shareholder. Australian tax resident Shareholders who are individuals or complying superannuation entities should include the dividend in their assessable income in the year the dividend is paid, together with any franking credit attached to that dividend. Such Shareholders should be entitled to a tax offset equal to the franking credit attached to the dividend, subject to being a "qualified person" (refer comments below). Where the tax offset exceeds the tax payable on the investor's taxable income, such Shareholders should be entitled to a tax refund.

To the extent that the dividend paid by the Company is unfranked, the investor will generally be taxed at their prevailing marginal rate on the dividend received with no tax offset.

Corporate Shareholders

Shareholders that are corporations (**Corporate Shareholders**) are also required to include both the dividend and the associated franking credit in their assessable income. A tax offset is then available up to the amount of the franking credit attached to the dividend. An Australian tax resident Corporate Shareholder should be entitled to a credit in its own franking account to the extent of the franking credit on the dividend received. This allows the Corporate Shareholder to pass on the benefit of the franking credits to their own shareholders on the payment of dividends.

Excess franking credits received by Corporate Shareholders cannot give rise to a refund, however may be converted into carry forward tax losses.

Trusts and partnerships

Shareholders who are trustees (other than trustees of complying superannuation entities) or partnerships should include the dividend and associated franking credit in determining the net income of the trust or partnership. The relevant beneficiary or partner may be entitled to a tax offset equal to the beneficiary or partner's share of the franking credits included in the net income of the trust or partnership.

Shares held at risk

The benefit of franking credits can be denied where a Shareholder is not a "qualified person", in which case the Shareholder will not need to include an amount for the franking credits in their assessable income and will not be entitled to a tax offset.

Broadly, to be a qualified person, a Shareholder must satisfy the holding period rule and, if necessary, the related payment rule. The holding period rule requires a Shareholder to hold the Shares "at risk" for more than 45 days continuously, measured as the period commencing the day after the Shares were acquired and ending on the 45th day after the Shares become ex-dividend. The dates the Shares are acquired and disposed of are ignored for the purposes of determining the 45-day period. The holding period rule is subject to certain exceptions, including where the total franking offsets of an individual in a year of income do not exceed $5,000. Special rules apply to trusts and beneficiaries.

Under the related payment rule, a different testing period applies where the Shareholder has made, or is under an obligation to make, a related payment in relation to the dividend. The related payment rule requires the Shareholder to have held the Shares at risk for the continuous 45-day period as above but within the period commencing on the 45th day before, and ending on the 45th day after the day the Shares become ex-dividend. Investors should seek professional advice to determine if these requirements, as they apply to them, have been satisfied.

The Australian Government has enacted a specific integrity rule that prevents taxpayers from obtaining a tax benefit from additional franking credits where dividends are received as a result of "dividend washing" arrangements. On 30 June 2014, the measure received royal assent and the new rule will apply to distributions made on or after 1 July 2013.

Shareholders should consider the impact of this legislative change and any guidance issued by the Australian Taxation Office in this regard, given their own personal circumstances.

9.17.2 Disposal of Shares

The disposal of a Share by a Shareholder will be a capital gains tax (**CGT**) event. A capital gain will arise where the capital proceeds received on disposal exceeds the CGT cost base of the share (broadly the amount paid to acquire the share plus any transaction/incidental costs). In the case of an arm's length on-market sale, the capital proceeds will generally be the cash proceeds received from the sale of Shares.

A CGT discount may be available on the capital gain for Shareholders that are individuals, trustees or complying superannuation entitles provided the particular Shares are held for more than 12 months prior to sale. Any current year or carry forward capital losses should offset the capital gain first before the CGT discount can be applied.

The CGT discount for individuals and trusts is 50% and for complying superannuation entities is 33%. In relation to trusts, the rules are complex, but this discount may flow up to beneficiaries of the trust.

A company is not entitled to a CGT discount.

A capital loss will be realised where the capital proceeds on disposal are less than the CGT reduced cost base of the Shares. Capital losses may only be offset against capital gains realised by the Shareholder in the same income year or future income years, subject to certain loss recoupment tests being satisfied. Capital losses cannot be offset against other assessable income.

9.17.3 Tax File Numbers

A Shareholder is not required to provide their tax file number (**TFN**) to the Company. However, if TFN or exemption details are not provided, Australian tax may be required to be deducted by the Company from distributions at the top marginal tax rate plus the Medicare levy.

A Shareholder that holds Shares as part of an enterprise may quote its Australian Business Number rather than its TFN.

9.17.4 Australian Goods and Services Tax

Shareholders should not be liable for Australian Goods and Services Tax (**GST**) in respect of their acquisition of the Shares.

An Australian resident Shareholder that is registered for GST may not be entitled to claim full input tax credits in respect of GST on expenses they incur that related to the acquisition, redemption or disposal of the Shares (e.g. lawyers' and accountants' fees). Shareholders should seek their own advice on the impact of GST in their own particular circumstances.

9. Additional information continued

9.17.5 Stamp duty

No stamp duty should be payable by Shareholders on the acquisition of Shares.

Investors should seek their own advice as to the impact of stamp duty in their own particular circumstances.

9.18 Governing Law

This Prospectus, the Offer and the contracts formed on acceptance of Applications under the Offer are governed by the laws in force in the state of New South Wales, Australia and each Applicant submits to the non-exclusive jurisdiction of the courts of New South Wales, Australia.

9.19 Authorisation

This Prospectus is issued by the Company. Each Director has consented (and has not withdrawn their consent) to the lodgement of this Prospectus with ASIC.

Dated 4 June 2021

Jayne Shaw

Chairman

Appendix A: Significant Accounting Policies

Appendix A: Significant Accounting Policies

(a) Basis of Preparation

The financial statements are general purpose financial statements which have been prepared in accordance with Australian Accounting Standards, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standard Board (AASB) and the *Corporations Act 2001*.

Australian Accounting Standards set out accounting policies that the AASB has concluded would result in financial reports containing relevant and reliable information about transactions, events and conditions. Compliance with Australian Accounting Standards ensures that the financial statements and notes also comply with International Financial Reporting Standards. Material accounting policies adopted in the preparation of this financial report are presented below. They have been consistently applied unless otherwise stated.

The financial reports have been prepared on an accruals basis and are based on historical costs, except for selected financial assets for which the fair value basis of accounting has been applied.

Critical accounting estimates

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in Section 4.11.

(b) Revenue Recognition

Revenue from contracts with customers

The Company currently has no revenue from the sale of goods or services.

Interest income

Interest income is recognised as interest accrues using the effective interest method. The effective interest method uses the effective interest rates which is the rate that exactly discounts the estimated future cash receipts over the expected future life of the financial asset.

When a receivable is impaired, the Company reduces the carrying amount to its recoverable amount, being the estimated future cash flow discounted at the original effective interest rate of the instrument and continues unwinding the discount as interest income. Interest income on impaired loans is recognised using the original effective interest rate.

Research and Development Tax Offset

Research and Development Tax Offset claims are recognised as other income in the period to which the incentive claims relate.

(c) Government Grants

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received, and the Company will comply with all attached conditions.

Government grants relating to costs are deferred and recognised in the profit and loss over the period necessary to match them with the costs that they are intended to compensate.

(d) Income Tax

The income tax expense or revenue for the period is the tax payable on the current period's taxable income based on the income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences between the tax base of assets and liabilities and their carrying amounts in the financial statements, and to unused tax losses.

Deferred tax assets and liabilities are recognised for all temporary differences, between carrying amounts of assets and liabilities for financial reporting purposes and their respective tax bases, at the tax rates expected to apply when the assets are recovered or liabilities settled, based on those tax rates which are enacted or substantively enacted for each jurisdiction. Exceptions are made for certain temporary differences arising on initial recognition of an asset or a liability if they arose in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit.

Deferred tax assets are only recognised for deductible temporary differences and unused tax losses if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Deferred tax assets and liabilities are not recognised for temporary differences between the carrying amount and tax bases of investments in subsidiaries, associated and interests in joint ventures where the parent entity is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

(e) Income Tax

Wages and salaries and annual leave

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the end of the reporting period are recognised in other payables in respect of employees' services rendered up to the end of the reporting period and are measured at amounts expected to be paid when the liabilities are settled.

Retirement benefit obligations

The Company does not maintain a company superannuation plan. The Company makes fixed percentage contributions for all Australian resident employees to complying third party superannuation funds. The Company's legal or constructive obligation is limited to these contributions.

Contributions to complying third party superannuation funds are recognised as an expense as they become payable. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in the future payments is available.

Share-based payments

The fair value of options granted under the Employee Share Option Plan is recognised as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognised over the period during which the employees become unconditionally entitled to the options.

The fair value at grant date is independently determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option.

The fair value of the options granted is adjusted to reflect market vesting conditions but excludes the impact of any non-market vesting conditions (for example, profitability and sales growth targets). Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. At each reporting date, the entity revises its estimate of the number of options that are expected to become exercisable.

Appendix A: Significant Accounting Policies continued

The employee benefit expense recognised each period takes into account the most recent estimate. The impact of the revision to original estimates, if any, is recognised in the Statement of Profit or Loss and Other Comprehensive Income with a corresponding adjustment to equity.

Where the terms of options are modified, the expense continues to be recognised from grant date to vesting date as if the terms had never been changed. In addition, at the date of the modification, a further expense is recognised for any increase in fair value of the transaction as a result of the change.

Upon the exercise of options, the balance of the share-based payments reserve relating to those options is transferred to share capital and the proceeds received, net of any directly attributable transaction costs, are credited to share capital.

(f) Contributed Equity

Costs directly attributable to the issue of new shares are shown as a deduction from the equity as a deduction proceeds net of any income tax benefit. Costs directly attributable to the issue of new shares or options associated with the acquisition of a business are included as part of the purchase consideration.

(g) Goods and services tax (GST)

Revenues, expenses and assets are recognised net GST, except where the GST incurred on the purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognised as part of the cost of acquisition of the asset or as part of the expense item.

Receivables and payables are stated with the amount of GST included. The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the Statement of Financial Position.

Cash flows are included in the Statement of Cash Flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority, are classified as operating cash flows.

Appendix B: IP Report

Appendix B: IP Report

SHELSTON
INTELLECTUAL PROPERTY

Level 9, 60 Margaret Street,
Sydney NSW 2000 Australia

T. +61 2 9777 1111
F. +61 2 9241 4666

email@ShelstonIP.com
ShelstonIP.com

ABN 23 608 104 070

The Directors
BCAL Diagnostics Limited
Suite 506 Level 5
50 Clarence Street
Sydney NSW 2000

19 May 2021

Our Ref: 65890AUM00

Dear Sirs

Intellectual Property Report

1. INTRODUCTION

This Intellectual Property Report has been prepared by Shelston IP Pty Ltd, Patent and Trade Mark Attorneys, and Shelston IP Lawyers Pty Ltd (collectively **Shelston IP**), for inclusion in a Prospectus to be issued by BCAL Diagnostics Limited (**BCAL Dx**).

This Report is current as at 10 March 2021. Shelston IP is not aware of any material changes to the status of matters discussed below since that date. The information provided below is subject to the matters set out in Section 5 of this Report.

This Report is essentially directed to the patents and patent applications identified in **Annex I** (**the ULRF Patents and Patent Applications**) and the licensing of the ULRF Patents and Patent Applications by BCAL Dx. These matters are discussed in Sections 3 and 4 of this Report. Before discussing the ULRF Patents and Patent Applications and associated licensing arrangements, Section 2 below provides general information about the patenting process. It is important to understand both the process and prerequisites to obtain a granted patent, and where the ULRF Patents and Patent Applications are currently up to in that process.

2. OVERVIEW OF INTELLECTUAL PROPERTY PROTECTION

Intellectual property (**IP**) is a valuable asset which needs to be carefully and diligently protected. It encompasses statutory and common law rights which provide protection in relation to products, processes, trade names, designs, drawings, copyright and circuit layouts in industry, science or commerce. In the context of the present Report, patents are particularly relevant and are discussed in some detail below. Although other forms of IP may be of interest to BCAL Dx, they are not discussed in any detail in this Report.

2.1 Patents

A patent is a statutory monopoly that confers on the owner of the patent the exclusive right to make, use, or sell the invention as defined in the patent claims throughout the territory of the country granting the patent.

The patent applicant/owner in each case needs to demonstrate that they have acquired the rights to the invention from the actual inventors by employment, assignment or other agreement.

The first step in obtaining patent rights is to file a patent application together with a patent specification. The specification describes the invention and includes a set of claims which define the monopoly sought. The text below outlines the steps involved in obtaining a granted patent.

2.2 Provisional patent application

In most jurisdictions, including Australia, the United States and Europe, it is possible to file a provisional application in order to establish a "priority date" in respect of the invention. (This provisional application does not mature into a granted patent – rather, it forms the basis for a later filed "complete" application – see below.)

An invention cannot be protected if it is not novel or inventive. In determining novelty and inventiveness, patent examiners search for pre-existing public material or disclosure (**prior art**) which may cast doubt on the novelty or inventiveness of the invention. Prior art can include publications or delivery of a presentation. The priority date of the provisional patent application effectively sets the date up to which patent examiners search for prior art. Publications or acts carried out after the priority date are not relevant to the examination of novelty or inventive step/non-obviousness. Generally, the earlier the priority date, the better as later-published prior art can be avoided. However, the impetus to obtain an early priority date must be balanced with the need to provide adequate disclosure of the invention in the description of the specification and to perform experiments supporting the idea behind the invention.

The priority date established by the provisional application is recognised in most industrialised countries, including Australia's major trading partners, as long as a corresponding "complete" application (which may be a PCT application followed by one or more "national phase applications) is filed within 12 months from the date of filing of the provisional application.

2.3 Patent protection must be sought in each jurisdiction

Each country has its own national patent laws and protection must be sought in each jurisdiction i.e. there is no system under which a "world patent" can be obtained.

Further, the grant of a patent in one country does not confer rights in any other country. Hence, the patentee must choose the countries in which patent protection is to be sought. (In some jurisdictions, the process is facilitated by a group of countries agreeing to grant patents based on a single examination process eg. Europe – see below.)

Based on long-standing international conventions, a provisional patent application may be used as the first step in obtaining patent rights in other countries. Most of the major industrialised countries are bound by these conventions including Australia, the US and many of the European countries. **Annex II** attached to this Report illustrates some of the routes by which a patent may be obtained assuming patentability and procedural requirements are met.

Commonly a single international patent application claiming priority from the provisional application is lodged under the provisions of the Patent Cooperation Treaty (**PCT**). A PCT application can be used to obtain patent rights in over 140 countries, including Australia, the US and many European countries. A PCT application is subject to an international search and International Preliminary Examination.

The PCT application does not itself become a granted patent. In order to obtain a granted patent, the PCT application must "enter national phase" in the jurisdictions in which patent protection is to be sought. National phase must be entered within 30 or 31 months (depending on the jurisdiction) from the priority date set by the provisional application. The purpose of lodging a PCT application is to defer the costs of lodging individual applications in each jurisdiction (i.e. instead of lodged individual applications within 12 months of the provisional application, the deadline for doing so is extended to 30/31 months) and to obtain, in the interim, a third party opinion on patentability of the invention in the form of the International Preliminary Examination before incurring the expense associated with lodgement of national phase applications.

A single patent application may be lodged in respect of the countries of the European Patent Organisation (currently 38 countries). All or only some of the countries may be selected. This is called a European patent application and it may also be extended to certain other countries that are not yet full signatories to the European Patent Convention. A European patent application is examined by the European Patent Office, and once granted, must be registered and maintained in each individual country in which it is desired to have a patent.

It is common to use both the PCT and European system since they are highly compatible. Specifically, rather than entering national phase in individual European countries, a "European regional phase" application may be lodged as a "national phase" application from a PCT application.

2.4 Entitlement to priority

In order for material disclosed in a patent application to be entitled to the priority date of a corresponding provisional application, the claims must be supported by matter disclosed in the provisional specification Subject matter that is not supported is not entitled to the claim to priority, which may affect patentability of the subject invention or the validity of any patent that may be granted.

2.5 Examination of a patent application

A patent application is examined by the relevant patent office before it can proceed to grant. The examination process differs across jurisdictions. Generally, during examination, the patent examiner investigates whether the claims in the patent application meet the patentability standards for the relevant jurisdiction. Typically, the examiner will assess whether the invention for which the monopoly is claimed is, *inter alia*, novel, involves an inventive step/is not obvious, and is adequately described in the specification.

In order to overcome objections by the patent examiner, amendment or limitation of the original claims is often required during examination. Hence, importantly, the scope of the monopoly conferred by the patent assuming it is eventually granted may be different to that in the original patent application. Usually amendments are made during examination to narrow the breadth of the claimed invention and it follows, therefore, that the scope of the monopoly conferred by the patent is commonly narrowed during examination.

In some cases, the patent application fails altogether because it does not meet the required legal tests for patentability of the invention. The end result is that a granted patent does not arise and the invention covered by the patent application is no longer protected in the country or countries where the application failed.

2.6 Divisional or Continuation applications

If the applicant is unsuccessful within the prescribed time period in gaining acceptance or there is subject matter which has been excised from the application in order to gain acceptance, a so-called divisional or continuation application can be filed. This essentially starts the prosecution process over again for those claims subject of the Divisional or Continuation application, giving the Applicant a further opportunity.

This Divisional or Continuation procedure is a well known and useful strategic tool to ensure all aspects of the invention are adequately covered in the jurisdiction of interest.

The original application is sometimes referred to as the "parent" application with the Divisional or Continuation applications known as the "daughter" or "child" applications. It should be noted that each Divisional or Continuation application will retain the earliest priority date of the parent application.

2.7 Examination reports in one country not binding in other countries

In most countries, patent applications undergo an independent search and examination by the local Patent Office, the results of which are not binding in other jurisdictions. Similarly, international PCT search and examination reports are not binding on national patent applications during subsequent examination in the national phase. Such reports should therefore be regarded as indicative only and not determinative of patentability. It should also be appreciated that the grant of a patent in one country provides no guarantee that patents will grant in other jurisdictions.

2.8 Changes to patent law

From time to time, the statutory basis governing patents and patentable subject matter in a particular jurisdiction may be amended by the relevant authority, typically the government of that jurisdiction. For example, the Australian government recently enacted changes to the *Patents Act 1990* which apply

higher thresholds for patentability to any patent application (or divisional patent application) for which examination was requested on or after 15 April 2013.

In addition, the practical effect of the statute may evolve by the development of case law, that is, by the interpretation of the statute by the relevant Courts. Recent decisions from the Australian Federal Court have confirmed that diagnostic methods are patent-eligible subject matter in Australia (*Meat & Livestock Australia Limited v Cargill, Inc* [2018] FCA 51; *Sequenom, Inc. v Ariosa Diagnostics, Inc.* [2019] FCA 1011). In Europe, diagnostic methods are also patentable although in a more restricted form; for example, such methods should not be performed on a human body but, rather, on a biological sample obtained from a subject. Recent US court decisions have substantially limited the patentability of diagnostic methods, and so we would rely on our US counsel for advice as laws and practices develop in that jurisdiction.

2.9 Scope of claims may vary during examination

It is often necessary during the examination of a patent application to define the invention more specifically by amendment of the claims, so as to distinguish relevant prior art. As a result of this process, there may be variations in the claims between countries, reflecting in part the different examination procedures and threshold requirements for patentability, according to national laws. Whilst this is relatively standard procedure, in certain circumstances, such amendments may affect the scope and hence the commercial significance of the resultant patent protection. It is also possible that an application may proceed to grant in one country but not be granted at all in another country due to different patentability requirements.

As Shelston IP was only responsible for prosecution of ULRF Patents and Patent Applications in Australia on instructions from ULRF's US Patent Attorneys, we are not in a position to comment on why the claims of the ULRF Patents and Patent Applications differ in various countries.

2.10 Grant of patent provides no guarantee of validity

Grant of a patent by a national patent office provides an indication rather than a guarantee of its validity. In most jurisdictions, a patent application is subject to substantive examination prior to grant. Although this process confers an initial presumption of validity, in most countries that "presumption" carries no binding legal weight and a patent may be challenged at any time after grant by way of revocation proceedings undertaken in a court of competent jurisdiction. In certain countries a granted patent may be subjected to re-examination by the relevant patent office, particularly if relevant prior art is identified that was not considered during initial examination of the application.

2.10 Grant of patent provides no guarantee of non-infringement

The grant of a patent provides no guarantee that the patentee is entitled to commercially exploit the patented invention, since the working of an invention, even if validly patented, may infringe an earlier patent or other intellectual property rights. We have undertaken no searches in respect of potentially conflicting prior patents.

2.11 Enforcement of patent rights

Upon grant of a patent, a patentee may initiate proceedings against an alleged infringer of the patent. In many jurisdictions, damages for infringement may be awarded for infringements occurring from the date of publication of the patent specification, provided certain criteria are met.

2.12 Infringement of the rights of others

As noted above, searches conducted during patent prosecution do not provide any guarantee that the subject inventions may be commercially exploited without risk of infringement of third parties. More particularly, searches focused on novelty and inventive step have different strategies from infringement searches (which seek to establish whether a specific activity is likely to infringe other parties' patent rights).

2.13 Term of patent

A patent has a variable term (based on generally annual renewal fees) with a maximum term in most countries of 20 years from the date of filing of the patent application.

This is also true of divisional applications in most countries whereby the 20 year term is based on the date of filing of the parent application. The term of a US patent may differ slightly since there are possible extensions of term available based on prosecution delays. Shelston IP is not responsible for prosecuting the patent application in the United States.

2.14 Opposition to grant of a patent/Revocation

In some countries, once the application has been allowed by the patent examiner the grant of a patent may be opposed by a competing party. For example, in Australia there is a pre-grant opposition procedure in which third parties may oppose the grant of a patent after it is allowed by the examiner but before it is granted. Conversely, in Europe, grant of the patent can only be opposed post-grant. Opposition may result in refusal or revocation of the patent, or may result in further limitation of the claims. Whether a country is a pre-grant or post-grant jurisdiction for opposition purposes can be relevant to licensing arrangements where royalties are determined by reference to sales of products in a jurisdiction covered by valid claims in a patent. That is, the licensing arrangements may provide that royalties are either not payable prior to grant of the patent, or are payable at a lower rate. This issue is potentially relevant to the ULRF Patents and Patent Applications. Refer to Section 4 below for further details.

Irrespective of whether a patent application proceeds to grant with or without having been opposed, throughout the life of a granted patent, third parties may seek revocation of the patent through the courts.

2.15 Assignment/licensing of patent rights

Patents and patent applications are property rights which can be sold, licensed, mortgaged etc. The ULRF Patents and Patent Applications covered by this Report are all licensed patent applications. Refer to Sections 3 and 4 below for further details.

3. LICENSED PATENT PORTFOLIO – THE ULRF PATENTS AND PATENT APPLICATIONS

3.1 General

A primary purpose of this Report is to provide details of the status of the ULRF Patents and Patent Applications subject of the technology licensed by BCAL Dx, as at the date of this Report, based on the information contained in the public registers maintained by the government bodies in relevant jurisdictions responsible for the registration of patents.

Annex I to this Report identifies the ULRF Patents and Patent Applications.

The ULRF Patents and Patent Applications licensed by BCAL Dx consists of one patent family. All members of the patent family are in the name of University of Louisville Research Foundation, Inc (**ULRF**). A brief description of the subject matter of the patent family is provided below with reference to the patent applications shown in **Annex I**.

As regards ownership, it appears each inventor in the present case has executed documents in support of the application and thus it appears no question arises as to the University of Louisville Research Foundation, Inc.'s entitlement to be named as owner of the relevant patents/applications.

3.2 Patent family entitled "Methods for detecting cancer"

The patent family derives priority from Provisional Patent Application US 61/357,642, which was filed by ULRF on 23 July 2010.

The patent family includes national phase applications filed in Australia, Europe, Japan, USA and Canada derived from PCT/US2011/041399, which was filed by ULRF on 22 June 2011, as well as

multiple divisional or continuation applications claiming priority from those national phase applications either directly or by an intervening divisional/continuation.

Subject to national patent term adjustments/extensions, any resulting granted patents will have a maximum term, such that they expire on 22 June 2031. It will be noted therefore that not all patents will have a 20 year term.

The invention disclosed in this patent family relates generally to methods of diagnosis of cancer types in a subject by measuring lipids in a body fluid sample.

Prosecution of the patent family is being co-ordinated by ULRF's nominated US patent attorneys under instruction by ULRF (as the owner of the ULRF Patents and Patent Applications). Shelston IP was responsible for the prosecution of the now granted Australian applications under instruction by the US patent attorney firm. Shelston IP also provides advice regarding patent prosecution, management and licensing to BCAL Dx when requested to do so. Shelston IP is not acting in relation to the prosecution of the European, Japanese, US or Canadian patent applications forming part of the ULRF Patents and Patent Applications.

Patents have been granted in Australia, Europe and Japan, to date. Applications are still pending in Canada and the US.

3.2.1 Australia

There are two granted patents in Australia namely patent nos. 2011270968 and 2016213855. The granted claims for these patents are under **Annex III** and **Annex IV** respectively.

Both granted Australian patent nos. 2011270968 and 2016213855 are directed to measuring specific fatty acid lipids for the diagnosis of breast cancer. They differ in the lipid set from which the measurements are taken.

An application has been lodged with IP Australia to record the BCAL licence.

3.2.2 Europe

There are two granted patents in Europe namely EP2585833 (application no. 2011798823) and EP3206034 (application no. 2017163073). The granted claims for these European patents are included in **Annex V and Annex VI** respectively. There is also pending application no. 2020176591 which is not yet finalised.

Granted patent EP2585833 (application no. 2011798823) is directed to measuring specific bis(monoacylglycero)phosphate BMP lipids for the diagnosis of a variety of cancers, including breast and lung cancer.

Granted patent EP3206034 (application no. 2017163073) is directed to measuring specific fatty acid FA(16:3) lipids for the diagnosis of a variety of cancers, including breast and lung cancer.

Pending application 2020176591 is not yet finalised.

A search report has been issued by the EPO, and a response filed with amended claims but no examination has yet taken place.

3.2.3 Japan

There are two granted patents in Japan namely patent nos. JP5944385 (application no. 2013516721) and JP6092302 (application no. 2015109485). A translation of the granted claims of these patents are included under **Annex VII** and **Annex VIII** respectively.

Granted patent JP5944385 (application no. 2013516721) is directed to measuring specific fatty acid, phospahtidylcholine, triacylglycerol, and lysophosphatidic acid lipids for the diagnosis of breast or lung cancer.

Granted patent JP6092302 (application no. 2015109485) is directed to measuring a more specific lipid set for the diagnosis of breast or lung cancer.

3.2.4 Canada and US

Applications are currently pending in Canada and the USA with several rounds of examination by the US patent office having already occurred. The final scope of the claims in these countries and whether the applications proceed to grant at all will depend on the nature of objections raised by the Canadian and US patent offices during examination.

It is not uncommon that the length of time for prosecuting a patent application to grant is different in different jurisdictions.

4. LICENSING ARRANGEMENTS IN RESPECT OF THE PATENTS

BCAL Dx and ULRF are parties to an Exclusive License Agreement dated 21 June 2013, as varied by Amendment 1 dated 17 November 2015, Amendment 2 dated 6 December 2017 and Amendment 3 dated 27 July 2020 by which BCAL Dx has acquired license rights to the ULRF Patents and Patent Applications described in Section 3.2 above (the **ULRF License Agreement**). The ULRF License Agreement covers the ULRF Patents and Patent Applications only, and not any associated knowhow.

The key features of the ULRF License Agreement are as follows:

(a) ULRF owns the ULRF Patents and Patent Applications.

(b) BCAL Dx has an exclusive license to use and exploit the ULRF Patents and Patent Applications (**License**). The License term is for the longer of 20 years from 21 June 2013 and the period ending when the last valid claim under one of the ULRF Patents and Patent Applications expires (which will be 22 June 2031 for any patents which proceed to grant, subject to any available term extensions or adjustments).

(c) The License extends to all fields for which the ULRF Patents and Patent Applications may be exploited including commercial detection, diagnosis and treatment of cancer (noting that the ULRF Patents and Patent Applications cover methods of diagnosis rather than treatment *per se*).

(d) The License is expressed to be worldwide but the corresponding patent rights would only be legally enforceable against third parties in countries where there are granted patents corresponding to the ULRF Patents and Patent Applications (and noting ULRF's first rights to pursue infringements as set out in paragraph (o) below) . As explained in paragraph (l) below, BCAL Dx only pays royalties on sales of products covered by valid claims under the ULRF Patents and Patent Applications so no royalties apply in countries where there is no granted patent or where the product sold is not covered by a valid claim in the patent granted for that country. As the Licence is worldwide and exclusive, ULRF is unable to grant licences to any other party in relation to the ULRF Patents while the Licence remains on foot.

(e) Under the ULRF License Agreement, ULRF would have owned any improvements made to the intellectual property comprised within the ULRF Patents and Patent Applications undertaken by ULRF. However, no further work was undertaken due to the transfer of the relevant academic staff to the University of Kentucky after the URLF License Agreement was signed.

(f) BCAL Dx has the right to sub-license to third parties the rights granted to it under the ULRF License Agreement.

(g) ULRF retains the right to use the ULRF Patents and Patent Applications for non-commercial research purposes.

(h) BCAL Dx is required to use reasonable efforts to achieve the commercial goals outlined in its development plan by the dates set out in the development plan. The development plan is attached to the ULRF License Agreement.

(i) BCAL Dx must have products based on the ULRF Patents and Patent Applications ready for commercial sale by 31 July 2023 (as agreed in Amendment 3 referred to above). Following the first commercial sale, BCAL Dx must reasonably fill market demand for the products at all times during the term of the Agreement. If BCAL Dx fails to comply with its development and commercial sale obligations (and is unable to negotiate an amendment to the ULRF License Agreement extending the first commercial sale date), ULRF may convert BCAL Dx's exclusive license under the ULRF License Agreement into a non-exclusive license.

(j) BCAL Dx paid ULRF a non-refundable license fee of US$25,000 at the time of entering into the ULRF License Agreement.

(k) BCAL Dx has the following royalty obligations to ULRF in respect of net sales revenue derived from sale of products in countries covered by valid claims in the ULRF Patents and Patent Applications by BCAL Dx and any sub-licensees:

- payment of a royalty of 2% of net sales revenue before the relevant ULRF Patent Application is granted, and a royalty of 3% of net sales revenue after the relevant ULRF Patent Application is granted;
- payment of a minimum annual royalty of US$5,000 payable by 31 July 2023 for the first 6 months ending 31 December 2023, US$10,000 payable by 31 January 2024 and 31 January 2025 for the 2024 and 2025 calendar years respectively, and then US$15,000 annually for the 2026 calendar year onwards, payable on each 31 January); and
- once the combined net sales revenue of BCAL Dx and any sub-licensees exceeds US$500,000 in a calendar year, payment of an additional royalty of 5% of net sales revenue for each year in which net sales exceed US$500,000. This additional royalty is subject to a maximum total payment of US$250,000. In calculating net sales revenue, any revenue (up front fees, ongoing license fees etc) BCAL Dx generates by way of sub-licensing the ULRF Patents and Patent Applications is included. This royalty is in addition to the 2/3% royalty referred to in the first bullet point above, potentially resulting in a maximum royalty of 8% of net sales revenue being payable.

(l) BCAL Dx must also pay to ULRF an amount equal to 20% of any other amounts BCAL Dx receives from sub-licenses BCAL Dx grants to third parties in respect of the ULRF Patents and Patent Applications, such as upfront fees, milestone payments and annual fees. Royalties BCAL Dx receives from sub-licensees are dealt with as provided in paragraph (j) above.

(m) ULRF is responsible for prosecuting and maintaining the ULRF Patents and Patent Applications in close consultation with BCAL Dx, working with Shelston IP for the ULRF Patent Application in Australia. BCAL Dx bears all costs for patent filings, prosecution and maintenance. BCAL Dx has reimbursed ULRF for prior patent costs in an amount of US$35,000 following execution of the ULRF License Agreement.

(n) ULRF has the right, but not the obligation, to take action for infringement of any granted patents within the ULRF Patents and Patent Applications, and may join BCAL Dx as a party. ULRF bears all costs if it initiates action, and retains all damages recovered. If ULRF does not initiate proceedings within 30 days, BCAL Dx may initiate proceedings at its sole cost. The ULRF License Agreements contains a reasonably complex provision setting out how any damages recovered are shared relative to expenses, royalties foregone and other matters.

(o) ULRF makes no warranties to BCAL Dx in relation to the validity or scope of the ULRF Patents and Patent Applications or that exploitation of the ULRF Patents and Patent Applications will be successful.

(p) ULRF has the right to terminate the ULRF License Agreement in the event of unremedied default by BCAL Dx, or if BCAL Dx becomes subject to an insolvency event.

(q) Each party is prohibited from assigning its rights under the ULRF License Agreement to a third party without prior written consent from the other party. A change of control of BCAL Dx is treated as an assignment. Change of control is defined to include a transfer of ownership of more than 50% of BCAL Dx's voting shares, a merger of BCAL Dx with another entity or a transfer of the assets of BCAL Dx to another entity. Accordingly, an initial public offering

involving a change in ownership exceeding 50%requires consent from ULRF. We understand that ULRF has provided the required consent.

5. LIMITATIONS & DISCLAIMERS

5.1 Scope of this Report

This Report was prepared using publicly available information in respect of patents/patent applications contained in the public registers operated by the government intellectual property offices in relevant jurisdictions. It provides information about the details and current status of the various patent applications and patents in that portfolio including owner and inventor information solely as disclosed by a search of the public registers.

Shelston IP provides no opinion about the commercial value of the various patent applications, validity, infringement risks or the likelihood that applications in progress will proceed to grant in their current form or at all.

5.2 Limitations

5.2.1 General

The prior art (or "novelty") searches conducted by the various patent offices during examination to determine whether a patent should be granted are limited in terms of the time periods and the geographical areas covered. Thus, the databases used in searching may not include older published documents and may not cover certain jurisdictions. Further, all searches are subject to the accuracy and scope of the material searched as well as the classification criteria adopted. Accordingly, whilst the searches conducted by various patent offices provide a reasonable indication of patentability, these and other factors make it impossible to guarantee that every relevant prior art record has been identified and considered. Hence, any conclusions regarding the validity of claims in a patent based on patent office searches should be regarded as indicative rather than conclusive

5.2.2 Unpublished documents

Searches cannot reveal potentially relevant patent documents which have not been officially published at the time of conducting the search. In most countries, publication of patent applications does not occur until 18 months from the earliest priority date and consequently, patent searches would not normally reveal applications filed in the preceding 18 months. There may also be delays between official publication and the implementation of information onto the relevant databases.

5.2.3 Forms of prior art other than patent documents

It should also be appreciated that no patent search can ever be entirely conclusive because some forms of prior art such as prior public use, prior commercial exploitation and prior publication in non-patent literature, cannot be systematically searched.

5.2.4 Commercialisation/Secret Use

The commercialization or secret use of an invention that is the subject of a patent application can affect the patentability of the invention and the validity of any patent granted on the invention. Such commercialization or secret use is unlikely to be identified by documentary searches of publicly accessible databases

5.2.5 Search results indicative but not conclusive

The searches conducted by different patent offices provide a reasonable indication of the patentability or otherwise of the inventions in the patent portfolio. However, the above and other factors make it impossible to guarantee that every conceivably relevant prior art record has been revealed. Any conclusions on validity based on these or any other searches should therefore be regarded as indicative, and not conclusive.

5.2.6 Reliance on cited prior art classification

The views expressed in relation to relevance of the prior art cited in various searching and examination reports are based on the relevant classification attributed in such reports.

5.2.7 Searching and other matters relevant to validity

Searching may not disclose other matters relevant to validity including, for example, matters relevant to obviousness (i.e. inventive step).

5.2.8 Searches provide no guarantee of non-infringement

Searches do not provide any guarantee that the subject inventions may be commercially exploited without risk of infringement of earlier patents.

5.2.9 Reliance on information provided

The preparation of this Report has included access to and reliance on information contained in publicly available databases relevant to the patent applications in **Annex I**. Shelston IP is not responsible for the accuracy of information available in public databases and we cannot guarantee the accuracy of those databases

6. SHELSTON IP'S INTEREST

Shelston IP currently manages the Australian aspects of the ULRF Patents and Patent Applications/Patents on behalf of BCAL Dx. Neither Shelston IP nor any of its Principals has any entitlement to any securities in BCAL Dx, or has any other interest in the promotion of BCAL Dx.

7. SHELSTON IP'S EXPERTISE

Shelston IP is an established firm of patent and trade mark attorneys and lawyers with a history dating back 160 years. With over 100 professional and support staff, and extensive experience in the development of efficient and responsive case management systems and practices, Shelston IP is a leading Australasian intellectual property firm providing high quality, commercially relevant, intellectual property advice and services.

Shelston IP offers a full range of professional advice in all areas of IP law including patents, designs, trade marks, copyright and fair trading. The firm offers a wealth of technical and IP expertise and experience across all disciplines, and has specialist teams practicing in the fields of chemistry, chemical engineering, pharmaceuticals and biotechnology.

8. CONSENT

Consent for the inclusion of this Report in a Prospectus to be issued by BCAL Dx, in the form in which it now appears, has been granted by Shelston IP and has not been revoked, as at the date of this Report.

Yours sincerely
Shelston IP

Paul Harrison
Principal

E. PaulHarrison@ShelstonIP.com

Our Ref: 65890AUM00

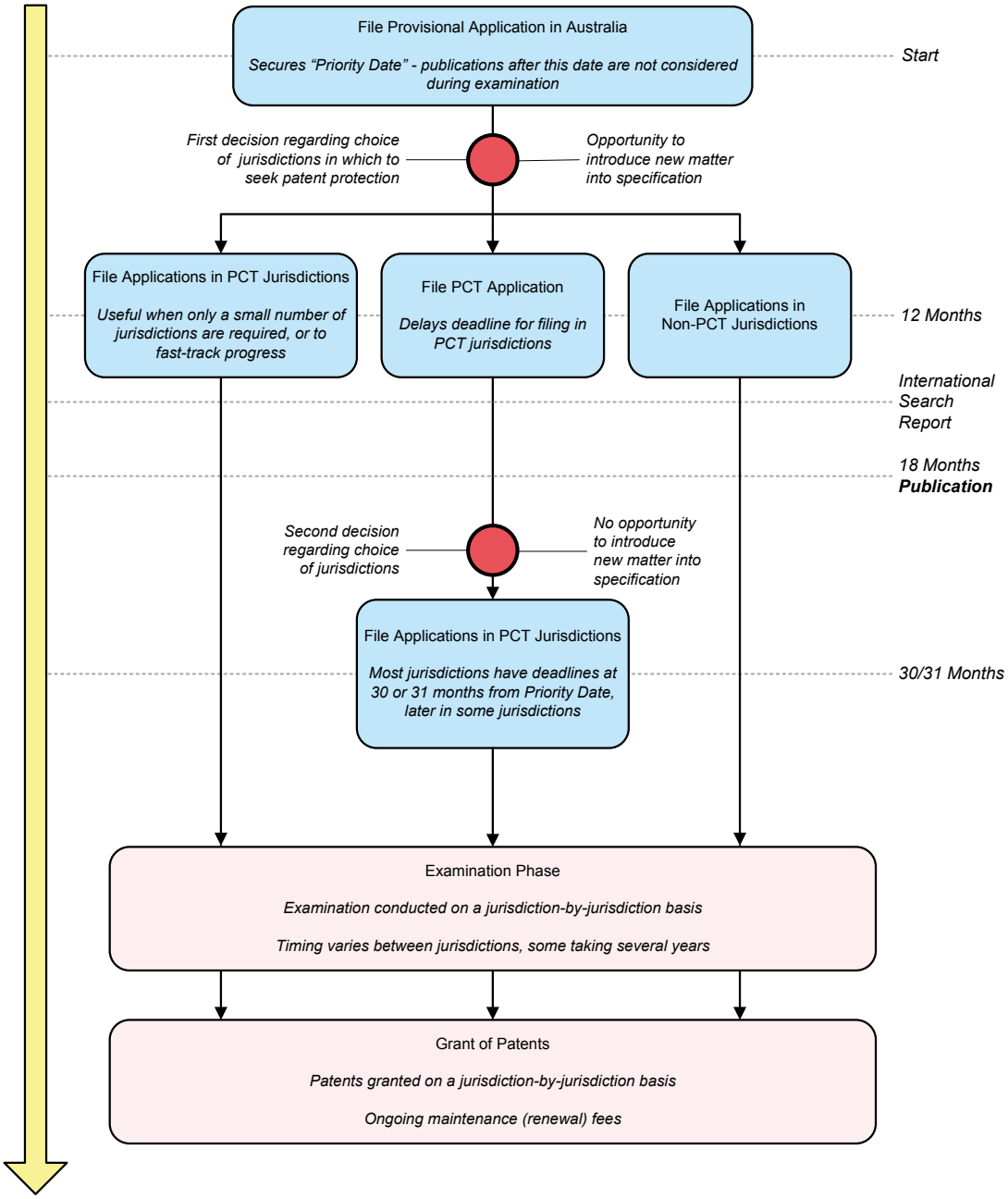
Annex I: ULRF Patents and Patent Applications

Applicant: University of Louisville Research Foundation, Inc.
Inventor: Fan, Teresa Whei-Mei; Lane, Andrew Nicholas; Higashi, Richard M.; Bousamra, Michael
Title: Methods for detecting cancer
Priority: US 61/357,642 (filed 23 July 2010)
PCT: PCT/US2011/041399 (filed 22 June 2011)
Expiry date: 22 June 2031 (subject to national patent term adjustments/extensions)

Official No.	Country	Case Status
2011270968	Australia	Granted (last renewal June 2020)
2016213855	Australia	Granted (last renewal June 2020)
2018236876	Australia	Lapsed (Jan 2019)
2803865	Canada	Pending (under exam, last action July 2020)
EP2585833 (2011798823)	Europe	Granted (last renewal July 2020)
EP3206034 (2017163073)	Europe	Granted (last renewal July 2020)
2020176591	Europe	Pending
JP5944385 (2013516721)	Japan	Granted
JP6092302 (2015109485)	Japan	Granted
2016218085	Japan	Refused (Jan 2018)
13/805352	USA	Pending (under exam, last action Sept 2020)

Shelston IP

Annex II: Overview of patent filing process



Appendix B: IP Report continued

Annex III: AU2011270968 Claims

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A method for determining the presence or absence of at least one cancer type in an animal comprising:

determining lipids amounts of lipids in a lipid set in a sample from the animal, and

determining the presence or absence of at least one cancer type in the animal with a predictive model;

wherein:

the lipid amounts of lipids in the lipid set comprise an input of the predictive model,

the lipid set comprises one or more lipids selected from the group consisting of FA (14:0), FA (15:0), and FA (18:0);

the sample comprises a bodily fluid or treatment thereof, and

the at least one cancer type is selected from the group consisting of breast cancer and tumors associated with breast cancer.

2. The method of claim 1, wherein the bodily fluid is selected from the group consisting of breast milk, mucus, saliva, sebum, sweat, tears, blood serum, endolymph, perilymph, blood, plasma, nipple aspirate fluid and urine.

3. The method of claim 1 or claim 2, wherein the bodily fluid is blood or plasma.

4. The method of any one of claims 1 to 3, wherein the sample comprises a lipid microvesicle fraction or an exosomal fraction.

5. The method of any one of claims 1 to 4, wherein the lipid set comprises at least 10 lipids.

6. The method of any one of claims 1 to 5, wherein the lipid set comprises at least 50 lipids.

7. The method of any one of claims 1 to 3, wherein the lipid set comprises FA (14:0), FA (15:0) and FA (18:0).

8. The method of any one of claims 1 to 3 or 7, wherein the lipid set further comprises LysoPA(18:3).

9. The method of any one of claims 1 to 3 or 7, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids

selected from the group consisting of BMP, CE, Cer, DAG, DH-LTB4, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

10. The method of any one of claims 1 to 3 or 7, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids selected from the group consisting of MAG, DAG, TAG, PI, PE, PS, PG, PA, LysoPC, LysoPE, LysoPS, LysoPI, LysoPG, LysoPA, LysoPC-pmg, LysoPE-pmg, BMP, SM, Cer, Cer-P, HexCer, GA1, GA2, GD1, GD2, GM1, GM2, GM3, GT1, and CE.

11. The method of any one of claims 1 to 3 or 7, wherein one or more lipids in the lipid set are further selected from the group consisting of BMP (30:1), BMP (32:1), BMP (34:1), BMP (35:4), BMP (36:3), BMP (37:1), BMP (37:7), BMP (38:1), BMP (38:2), BMP (38:4), BMP (39:1), BMP (39:4), BMP (40:1), BMP (40:2), BMP (40:3), BMP (40:4), BMP (40:7), BMP (42:10), BMP (42:2), BMP (42:5), BMP (44:8), CE (16:2), CE (18:2), CE (18:3), CE (18:4), CE (20:2), CE (20:4), CE (20:5), Cer (32:1), Cer (34:1), Cer (36:1), Cer (38:1), Cer (38:4), Cer (40:2), Cer (40:4), DAG (28:0), DAG (32:0), DAG (32:2), DAG (34:0), DAG (34:3), DAG (34:5), DAG (36:0), DAG (36:1), DAG (36:2), DAG (36:3), DAG (36:8), DAG (38:1), DAG (38:10), DAG (38:2), DAG (38:3), DAG (38:5), DAG (40:1), DAG (40:2), DAG (40:5), DH-LTB4 (20:3), FA (16:3), FA (19:1), GA2 (30:0), GA2 (33:2), GA2 (35:2), GA2 (37:2), GM3 (41:1), HexCer (32:1), HexDHCer (34:0), LacCer (30:0), LacCer (30:1), LacCer (32:2), LysoPA (16:2), LysoPA (16:3), LysoPA (18:1), LysoPA (18:3), LysoPA (22:0), LysoPA (22:1), LysoPC (16:0), LysoPC (18:0), LysoPC (18:1), LysoPC (18:4), LysoPC (20:4), LysoPC (20:5), LysoPC (26:6), LysoPC-pmg (12:0), LysoPC-pmg (18:3), LysoPC-pmg (24:4), LysoPC-pmg (26:0), LysoPE (10:1), LysoPE (16:2), LysoPE (18:2), LysoPE-pmg (18:4), LysoPS (24:1), MAG (18:0), MAG (20:3), MAG (24:2), PC (32:0), PC (32:1), PC (34:1), PC (34:1) , PC (34:2), PC (34:3), PC (34:4), PC (34:6), PC (36:1), PC (36:2), PC (36:3), PC (36:4), PC (36:5), PC (36:6), PC (36:9), PC (38:2), PC (38:3), PC (38:4), PC (38:5), PC (38:6), PC (38:7), PC (38:8), PC (38:9), PC (40:5), PC (40:6), PC (40:7), PC (40:8), PC (40:9), PC (44:12), PC-pmg (30:1), PC-pmg (36:4), PC-pmg (38:5), PC-pmg (38:7), PC-pmg (40:11), PC-pmg (42:1), PE (34:7), PE (36:5), PE (36:7), PE (38:2), PE (38:3), PE (38:4), PE (38:5), PE (38:7), PE (40:4), PE (40:9), PE (42:12), PE (44:11), PE-pmg (28:2), PE-pmg (30:3), PE-pmg (34:6), PE-pmg (34:8), PE-pmg (36:5), PE-pmg (36:6), PE-pmg (40:7), PE-pmg (40:8), PE-pmg (42:10), PE-pmg (42:12), PE-pmg (42:4), PE-pmg (42:7), PE-pmg (42:8), PE-pmg (42:9), PE-pmg (44:10), PE-pmg (44:11), PE-pmg

(44:12), PE-pmg (44:7), PE-pmg (44:8), PE-pmg (44:9), PGA1 (20:1), PGB1 (20:1), SM (34:1), SM (34:2), SM (36:1), SM (38:1), SM (40:1), SM (40:2), SM (42:1), SM (42:2), SM (42:3), Sphingosine (18:0), TAG (44:1), TAG (44:3), TAG (46:0), TAG (46:1), TAG (46:2), TAG (46:3), TAG (46:4), TAG (48:0), TAG (48:1), TAG (48:2), TAG (48:3), TAG (48:4), TAG (48:5), TAG (49:1), TAG (49:2), TAG (49:3), TAG (50:0), TAG (50:1), TAG (50:2), TAG (50:3), TAG (50:4), TAG (50:5), TAG (50:6), TAG (51:2), TAG (51:4), TAG (52:2), TAG (52:3), TAG (52:4), TAG (52:5), TAG (52:6), TAG (52:7), TAG (53:4), TAG (54:2), TAG (54:3), TAG (54:4), TAG (54:5), TAG (54:6), TAG (54:7), TAG (54:8), TAG (55:5), TAG (55:6), TAG (55:7), TAG (56:4), TAG (56:5), TAG (56:6), TAG (56:7), TAG (56:8), TAG (56:9), TAG (58:10), TAG (58:6), TAG (58:8), TAG (58:9), TAG (60:12), and TH-12-keto-LTB4(20:2).

12. The method of any one of claims 1 to 3 or 7, wherein one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PE-pmg (42:9), CE (20:5), TAG (52:3), LysoPA (22:0), LysoPA (18:3), PC (36:3), PC (36:4), PC (36:2), PC (34:2), and PC (34:1).

13. The method of any one of claims 1 to 3 or 7, wherein one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (18:3), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), CE (20:5), Cer (36:1), CE (18:2), DAG (34:0), SM (34:1), DAG (32:0), PE-pmg (40:8), PC (38:3), DAG (36:0), PC (36:1), TAG (54:5), TAG (54:6), PE-pmg (44:11), PE-pmg (42:8), TAG (52:2), SM (42:2), PC (38:6), TAG (54:7), PC (40:6), PC (40:7), LysoPC (16:0), FA (16:3), TAG (52:5), TAG (44:3), BMP (38:2), BMP (30:1), SM (40:1), PE-pmg (42:10), BMP (40:2), PE-pmg (40:7), SM (36:1), PE (38:2), PC (34:3), PC (36:5), PC (32:0), PC (32:1), BMP (37:1), BMP (40:3), PC (36:9), SM (42:3), PC-pmg (36:4), PC-pmg (38:5), PC (40:9), TAG (54:3), PE-pmg (44:12), BMP (36:3), FA (19:1), BMP (39:1), TAG (50:3), BMP (42:10), PC (34:6), GA2 (35:2), TAG (58:9), PE-pmg (42:7), and LysoPC (18:0).

14. The method of any one of claims 1 to 3 or 7, wherein one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (18:3), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), and CE (20:5).

15. The method of any one of claims 1 to 14, wherein the lipid amounts are determined using mass spectrometry.

16. The method of any one of claims 1 to 14, wherein the lipid amounts are determined using a Fourier transform ion cyclotron resonance mass analyzer.

17. The method of any one of claims 1 to 16, wherein the sample is a treatment of a bodily fluid.

18. The method of any one of claims 1 to 16, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

19. The method of any one of claims 1 to 18, wherein the predictive model comprises one or more dimension reduction methods.

20. The method of any one of claims 1 to 18, wherein the predictive model comprises one or more methods selected from the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

21. The method of any one of claims 1 to 20, wherein the animal is a human.

22. The method of any one of claims 1 to 8 or 15 to 21, wherein the at least one cancer type is breast cancer.

23. A method for determining the presence or absence of at least one cancer type in an animal comprising:

determining the presence or absence of at least one cancer type in the animal with a predictive model by analyzing lipid amounts of lipids in a lipid set in a sample from the animal;

wherein:

the lipid amounts of lipids in the lipid set comprise an input of the predictive model,

the lipid set comprises one or more lipids selected from the group consisting of FA (14:0), FA (15:0), and FA (18:0);

the sample comprises a bodily fluid or treatment thereof, and

the at least one cancer type is selected from the group consisting of breast cancer and tumors associated with breast cancer.

Appendix B: IP Report continued

24. The method of claim 1 or claim 23, substantially as herein described with reference to any one or more of the examples but excluding comparative examples.

Annex IV: AU2016213855 Claims

CLAIMS

1. A method for determining the presence or absence of at least one cancer type in an animal comprising

- determining lipids amounts of lipids in a lipid set in a sample from the animal, and
- determining the presence or absence of at least one cancer type in the animal with a predictive model;

wherein

- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
- the lipid set comprises PC (40:5),
- the sample comprises a bodily fluid or treatment thereof,
- the bodily fluid is selected from the group consisting of breast milk, blood serum, blood, plasma, and nipple aspirate fluid, and
- the at least one cancer type comprises breast cancer or tumors associated with breast cancer.

2. The method of claim 1 wherein the lipid set further comprises one or more lipids selected from the group consisting of PC (32:1), PC (34:4) and PC (38:3).

3. The method of claim 1 or claim 2, wherein the bodily fluid is selected from the group consisting of blood serum, blood, and plasma.

4. The method of any one of claims 1 to 3, wherein the bodily fluid is blood or plasma.

5. The method of any one of claims 1-4, wherein the sample comprises a lipid microvesicle fraction or an exosomal fraction.

6. The method of any one of claims 1-5, wherein the lipid set comprises at least 10 lipids.

7. The method of any one of claims 1-6, wherein the lipid set comprises at least 50 lipids.

8. The method of any one of claims 1-7, wherein the lipid set comprises PC (32:1), PC (34:4), PC (38:3), and PC (40:5).

9. The method of any one of claims 1-8, wherein the lipid set further comprises one or more classes of lipids selected from the group consisting of BMP, CE, Cer, DAG, DH-LTB4, FA, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

10. The method of any one of claims 1-8, wherein the lipid set further comprises one or more classes of lipids selected from the group consisting of FA, CE, PC, and LysoPC.

11. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of (a) the set of CE lipids with an acyl chain length of 10-26 carbons and 0-6 double bonds in the acyl chain, (b) the set of LysoPC lipids with an even number of carbons in the acyl chain of 10-26 carbons and 0-6 double bonds in the acyl chain, and (c) the set of PC lipids with an even number of carbons in the acyl chain of 28-44 carbons and 0-12 double bonds in the acyl chain.

12. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of BMP (30:1), BMP (32:1), BMP (34:1), BMP (35:4), BMP (36:3), BMP (37:1), BMP (37:7), BMP (38:1), BMP (38:2), BMP (38:4), BMP (39:1), BMP (39:4), BMP (40:1), BMP (40:2), BMP (40:3), BMP (40:4), BMP (40:7), BMP (42:10), BMP (42:2), BMP (42:5), BMP (44:8), CE (16:2), CE (18:2), CE (18:3), CE (18:4), CE (20:2), CE (20:4), CE (20:5), Cer (32:1), Cer (34:1), Cer (36:1), Cer (38:1), Cer (38:4), Cer (40:2), Cer (40:4), DAG (28:0), DAG (32:0), DAG (32:2), DAG (34:0), DAG (34:3), DAG (34:5), DAG (36:0), DAG (36:1), DAG (36:2), DAG (36:3), DAG (36:8), DAG (38:1), DAG (38:10), DAG (38:2), DAG (38:3), DAG (38:5), DAG (40:1), DAG (40:2), DAG (40:5), DH-LTB4 (20:3), FA (16:3), FA (19:1), GA2 (30:0), GA2 (33:2), GA2 (35:2), GA2 (37:2), GM3 (41:1), HexCer (32:1), HexDHCer (34:0), LacCer (30:0), LacCer (30:1), LacCer (32:2), LysoPA (16:2), LysoPA (16:3), LysoPA (18:1), LysoPA (22:0), LysoPA (22:1), LysoPC (16:0), LysoPC (18:0), LysoPC (18:1), LysoPC (18:4), LysoPC (20:4), LysoPC (20:5), LysoPC (26:6), LysoPC-pmg (12:0), LysoPC-pmg (18:3), LysoPC-pmg (24:4), LysoPC-pmg (26:0), LysoPE (10:1), LysoPE (16:2), LysoPE (18:2), LysoPE-pmg (18:4), LysoPS (24:1), MAG (18:0), MAG (20:3), MAG (24:2), PC (32:0), PC (34:1), PC (34:2), PC (34:3), PC (34:6), PC (36:1), PC (36:2), PC (36:3), PC (36:4), PC (36:5), PC (36:6), PC (36:9), PC (38:2), PC (38:4), PC (38:5), PC (38:6), PC (38:7), PC (38:8), PC (38:9), PC (40:6), PC (40:7), PC (40:8), PC (40:9), PC (44:12), PC-pmg (30:1), PC-pmg (36:4), PC-pmg (38:5), PC-pmg (38:7), PC-pmg (40:11), PC-pmg (42:1), PE (34:7), PE (36:5), PE (36:7), PE (38:2), PE (38:3), PE (38:4), PE (38:5), PE (38:7), PE (40:4), PE (40:9), PE

(42:12), PE (44:11), PE-pmg (28:2), PE-pmg (30:3), PE-pmg (34:6), PE-pmg (34:8), PE-pmg (36:5), PE-pmg (36:6), PE-pmg (40:7), PE-pmg (40:8), PE-pmg (42:10), PE-pmg (42:12), PE-pmg (42:4), PE-pmg (42:7), PE-pmg (42:8), PE-pmg (42:9), PE-pmg (44:10), PE-pmg (44:11), PE-pmg (44:12), PE-pmg (44:7), PE-pmg (44:8), PE-pmg (44:9), PGA1 (20:1), PGB1 (20:1), SM (34:1), SM (34:2), SM (36:1), SM (38:1), SM (40:1), SM (40:2), SM (42:1), SM (42:2), SM (42:3), Sphingosine (18:0), TAG (44:1), TAG (44:3), TAG (46:0), TAG (46:1), TAG (46:2), TAG (46:3), TAG (46:4), TAG (48:0), TAG (48:1), TAG (48:2), TAG (48:3), TAG (48:4), TAG (48:5), TAG (49:1), TAG (49:2), TAG (49:3), TAG (50:0), TAG (50:1), TAG (50:2), TAG (50:3), TAG (50:4), TAG (50:5), TAG (50:6), TAG (51:2), TAG (51:4), TAG (52:2), TAG (52:3), TAG (52:4), TAG (52:5), TAG (52:6), TAG (52:7), TAG (53:4), TAG (54:2), TAG (54:3), TAG (54:4), TAG (54:5), TAG (54:6), TAG (54:7), TAG (54:8), TAG (55:5), TAG (55:6), TAG (55:7), TAG (56:4), TAG (56:5), TAG (56:6), TAG (56:7), TAG (56:8), TAG (56:9), TAG (58:10), TAG (58:6), TAG (58:8), TAG (58:9), TAG (60:12), and TH-12-keto-LTB4(20:2).

13. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of PC (40:3), PC (44:11), LysoPC (18:3), LysoPC (20:2), LysoPC (20:1), LysoPC (20:0) CE (19:1), CE (19:0), and CE (20:0).

14 The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of LysoPA (22:1), PE-pmg (42:9), CE (20:5), TAG (52:3), LysoPA (22:0), PC (36:3), PC (36:4), PC (36:2), PC (34:2), and PC (34:1).

15. The method of any one of claims 1-8 wherein the lipid set further comprises one or more lipids selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), CE (20:5), Cer (36:1), CE (18:2), DAG (34:0), SM (34:1), DAG (32:0), PE-pmg (40:8), DAG (36:0), PC (36:1), TAG (54:5), TAG (54:6), PE-pmg (44:11), PE-pmg (42:8), TAG (52:2), SM (42:2), PC (38:6), TAG (54:7), PC (40:6), PC (40:7), LysoPC (16:0), FA (16:3), TAG (52:5), TAG (44:3), BMP (38:2), BMP (30:1), SM (40:1), PE-pmg (42:10), BMP (40:2), PE-pmg (40:7), SM (36:1), PE (38:2), PC (34:3), PC (36:5), PC (32:0), BMP (37:1), BMP (40:3), PC (36:9), SM (42:3), PC-pmg (36:4), PC-pmg (38:5), PC (40:9), TAG (54:3), PE-pmg (44:12), BMP (36:3), FA (19:1), BMP (39:1), TAG (50:3), BMP (42:10), PC (34:6), GA2 (35:2), TAG (58:9), PE-pmg (42:7), and LysoPC (18:0).

16. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), and CE (20:5).

17. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of LysoPA (22:1), PC (36:5), TAG (52:3), PC (38:5), CE (20:5), TAG (50:2), BMP (39:1), PC (34:2), CE (18:2), and PC (34:1).

18. The method of any one of claims 1-8, wherein the lipid set further comprises one or more lipids selected from the group consisting of PC (34:2), PC (36:2), TAG (44:3), CE (18:2), PC (34:1), LysoPA (22:1), PC (36:5), Cer (36:1), CE (20:5), PC (36:3), PC (38:4), PC (36:4), Cer (38:4), PC (38:5), PC (38:7), Cer (38:1), TAG (50:2), Cer (34:1), SM (34:1), Cer (40:4), MAG (18:0), MAG (24:2), PE-pmg (40:8), PE-pmg (42:8), TAG (50:1), DAG (32:0), PC (36:1), DAG (34:0), LysoPC (16:0), PE-pmg (34:6), DAG (36:3), PC (36:9), PE (36:5), TAG (52:6), FA (19:1), PE-pmg (44:11), BMP (38:2), PE (44:11), TAG (48:2), SM (42:2), BMP (40:2), PE-pmg (42:10), PE (36:7), PE-pmg (40:7), BMP (39:1), BMP (37:1), PE-pmg (36:6), PE (38:5), PC (32:0), PE (38:2), GA2 (35:2), DAG (34:3), PE-pmg (44:12), MAG (16:0), LysoPE (10:1), SM (36:1), BMP (39:4), TAG (56:7), and PE-pmg (42:9).

19. The method of any one of claims 1-8, wherein the lipid set further comprises one or more additional lipids selected from the one or more sets of lipids selected from the group consisting of (a) the set of CE lipids with an acyl chain length of 10-26 carbons and 0-6 double bonds in the acyl chain, (b) the set of LysoPC lipids with an even number of carbons in the acyl chain of 10-26 carbons and 0-6 double bonds in the acyl chain, and (c) the set of PC lipids with an even number of carbons in the acyl chain of 28-44 carbons and 0-12 double bonds in the acyl chain.

20. The method of any one of claims 1-19, wherein the lipid amounts are determined using mass spectrometry.

21. The method of any one of claims 1-20, wherein the lipid amounts are determined using a Fourier transform ion cyclotron resonance mass analyzer.

22. The method of any one of claims 1-21, wherein the sample is a treatment of a bodily fluid.

23. The method of any one of claims 1-22, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising

acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

24. The method of any one of claims 1-23, wherein the predictive model comprises one or more dimension reduction methods.

25. The method of any one of claims 1-24, wherein the predictive model comprises one or more methods selected from the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

26. The method of any one of claims 1-25, wherein the animal is human.

27. The method of any one of claims 1-26, comprising determining the presence or absence of more than one cancer type.

28. A method for determining the presence or absence of at least one cancer type in a human comprising

- determining the presence or absence of at least one cancer type in the human with a predictive model by analyzing lipid amounts of lipids in a lipid set in a sample from the human;

wherein

- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
- the lipid set comprises PC (40:5),
- the sample comprises a bodily fluid or treatment thereof,
- the bodily fluid is blood or plasma, and
- the at least one cancer type comprises breast cancer or tumors associated with breast cancer.

Annex V: EP2585833 Claims

EP 2 585 833 B1

also vary substantially, which was part of the classification. Most of the variance arose from intersubject variability rather than analytical variance. The difference in abundance between classes for discrimination was >4 fold with a coefficient of variation within a class of up to 50%. For example, the PC (36:3) showed mean and sd of 1.38 ' 0.34 (BrCA) versus 0.23 ' 0.1 (healthy) versus 0.19 ' 0.28 (NSCLC). This single instance provided statistical separation with p values of <0.0001 (BrCA versus healthy), <0.0001 (BrCa versus NSCLC). NSCLC versus healthy did not reach statistical significance. However, other lipids gave high statistical separation between NSCLC and healthy. Therefore, several classes together were used to discriminate among healthy individuals and those with cancer. Optimal segregation was achieved using sets of lipids where at least two of the subject classes differed with p values better than 0.01, and a minimum of ten such lipid classes were used for reliable discrimination

Claims

1. A method for determining the presence or absence of at least one cancer type in an animal comprising

   - determining lipids amounts of lipids in a lipid set in a sample from the animal, and
   - determining the presence or absence of at least one cancer type in the animal with a predictive model; wherein

   - the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
   - the sample comprises a bodily fluid or treatment thereof;
   - the at least one cancer type is selected from the group consisting of carcinomas, sarcomas, hematologic cancers, neurological malignancies, thyroid cancer, neuroblastoma, melanoma, renal cell carcinoma, hepatocellular carcinoma, breast cancer, colon cancer, lung cancer, pancreatic cancer, brain cancer, prostate cancer, chronic lymphocytic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, Glioblastoma multiforme, meningioma, bladder cancer, gastric cancer, Glioma, oral cancer, nasopharyngeal carcinoma, kidney cancer, rectal cancer, lymph node cancer, bone marrow cancer, stomach cancer, uterine cancer, leukemia, basal cell carcinoma, cancers related to epithelial cells, cancers that can alter the regulation or activity of Pyruvate Carboxylase, and tumors associated with any of the aforementioned cancer types;
   - the lipid set comprises a lipid from the class of BMP, preferably BMP (30:1), BMP (32:1), BMP (34:1), BMP (35:4), BMP (36:3), BMP (37:1), BMP (37:7), BMP (38:1), BMP (38:2), BMP (38:4), BMP (39:1), BMP (39:4), BMP (40:1), BMP (40:2), BMP (40:3), BMP (40:4), BMP (40:7), BMP (42:10), BMP (42:2), BMP (42:5), or BMP (44:8), and
   - the predictive model comprises one or more of dimension reduction method, clustering method, machine learning method, principle component analysis, soft independent modeling of class analogy, partial least squares regression, orthogonal least squares regression, partial least squares discriminant analysis, orthogonal partial least squares discriminant analysis, mean centering, median centering, Pareto scaling, unit variance scaling, orthogonal signal correction, integration, differentiation, cross validation, or receiver operating characteristic curves.

2. The method of claim 1, wherein the bodily fluid is selected from the group consisting of plasma vomit, cerumen, gastric juice, breast milk, mucus, saliva, sebum, semen, sweat, tears, vaginal secretion, blood serum, aqueous humor, vitreous humor, endolymph, perilymph, peritoneal fluid, pleural fluid, cerebrospinal fluid, blood, plasma, nipple aspirate fluid, urine, stool, and bronchioalveolar lavage fluid.

3. The method of claim 1 or 2, wherein the sample comprises a lipid micro vesicle fraction.

4. The method of claim 1, 2 or 3, wherein the lipid set comprises at least 10, at least 50, at least 100, at least 200 or no more than 100,000 lipids.

5. The method of any preceding claim, wherein the lipid set further comprises one or more lipids selected from the one or more classes of lipids selected from the group consisting of CE, Cer, DAG, DH-LTB4, FA, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

6. The method of any of claims 1 to 4, wherein the lipid set further comprises one or more lipids selected from the one or more classes of lipids selected from the group consisting of FA, MAG, DAG, TAG, PI, PE, PS, PI, PG, PA, LysoPC, LysoPE, LysoPS, LysoPI, LysoPG, LysoPA, LysoPC, LysoPE, SM, Cer, Cer-P, HexCer, GA1, GA2, GD1, GD2,

GM1, GM2, GM3, GT1, and CE.

7. The method of any of claims 1 to 4, wherein one or more lipids in the lipid set are further selected from the group consisting of CE (16:2), CE (18:2), CE (18:3), CE (18:4), CE (20:2), CE (20:4), CE (20:5), Cer (32:1), Cer (34:1), Cer (36:1), Cer (38:1), Cer (38:4), Cer (40:2), Cer (40:4), DAG (28:0), DAG (32:0), DAG (32:2), DAG (34:0), DAG (34:3), DAG (34:5), DAG (36:0), DAG (36:1), DAG (36:2), DAG (36:3), DAG (36:8), DAG (38:1), DAG (38:10), DAG (38:2), DAG (38:3), DAG (38:5), DAG (40:1), DAG (40:2), DAG (40:5), DH-LTB4 (20:3), FA (16:3), FA (19:1), GA2 (30:0), GA2 (33:2), GA2 (35:2), GA2 (37:2), GM3 (41:1), HexCer (32:1), HexDHCer (34:0), LacCer (30:0), LacCer (30:1), LacCer (32:2), LysoPA (16:2), LysoPA (16:3), LysoPA (18:1), LysoPA (22:0), LysoPA (22:1), LysoPC (16:0), LysoPC (18:0), LysoPC (18:1), LysoPC (18:4), LysoPC (20:4), LysoPC (20:5), LysoPC (26:6), LysoPC-pmg (12:0), LysoPC-pmg (18:3), LysoPC-pmg (24:4), LysoPC-pmg (26:0), LysoPE (10:1), LysoPE (16:2), LysoPE (18:2), LysoPE-pmg (18:4), LysoPS (24:1), MAG (18:0), MAG (20:3), MAG (24:2), PC (32:0), PC (32:1), PC (34:1), PC (34:2), PC (34:3), PC (34:4), PC (34:6), PC (36:1), PC (36:2), PC (36:3), PC (36:4), PC (36:5), PC (36:6), PC (36:9), PC (38:2), PC (38:3), PC (38:4), PC (38:5), PC (38:6), PC (38:7), PC (38:8), PC (38:9), PC (40:5), PC (40:6), PC (40:7), PC (40:8), PC (40:9), PC (44:12), PC-pmg (30:1), PC-pmg (36:4), PC-pmg (38:5), PC-pmg (38:7), PC-pmg (40:11), PC-pmg (42:1), PE (34:7), PE (36:5), PE (36:7), PE (38:2), PE (38:3), PE (38:4), PE (38:5), PE (38:7), PE (40:4), PE (40:9), PE (42:12), PE (44:11), PE-pmg (28:2), PE-pmg (30:3), PE-pmg (34:6), PE-pmg (34:8), PE-pmg (36:5), PE-pmg (36:6), PE-pmg (40:7), PE-pmg (40:8), PE-pmg (42:10), PE-pmg (42:12), PE-pmg (42:4), PE-pmg (42:7), PE-pmg (42:8), PE-pmg (42:9), PE-pmg (44:10), PE-pmg (44:11), PE-pmg (44:12), PE-pmg (44:7), PE-pmg (44:8), PE-pmg (44:9), PGA1 (20:1), PGB1 (20:1), SM (34:1), SM (34:2), SM (36:1), SM (38:1), SM (40:1), SM (40:2), SM (42:1), SM (42:2), SM (42:3), Sphingosine (18:0), TAG (44:1), TAG (44:3), TAG (46:0), TAG (46:1), TAG (46:2), TAG (46:3), TAG (46:4), TAG (48:0), TAG (48:1), TAG (48:2), TAG (48:3), TAG (48:4), TAG (48:5), TAG (49:1), TAG (49:2), TAG (49:3), TAG (50:0), TAG (50:1), TAG (50:2), TAG (50:3), TAG (50:4), TAG (50:5), TAG (50:6), TAG (51:2), TAG (51:4), TAG (52:2), TAG (52:3), TAG (52:4), TAG (52:5), TAG (52:6), TAG (52:7), TAG (53:4), TAG (54:2), TAG (54:3), TAG (54:4), TAG (54:5), TAG (54:6), TAG (54:7), TAG (54:8), TAG (55:5), TAG (55:6), TAG (55:7), TAG (56:4), TAG (56:5), TAG (56:6), TAG (56:7), TAG (56:8), TAG (56:9), TAG (58:10), TAG (58:6), TAG (58:8), TAG (58:9), TAG (60:12), and TH-12-keto-LTB4(20:2).

8. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:0), PE-pmg (42:9), FA (16:3), FA (19:1), CE (18:2), Cer (36:1), Cer (38:4), PC (38:5), Cer (38:1), and TAG (44:3).

9. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), Cer (36:1), PC (40:7), TAG (54:5), TAG (54:6), CE (18:2), PC (36:4), FA (16:3), PE-pmg (44:11), TAG (52:5), Cer (40:4), CE (20:5), PC (38:6), TAG (50:2), MAG (18:0), FA (19:1), TAG (52:2), LysoPA (22:1), MAG (24:2), TAG (54:7), TAG (50:3), TAG (50:1), DAG (36:3), PC (34:1), TAG (52:6), PE-pmg (44:12), CE (20:4), PE (44:11), PC (40:8), TAG (56:9), PE-pmg (34:6), PE (36:7), PE (36:5), TAG (56:7), TAG (56:8), DAG (34:3), TAG (56:6), TAG (52:3), TAG (54:3), TAG (56:5), TAG (54:8), PC (34:6), PC (40:6), DAG (36:0), LysoPE (10:1), DAG (40:5), Cer (32:1), TAG (50:5), TAG (50:4), PE-pmg (36:6), TAG (46:3), and PE (38:5).

10. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), and Cer (36:1).

11. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PE-pmg (42:9), CE (20:5), TAG (52:3), LysoPA (22:0), PC (36:3), PC (36:4), PC (36:2), PC (34:2), and PC (34:1).

12. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), CE (20:5), Cer (36:1), CE (18:2), DAG (34:0), SM (34:1), DAG (32:0), PE-pmg (40:8), PC (38:3), DAG (36:0), PC (36:1), TAG (54:5), TAG (54:6), PE-pmg (44:11), PE-pmg (42:8), TAG (52:2), SM (42:2), PC (38:6), TAG (54:7), PC (40:6), PC (40:7), LysoPC (16:0), FA (16:3), TAG (52:5), TAG (44:3), SM (40:1), PE-pmg (42:10), PE-pmg (40:7), SM (36:1), PE (38:2), PC (34:3), PC (36:5), PC (32:0), PC (32:1), PC (36:9), SM (42:3), PC-pmg (36:4), PC-pmg (38:5), PC (40:9), TAG (54:3), PE-pmg (44:12), FA (19:1), TAG (50:3), PC (34:6), GA2 (35:2), TAG (58:9), PE-pmg (42:7), and LysoPC (18:0).

Appendix B: IP Report continued

13. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), and CE (20:5).

14. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PC (36:5), TAG (52:3), PC (38:5), CE (20:5), TAG (50:2), PC (34:2), CE (18:2), and PC (34:1).

15. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (36:2), TAG (44:3), CE (18:2), PC (34:1), LysoPA (22:1), PC (36:5), Cer (36:1), CE (20:5), PC (36:3), PC (38:4), PC (36:4), Cer (38:4), PC (38:5), PC (38:7), Cer (38:1), TAG (50:2), Cer (34:1), SM (34:1), Cer (40:4), MAG (18:0), MAG (24:2), PC (38:3), PE-pmg (40:8), PE-pmg (42:8), TAG (50:1), DAG (32:0), PC (36:1), DAG (34:0), LysoPC (16:0), PE-pmg (34:6), DAG (36:3), PC (36:9), PE (36:5), TAG (52:6), FA (19:1), PE-pmg (44:11), PE (44:11), TAG (48:2), SM (42:2), PE-pmg (42:10), PE (36:7), PE-pmg (40:7), PE-pmg (36:6), PE (38:5), PC (32:0), PE (38:2), GA2 (35:2), DAG (34:3), PE-pmg (44:12), MAG (16:0), PC (32:1), LysoPE (10:1), SM (36:1), TAG (56:7), and PE-pmg (42:9).

16. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (36:2), TAG (44:3), CE (18:2), PC (34:1), LysoPA (22:1), PC (36:5), Cer (36:1), CE (20:5), and PC (36:3).

17. The method of any preceding claim, wherein the lipid amounts are determined using mass spectrometry, such as a Fourier transform ion cyclotron resonance mass analyzer.

18. The method of any preceding claim, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

19. The method of any preceding claim, wherein the predictive model comprises one or more dimension reduction methods.

20. The method of any preceding claim, wherein the predictive model comprises one or more methods selected from the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

21. The method of any preceding claim, wherein the animal is selected from the group consisting of human, dog, cat, horse, cow, pig, sheep, chicken, turkey, mouse, and rat.

22. The method of any preceding claim, wherein the at least one cancer type is lung or breast cancer.

Patentansprüche

1. Verfahren für die Bestimmung der Gegenwart oder Abwesenheit von mindestens einer Krebsart bei einem Tier, das Folgendes umfasst:

   - Bestimmen von Lipidmengen von Lipiden in einer Lipidreihe in einer Probe von dem Tier und
   - Bestimmen der Gegenwart oder Abwesenheit von mindestens einer Krebsart bei dem Tier mit einem Vorhersagemodell;
   wobei

   - die Lipidmengen von Lipiden in der Lipidreihe eine Eingabe des Vorhersagemodells umfassen;
   - die Probe eine Körperflüssigkeit oder Behandlung davon umfasst;
   - die mindestens eine Krebsart aus der Gruppe ausgewählt ist, die aus Folgenden besteht: Karzinomen, Sarkomen, Blutkrebsarten, neurologischen Malignomen, Schilddrüsenkrebs, Neuroblastom, Melanom, Nierenzellkarzinom, Leberzellkarzinom, Brustkrebs, Kolonkrebs, Lungenkrebs, Bauchspeicheldrüsenkrebs, Hirnkrebs, Prostatakrebs, chronischer lymphozytischer Leukämie, akuter lymphoblastischer Leukämie,

Annex VI: EP3206034 Claims

EP 3 206 034 B1

Claims

1. A method for determining the presence or absence of at least one cancer type in an animal comprising

   - determining lipids amounts of lipids in a lipid set in a sample from the animal, and
   - determining the presence or absence of at least one cancer type in the animal with a predictive model; wherein

   - the lipid amounts of lipids in the lipid set comprise an input of the predictive model, and
   - the sample comprises a bodily fluid or treatment thereof,
   - the at least one cancer type is selected from the group consisting of lung cancer, breast cancer, and tumors associated with any of the aforementioned cancer types,
   - the lipid set comprises FA (16:3), and
   - the predictive model comprises one or more of dimension reduction method, clustering method, machine learning method, principle component analysis, soft independent modeling of class analogy, partial least squares regression, orthogonal least squares regression, partial least squares discriminant analysis, orthogonal partial least squares discriminant analysis, mean centering, median centering, Pareto scaling, unit variance scaling, orthogonal signal correction, integration, differentiation, cross validation, or receiver operating characteristic curves.

2. The method of claim 1, wherein the bodily fluid is selected from the group consisting of plasma, vomit, cerumen, gastric juice, breast milk, mucus, saliva, sebum, semen, sweat, tears, vaginal secretion, blood serum, aqueous humor, vitreous humor, endolymph, perilymph, peritoneal fluid, pleural fluid, cerebrospinal fluid, blood, plasma, nipple aspirate fluid, urine, stool, and bronchioalveolar lavage fluid.

3. The method of claim 1 or 2, wherein the sample is an exosomal fraction.

4. The method of claim 1, 2 or 3, wherein the lipid set comprises at least 10 , at least 50, at least 100, at least 200 or no more than 100,000 lipids.

5. The method of any preceding claim, wherein the lipid set further comprises one or more lipids selected from the one or more classes of lipids selected from the group consisting of BMP, CE, Cer, DAG, DH-LTB4, FA, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

6. The method of any of claims 1 to 4, wherein the lipid set further comprises one or more lipids selected from the one or more classes of lipids selected from the group consisting of FA, MAG, DAG, TAG, PI, PE, PS, PI, PG, PA, LysoPC, LysoPE, LysoPS, LysoPI, LysoPG, LysoPA, LysoPC, LysoPE, BMP, SM, Cer, Cer-P, HexCer, GA1, GA2, GD1, GD2, GM1, GM2, GM3, GT1, and CE.

7. The method of any of claims 1 to 4, wherein one or more lipids in the lipid set are further selected from one or more FA lipids with an acyl chain range of 10-26 and a number of unsaturated sites of 0-6.

8. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises lung cancer.

9. The method of any one of claims 1 to 4, wherein the at least one cancer type comprises breast cancer.

10. The method of any preceding claim, wherein the lipid amounts are determined using mass spectrometry, such as a Fourier transform ion cyclotron resonance mass analyzer.

11. The method of any preceding claim, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

12. The method of any preceding claim, wherein the predictive model comprises one or more dimension reduction methods.

13. The method of any preceding claim, wherein the predictive model comprises one or more methods selected from

the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

14. The method of any preceding claim, wherein the animal is selected from the group consisting of human, dog, cat, horse, cow, pig, sheep, chicken, turkey, mouse, and rat.

15. A method for determining the presence or absence of at least one cancer type in an animal comprising

- determining lipids amounts of lipids in a lipid set in a sample from the animal, and
- determining the presence or absence of at least one cancer type in the animal with a predictive model;

wherein

- the lipid amounts of lipids in the lipid set comprise an input of the predictive model, and
- the sample comprises a bodily fluid or treatment thereof,
- the at least one cancer type is selected from the group consisting of carcinomas, sarcomas, hematologic cancers, neurological malignancies, thyroid cancer, neuroblastoma, melanoma, renal cell carcinoma, hepatocellular carcinoma, breast cancer, colon cancer, lung cancer, pancreatic cancer, brain cancer, prostate cancer, chronic lymphocytic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, Glioblastoma multiforme, meningioma, bladder cancer, gastric cancer, Glioma, oral cancer, nasopharyngeal carcinoma, kidney cancer, rectal cancer, lymph node cancer, bone marrow cancer, stomach cancer, uterine cancer, leukemia, basal cell carcinoma, cancers related to epithelial cells, cancers that can alter the regulation or activity of Pyruvate Carboxylase, and tumors associated with any of the aforementioned cancer types,
- the lipid set comprises FA (16:3), and

- the predictive model comprises one or more of dimension reduction method, clustering method, machine learning method, principle component analysis, soft independent modeling of class analogy, partial least squares regression, orthogonal least squares regression, partial least squares discriminant analysis, orthogonal partial least squares discriminant analysis, mean centering, median centering, Pareto scaling, unit variance scaling, orthogonal signal correction, integration, differentiation, cross validation, or receiver operating characteristic curves.

Patentansprüche

1. Verfahren für die Bestimmung der Gegenwart oder Abwesenheit von mindestens einer Krebsart bei einem Tier, das Folgendes umfasst:

- Bestimmen von Lipidmengen von Lipiden in einer Lipidreihe in einer Probe von dem Tier und
- Bestimmen der Gegenwart oder Abwesenheit von mindestens einer Krebsart bei dem Tier mit einem Vorhersagemodell;

wobei

- die Lipidmengen von Lipiden in der Lipidreihe eine Eingabe des Vorhersagemodells umfassen und
- die Probe eine Körperflüssigkeit oder Behandlung davon umfasst,
- die mindestens eine Krebsart aus der Gruppe ausgewählt ist, die aus Folgenden besteht: Lungenkrebs, Brustkrebs und Tumoren, die mit jedweder der vorgenannten Krebsarten verbunden sind;
- die Lipidreihe FA (16:3) umfasst und
- das Vorhersagemodell eines oder mehrere von Folgenden umfasst: Dimensionsreduktionsverfahren, Clustering-Verfahren, maschinelles Lernverfahren, Hauptkomponentenanalyse, Soft Independent Modeling of Class Analogy, Partial Least Squares Regression, Orthogonal Least Squares Regression, Partial Least Squares Discriminant Analysis, Orthogonal Partial Least Squares Discriminant Analysis, Mittelwertzentrierung, Medianzentrierung, Pareto Scaling, Unit Variance Scaling, orthogonale Signalkorrektur, Integration, Differentiation, Kreuzvalidierung oder Receiver-Operating-Characteristic-Kurven.

2. Verfahren nach Anspruch 1, wobei die Körperflüssigkeit aus der Gruppe ausgewählt ist, die aus Folgenden besteht: Plasma, Erbrochenem, Cerumen, Magensaft, Muttermilch, Schleim, Speichel, Talg, Sperma, Schweiß, Tränen, Vaginalsekret, Blutserum, Kammerwasser, Glaskörperflüssigkeit, Endolymphe, Perilymphe, Peritonealflüssigkeit,

Annex VII: JP5944385 Claims

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

1. A method of using lipids amounts of lipids in a lipid set as an indicative for the presence or absence of at least one cancer type in an animal comprising

- determining lipids amounts of lipids in a lipid set in a sample from the animal, and

wherein the lipids amounts are analyzed with a predictive model and the analyzed results indicate the presence or absence of at least one cancer type in the animal;

wherein

- the animal is human,
- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
- the lipid set comprises at least 10 lipids and no more than 200 lipids,
- the lipid set comprises one or more lipids selected from the group consisting of PC (36:3), PC (34:6), PC (32:0), FA (14:0), FA (15:0), FA (18:0), LysoPA (18:3), TAG (50:0), TAG (46:4), and TAG (52:2),
- the sample comprises a bodily fluid or treatment thereof, wherein the bodily fluid is blood, plasma, blood serum, urine, or nipple aspirate fluid, and
- the at least one cancer type is breast cancer or lung cancer.

2. A method of using lipids amounts of lipids in a lipid set as an indicative for the presence or absence of at least one cancer type in an animal comprising

- determining lipids amounts of lipids in a lipid set in a sample from the animal, and

wherein the lipids amounts are analyzed with a predictive model and the analyzed results indicate the presence or absence of at least one cancer type in the animal;

wherein

- the animal is human,
- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
- the lipid set comprises at least 10 lipids and no more than 200 lipids,

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

- the lipid set comprises one or more lipids selected from the group consisting of PC (36:3), PC (34:6), PC (32:0), FA (14:0), FA (15:0), FA (18:0), LysoPA (18:3), TAG (50:0), TAG (46:4), and TAG (52:2),

- the sample comprises a bodily fluid or treatment thereof, wherein the bodily fluid is saliva, blood, plasma, blood serum, or nipple aspirate fluid and

- the at least one cancer type is breast cancer or lung cancer.

3. The method of claim 1, wherein the bodily fluid is blood.

4. The method of claim 1, wherein the sample comprises a lipid microvesicle fraction.

5. The method of claim 1, wherein the lipid set comprises at least 50 lipids and no more than 200 lipids.

6. The method of claim 1, wherein the lipid set comprises at least 100 lipids and no more than 200 lipids.

7. The method of claim 1, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids selected from the group consisting of BMP, CE, Cer, DAG, DH-LTB4, FA, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

8. The method of claim 1, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids selected from the group consisting of FA, MAG, DAG, TAG, PE, PS, PI, PG, PA, LysoPC, LysoPE, LysoPS, LysoPI, LysoPG, LysoPA, BMP, SM, Cer, Cer-P, HexCer, GA1, GA2, GD1, GD2, GM1, GM2, GM3, GT1, and CE.

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

9. The method of claim 1, wherein one or more lipids in the lipid set are further selected from the group consisting of BMP (30:1), BMP (32:1), BMP (34:1), BMP (35:4), BMP (36:3), BMP (37:1), BMP (37:7), BMP (38:1), BMP (38:2), BMP (38:4), BMP (39:1), BMP (39:4), BMP (40:1), BMP (40:2), BMP (40:3), BMP (40:4), BMP (40:7), BMP (42:10), BMP (42:2), BMP (42:5), BMP (44:8), CE (16:2), CE (18:2), CE (18:3), CE (18:4), CE (20:2), CE (20:4), CE (20:5), Cer (32:1), Cer (34:1), Cer (36:1), Cer (38:1), Cer (38:4), Cer (40:2), Cer (40:4), DAG (28:0), DAG (32:0), DAG (32:2), DAG (34:0), DAG (34:3), DAG (34:5), DAG (36:0), DAG (36:1), DAG (36:2), DAG (36:3), DAG (36:8), DAG (38:1), DAG (38:10), DAG (38:2), DAG (38:3), DAG (38:5), DAG (40:1), DAG (40:2), DAG (40:5), DH-LTB4 (20:3), FA (16:3), FA (19:1), GA2 (30:0), GA2 (33:2), GA2 (35:2), GA2 (37:2), GM3 (41:1), HexCer (32:1), HexDHCer (34:0), LacCer (30:0), LacCer (30:1), LacCer (32:2), LysoPA (16:2), LysoPA (16:3), LysoPA (18:1), LysoPA (22:0), LysoPA (22:1), LysoPC (16:0), LysoPC (18:0), LysoPC (18:1), LysoPC (18:4), LysoPC (20:4), LysoPC (20:5), LysoPC (26:6), LysoPC-pmg (12:0), LysoPC-pmg (18:3), LysoPC-pmg (24:4), LysoPC-pmg (26:0), LysoPE (10:1), LysoPE (16:2), LysoPE (18:2), LysoPE-pmg (18:4), LysoPS (24:1), MAG (18:0), MAG (20:3), MAG (24:2), PC (32:1), PC (34:1), PC (34:1) , PC (34:2), PC (34:3), PC (34:4), PC (36:1), PC (36:2), PC (36:4), PC (36:5), PC (36:6), PC (36:9), PC (38:2), PC (38:3), PC (38:4), PC (38:5), PC (38:6), PC (38:7), PC (38:8), PC (38:9), PC (40:5), PC (40:6), PC (40:7), PC (40:8), PC (40:9), PC (44:12), PC-pmg (30:1), PC-pmg (36:4), PC-pmg (38:5), PC-pmg (38:7), PC-pmg (40:11), PC-pmg (42:1), PE (34:7), PE (36:5), PE (36:7), PE (38:2), PE (38:3), PE (38:4), PE (38:5), PE (38:7), PE (40:4), PE (40:9), PE (42:12), PE (44:11), PE-pmg (28:2), PE-pmg (30:3), PE-pmg (34:6), PE-pmg (34:8), PE-pmg (36:5), PE-pmg (36:6), PE-pmg (40:7), PE-pmg (40:8), PE-pmg (42:10), PE-pmg (42:12), PE-pmg (42:4), PE-pmg (42:7), PE-pmg (42:8), PE-pmg (42:9), PE-pmg (44:10), PE-pmg (44:11), PE-pmg (44:12), PE-pmg (44:7), PE-pmg (44:8), PE-pmg (44:9), PGA1 (20:1), PGB1 (20:1), SM (34:1), SM (34:2), SM (36:1), SM (38:1), SM (40:1), SM (40:2), SM (42:1), SM (42:2), SM (42:3), Sphingosine (18:0),

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

TAG (44:1), TAG (44:3), TAG (46:0), TAG (46:1), TAG (46:2), TAG (46:3), TAG (48:0), TAG (48:1), TAG (48:2), TAG (48:3), TAG (48:4), TAG (48:5), TAG (49:1), TAG (49:2), TAG (49:3), TAG (50:1), TAG (50:2), TAG (50:3), TAG (50:4), TAG (50:5), TAG (50:6), TAG (51:2), TAG (51:4), TAG (52:3), TAG (52:4), TAG (52:5), TAG (52:6), TAG (52:7), TAG (53:4), TAG (54:2), TAG (54:3), TAG (54:4), TAG (54:5), TAG (54:6), TAG (54:7), TAG (54:8), TAG (55:5), TAG (55:6), TAG (55:7), TAG (56:4), TAG (56:5), TAG (56:6), TAG (56:7), TAG (56:8), TAG (56:9), TAG (58:10), TAG (58:6), TAG (58:8), TAG (58:9), TAG (60:12), and TH-12-keto-LTB4(20:2).

10. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:0), PE-pmg (42:9), FA (16:3), FA (19:1), CE (18:2), Cer (36:1), Cer (38:4), PC (38:5), Cer (38:1), and TAG (44:3).

11. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), Cer (36:1), PC (40:7), TAG (54:5), TAG (54:6), CE (18:2), PC (36:4), FA (16:3), PE-pmg (44:11), TAG (52:5), Cer (40:4), CE (20:5), PC (38:6), TAG (50:2), MAG (18:0), FA (19:1), LysoPA (22:1), MAG (24:2), TAG (54:7), TAG (50:3), TAG (50:1), DAG (36:3), PC (34:1), TAG (52:6), BMP (30:1), PE-pmg (44:12), CE (20:4), BMP (40:3), PE (44:11), PC (40:8), TAG (56:9), PE-pmg (34:6), PE (36:7), PE (36:5), TAG (56:7), TAG (56:8), DAG (34:3), TAG (56:6), BMP (42:10), TAG (52:3), BMP (39:4), BMP (36:3), TAG (54:3), TAG (56:5), TAG (54:8), PC (40:6), DAG (36:0), LysoPE (10:1), DAG (40:5), Cer (32:1), TAG (50:5), TAG (50:4), PE-pmg (36:6), BMP (42:5), TAG (46:3), and PE (38:5).

12. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), and Cer (36:1).

13. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PE-pmg (42:9), CE (20:5), TAG (52:3), LysoPA (22:0), PC (36:4), PC (36:2), PC (34:2), and PC (34:1).

14. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), CE (20:5), Cer (36:1), CE (18:2), DAG (34:0), SM (34:1), DAG (32:0), PE-pmg (40:8), PC (38:3), DAG (36:0), PC (36:1), TAG (54:5), TAG (54:6), PE-pmg (44:11), PE-pmg (42:8), SM (42:2), PC (38:6), TAG (54:7), PC (40:6), PC (40:7), LysoPC (16:0), FA (16:3), TAG (52:5), TAG (44:3), BMP (38:2), BMP (30:1), SM (40:1), PE-pmg (42:10), BMP (40:2), PE-pmg (40:7), SM (36:1), PE (38:2), PC (34:3), PC (36:5), PC (32:1), BMP (37:1), BMP (40:3), PC (36:9), SM (42:3), PC-pmg (36:4), PC-pmg (38:5), PC (40:9), TAG (54:3), PE-pmg (44:12), BMP (36:3), FA (19:1), BMP (39:1), TAG (50:3), BMP (42:10), GA2 (35:2), TAG (58:9), PE-pmg (42:7), and LysoPC (18:0).

15. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), and CE (20:5).

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

16. The method of claim 1, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PC (36:5), TAG (52:3), PC (38:5), CE (20:5), TAG (50:2), BMP (39:1), PC (34:2), CE (18:2), and PC (34:1).

17. The method of claim 1, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (36:2), TAG (44:3), CE (18:2), PC (34:1), LysoPA (22:1), PC (36:5), Cer (36:1), CE (20:5), PC (38:4), PC (36:4), Cer (38:4), PC (38:5), PC (38:7), Cer (38:1), TAG (50:2), Cer (34:1), SM (34:1), Cer (40:4), MAG (18:0), MAG (24:2), PC (38:3), PE-pmg (40:8), PE-pmg (42:8), TAG (50:1), DAG (32:0), PC (36:1), DAG (34:0), LysoPC (16:0), PE-pmg (34:6), DAG (36:3), PC (36:9), PE (36:5), TAG (52:6), FA (19:1), PE-pmg (44:11), BMP (38:2), PE (44:11), TAG (48:2), SM (42:2), BMP (40:2), PE-pmg (42:10), PE (36:7), PE-pmg (40:7), BMP (39:1), BMP (37:1), PE-pmg (36:6), PE (38:5), PE (38:2), GA2 (35:2), DAG (34:3), PE-pmg (44:12), MAG (16:0), PC (32:1), LysoPE (10:1), SM (36:1), BMP (39:4), TAG (56:7), and PE-pmg (42:9).

18. (canceled)

19. The method of claim 1, wherein the lipid amounts are determined using mass spectrometry.

20. The method of claim 1, wherein the lipid amounts are determined using a Fourier transform ion cyclotron resonance mass analyzer.

21. The method of claim 1, wherein the sample is a treatment of a bodily fluid.

22. The method of claim 1, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

23. The method of claim 1, wherein the predictive model comprises one or more dimension reduction methods.

24. The method of claim 1, wherein the predictive model comprises one or more methods selected from the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

25. The method of claim 1, wherein the at least one cancer type is lung cancer or breast cancer.

26. The method of claim 1, wherein the analyzed results indicate the presence or absence of more than one cancer type.

27. A method of using lipids amounts of lipids in a lipid set as an indicative for the presence or absence of at least one cancer type in an animal comprising

- determining lipid amounts of lipids in a lipid set in a sample from the animal;
- analyzing the lipid amounts of lipids with a predicative model;

wherein the analyzed results of the lipid amounts of lipids indicate the presence or absence of at least one cancer type in the animal;

wherein

- the animal is human,

Allowed Claims - May 2016

Japanese Patent Application No: 2013-516721
Calfee Ref: 35783.04011

- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,

- the lipid set comprises at least 10 lipids and no more than 200 lipids,

- the lipid set comprises one or more lipids selected from the group consisting of PC (36:3), PC (34:6), PC (32:0), FA (14:0), FA (15:0), FA (18:0), LysoPA (18:3), TAG (50:0), TAG (46:4), and TAG (52:2),

- the sample comprises a bodily fluid or treatment thereof, wherein the bodily fluid is saliva, blood, blood plasma, blood serum, urine, or nipple aspirate fluid, and

- the at least one cancer type is lung cancer or breast cancer.

Annex VIII: JP6092302 Claims

ULRF 10090-09 (JP2)
35783.04058

ALLOWED CLAIMS FOR JP DIVISIONAL - JANUARY 2017

1. A method of using lipids amounts of lipids in a lipid set as an indicative for the presence or absence of at least one cancer type in an animal comprising

- determining lipids amounts of lipids in a lipid set in a sample from the animal, and the lipids amounts are analyzed with a predictive model and the analyzed results indicate the presence or absence of at least one cancer type in the animal

wherein

- the animal is human,
- the lipid amounts of lipids in the lipid set comprise an input of the predictive model,
- the lipid set comprises no more than 200 lipids,
- the lipid set comprises one or more lipids selected from the group consisting of PC (32:1), PC (34:4), PC (38:3), and PC (40:5),
- the at least one cancer type is breast cancer or lung cancer, and
- the sample comprises a bodily fluid or treatment thereof, wherein the bodily fluid is blood, plasma, or blood serum.

2. The method of claim 1, wherein the bodily fluid is blood or plasma.

3. The method of claim 1, wherein the bodily fluid is blood.

4. The method of claim 1, wherein the sample comprises a lipid microvesicle fraction or an exosomal fraction.

5. The method of claim 1, wherein the lipid set comprises at least 10 lipids and no more than 200 lipids.

6. The method of claim 1, wherein the lipid set comprises at least 50 lipids and no more than 200 lipids.

7. The method of claim 1, wherein the lipid set comprises at least 100 lipids and no more than 200 lipids.

8. The method of claim 1, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids selected from the group consisting of BMP, CE, Cer, DAG, DH-LTB4, FA, GA2, GM3, HexCer, HexDHCer, LacCer, LysoPA, LysoPC, LysoPC-pmg, LysoPE, LysoPE-pmg, LysoPS, MAG, PC, PC-pmg, PE, PE-pmg, PGA1, PGB1, SM, Sphingosine, TAG, and TH-12-keto-LTB4.

9. The method of claim 1, wherein the lipid set further comprises one or more additional lipids selected from the one or more classes of lipids selected from the group consisting of FA, CE, PC, and LysoPC.

10. The method of claim 1, wherein the lipid set further comprises one or more additional lipids selected from the one or more sets of lipids selected from the group consisting of (a) the set of CE lipids with an acyl chain length of 10-26 carbons and 0-6 double bonds in the acyl chain, (b) the set of LysoPC lipids with an even number of carbons in the acyl chain of 10-26 carbons and 0-6 double bonds in the acyl chain, and (c) the set of PC lipids with an even number of carbons in the acyl chain of 28-44 carbons and 0-12 double bonds in the acyl chain.

11. The method of claim 1, wherein one or more lipids in the lipid set are further selected from the group consisting of BMP (30:1), BMP (32:1), BMP (34:1), BMP (35:4), BMP (36:3), BMP

(37:1), BMP (37:7), BMP (38:1), BMP (38:2), BMP (38:4), BMP (39:1), BMP (39:4), BMP (40:1), BMP (40:2), BMP (40:3), BMP (40:4), BMP (40:7), BMP (42:10), BMP (42:2), BMP (42:5), BMP (44:8), CE (16:2), CE (18:2), CE (18:3), CE (18:4), CE (20:2), CE (20:4), CE (20:5), Cer (32:1), Cer (34:1), Cer (36:1), Cer (38:1), Cer (38:4), Cer (40:2), Cer (40:4), DAG (28:0), DAG (32:0), DAG (32:2), DAG (34:0), DAG (34:3), DAG (34:5), DAG (36:0), DAG (36:1), DAG (36:2), DAG (36:3), DAG (36:8), DAG (38:1), DAG (38:10), DAG (38:2), DAG (38:3), DAG (38:5), DAG (40:1), DAG (40:2), DAG (40:5), DH-LTB4 (20:3), FA (16:3), FA (19:1), GA2 (30:0), GA2 (33:2), GA2 (35:2), GA2 (37:2), GM3 (41:1), HexCer (32:1), HexDHCer (34:0), LacCer (30:0), LacCer (30:1), LacCer (32:2), LysoPA (16:2), LysoPA (16:3), LysoPA (18:1), LysoPA (22:0), LysoPA (22:1), LysoPC (16:0), LysoPC (18:0), LysoPC (18:1), LysoPC (18:4), LysoPC (20:4), LysoPC (20:5), LysoPC (26:6), LysoPC-pmg (12:0), LysoPC-pmg (18:3), LysoPC-pmg (24:4), LysoPC-pmg (26:0), LysoPE (10:1), LysoPE (16:2), LysoPE (18:2), LysoPE-pmg (18:4), LysoPS (24:1), MAG (18:0), MAG (20:3), MAG (24:2), PC (32:0), PC (34:1), PC (34:1), PC (34:2), PC (34:3), PC (34:6), PC (36:1), PC (36:2), PC (36:3), PC (36:4), PC (36:5), PC (36:6), PC (36:9), PC (38:2), PC (38:4), PC (38:5), PC (38:6), PC (38:7), PC (38:8), PC (38:9), PC (40:6), PC (40:7), PC (40:8), PC (40:9), PC (44:12), PC-pmg (30:1), PC-pmg (36:4), PC-pmg (38:5), PC-pmg (38:7), PC-pmg (40:11), PC-pmg (42:1), PE (34:7), PE (36:5), PE (36:7), PE (38:2), PE (38:3), PE (38:4), PE (38:5), PE (38:7), PE (40:4), PE (40:9), PE (42:12), PE (44:11), PE-pmg (28:2), PE-pmg (30:3), PE-pmg (34:6), PE-pmg (34:8), PE-pmg (36:5), PE-pmg (36:6), PE-pmg (40:7), PE-pmg (40:8), PE-pmg (42:10), PE-pmg (42:12), PE-pmg (42:4), PE-pmg (42:7), PE-pmg (42:8), PE-pmg (42:9), PE-pmg (44:10), PE-pmg (44:11), PE-pmg (44:12), PE-pmg (44:7), PE-pmg (44:8), PE-pmg (44:9), PGA1 (20:1), PGB1 (20:1), SM (34:1), SM (34:2), SM (36:1), SM (38:1), SM (40:1), SM (40:2), SM (42:1), SM (42:2), SM (42:3), Sphingosine (18:0), TAG (44:1), TAG (44:3), TAG (46:0), TAG (46:1), TAG (46:2), TAG (46:3), TAG (46:4), TAG (48:0), TAG (48:1), TAG (48:2), TAG (48:3), TAG (48:4), TAG (48:5), TAG (49:1), TAG (49:2), TAG (49:3), TAG (50:0), TAG (50:1), TAG (50:2), TAG (50:3), TAG (50:4), TAG (50:5), TAG (50:6), TAG (51:2), TAG (51:4), TAG (52:2), TAG

(52:3), TAG (52:4), TAG (52:5), TAG (52:6), TAG (52:7), TAG (53:4), TAG (54:2), TAG (54:3), TAG (54:4), TAG (54:5), TAG (54:6), TAG (54:7), TAG (54:8), TAG (55:5), TAG (55:6), TAG (55:7), TAG (56:4), TAG (56:5), TAG (56:6), TAG (56:7), TAG (56:8), TAG (56:9), TAG (58:10), TAG (58:6), TAG (58:8), TAG (58:9), TAG (60:12), and TH-12-keto-LTB4(20:2).

12. The method of claim 1, wherein one or more lipids in the lipid set are further selected from the group consisting of PC (40:3), PC (44:11), LysoPC (18:3), LysoPC (20:2), LysoPC (20:1), LysoPC (20:0) CE (19:1), CE (19:0), and CE (20:0).

13. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:0), PE-pmg (42:9), FA (16:3), FA (19:1), CE (18:2), Cer (36:1), Cer (38:4), PC (38:5), Cer (38:1), and TAG (44:3).

14. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), Cer (36:1), PC (40:7), TAG (54:5), TAG (54:6), CE (18:2), PC (36:4), FA (16:3), PE-pmg (44:11), TAG (52:5), Cer (40:4), CE (20:5), PC (38:6), TAG (50:2), MAG (18:0), FA (19:1), TAG (52:2), LysoPA (22:1), MAG (24:2), TAG (54:7), TAG (50:3), TAG (50:1), DAG (36:3), PC (34:1), TAG (52:6), BMP (30:1), PE-pmg (44:12), CE (20:4), BMP (40:3), PE (44:11), PC (40:8), TAG (56:9), PE-pmg (34:6), PE (36:7), PE (36:5), TAG (56:7), TAG (56:8), DAG (34:3), TAG (56:6), BMP (42:10), TAG (52:3), BMP (39:4), BMP (36:3), TAG (54:3), TAG (56:5), TAG (54:8), PC (34:6), PC (40:6), DAG (36:0), LysoPE (10:1), DAG (40:5), Cer (32:1), TAG (50:5), TAG (50:4), PE-pmg (36:6), BMP (42:5), TAG (46:3), and PE (38:5).

15. The method of claim 1, wherein the at least one cancer type comprises lung cancer and one or more lipids in the lipid set are further selected from the group consisting of TAG (44:3), PC (36:5), PC (38:5), Cer (38:4), PE-pmg (42:9), PC (38:7), LysoPA (22:0), Cer (38:1), Cer (34:1), and Cer (36:1).

16. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PE-pmg (42:9), CE (20:5), TAG (52:3), LysoPA (22:0), PC (36:3), PC (36:4), PC (36:2), PC (34:2), and PC (34:1).

17. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), CE (20:5), Cer (36:1), CE (18:2), DAG (34:0), SM (34:1), DAG (32:0), PE-pmg (40:8), DAG (36:0), PC (36:1), TAG (54:5), TAG (54:6), PE-pmg (44:11), PE-pmg (42:8), TAG (52:2), SM (42:2), PC (38:6), TAG (54:7), PC (40:6), PC (40:7), LysoPC (16:0), FA (16:3), TAG (52:5), TAG (44:3), BMP (38:2), BMP (30:1), SM (40:1), PE-pmg (42:10), BMP (40:2), PE-pmg (40:7), SM (36:1), PE (38:2), PC (34:3), PC (36:5), PC (32:0), BMP (37:1), BMP (40:3), PC (36:9), SM (42:3), PC-pmg (36:4), PC-pmg (38:5), PC (40:9), TAG (54:3), PE-pmg (44:12), BMP (36:3), FA (19:1), BMP (39:1), TAG (50:3), BMP (42:10), PC (34:6), GA2 (35:2), TAG (58:9), PE-pmg (42:7), and LysoPC (18:0).

18. The method of claim 1, wherein the at least one cancer type comprises breast cancer and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (34:1), PC (36:2), PC (36:4), PC (36:3), PC (38:4), LysoPA (22:1), PE-pmg (42:9), LysoPA (22:0), and CE (20:5).

19. The method of claim 1, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of LysoPA (22:1), PC (36:5), TAG (52:3), PC (38:5), CE (20:5), TAG (50:2), BMP (39:1), PC (34:2), CE (18:2), and PC (34:1).

20. The method of claim 1, wherein the at least one cancer type comprises lung cancer and breast cancer, and one or more lipids in the lipid set are further selected from the group consisting of PC (34:2), PC (36:2), TAG (44:3), CE (18:2), PC (34:1), LysoPA (22:1), PC (36:5), Cer (36:1), CE (20:5), PC (36:3), PC (38:4), PC (36:4), Cer (38:4), PC (38:5), PC (38:7), Cer (38:1), TAG (50:2), Cer (34:1), SM (34:1), Cer (40:4), MAG (18:0), MAG (24:2), PE-pmg (40:8), PE-pmg (42:8), TAG (50:1), DAG (32:0), PC (36:1), DAG (34:0), LysoPC (16:0), PE-pmg (34:6), DAG (36:3), PC (36:9), PE (36:5), TAG (52:6), FA (19:1), PE-pmg (44:11), BMP (38:2), PE (44:11), TAG (48:2), SM (42:2), BMP (40:2), PE-pmg (42:10), PE (36:7), PE-pmg (40:7), BMP (39:1), BMP (37:1), PE-pmg (36:6), PE (38:5), PC (32:0), PE (38:2), GA2 (35:2), DAG (34:3), PE-pmg (44:12), MAG (16:0), LysoPE (10:1), SM (36:1), BMP (39:4), TAG (56:7), and PE-pmg (42:9).

21. The method of claim 1, wherein the at least one cancer type comprises lung cancer and breast cancer, and the lipid set further comprises one or more additional lipids selected from the one or more sets of lipids selected from the group consisting of (a) the set of CE lipids with an acyl chain length of 10-26 carbons and 0-6 double bonds in the acyl chain, (b) the set of LysoPC lipids with an even number of carbons in the acyl chain of 10-26 carbons and 0-6 double bonds in the acyl chain, and (c) the set of PC lipids with an even number of carbons in the acyl chain of 28-44 carbons and 0-12 double bonds in the acyl chain.

22. The method of claim 1, wherein the lipid amounts are determined using mass spectrometry.

23. The method of claim 1, wherein the lipid amounts are determined using a Fourier transform ion cyclotron resonance mass analyzer.

24. The method of claim 1, wherein the sample is a treatment of a bodily fluid.

25. The method of claim 1, wherein the sample is a treatment of a bodily fluid and the treatment comprises one or more extractions using one or more solutions comprising acetonitrile, water, chloroform, methanol, butylated hydroxytoluene, trichloroacetic acid, or combinations thereof.

26. The method of claim 1, wherein the predictive model comprises one or more dimension reduction methods.

27. The method of claim 1, wherein the predictive model comprises one or more methods selected from the group consisting of principal component analysis (PCA), soft independent modeling of class analogy (SIMCA), partial least squares discriminant analysis (PLS-DA), and orthogonal partial least squares discriminant analysis (OPLS-DA).

28. The method of claim 1, comprising determining the presence or absence of more than one cancer type.

Appendix C: Glossary

Appendix C: Glossary

In this document:

Term	Definition
AAS	means Australian Accounting Standards.
AASB	means Australian Accounting Standards Board.
Accuracy	means the ability of a diagnostic test to discriminate between the target condition and health.
Allotment Date	means the date the Company anticipates the Shares will be allotted and issued to Applicants.
Applicant	means a person or entity who submits an Application Form.
Application	means an application to subscribe for Shares under this Prospectus.
Application Form	means the application form attached to this Prospectus.
Application Money or **Application Monies**	means the money received by the Company under the Offer, being the Offer Price multiplied by the number of Shares applied for.
ASIC	means Australian Securities and Investments Commission.
ASX	means ASX Limited (ACN 008 624 691) or the securities exchange operated by it (as the case requires).
ASX Listing Rules	means the listing rules of the ASX.
ASX Recommendations	means the Corporate Governance Principles and Recommendations (4th Edition) developed by the ASX Corporate Governance Council.
ASX Settlement	means ASX Settlement Pty Ltd (ACN 008 504 532).
ASX Settlement Operating Rules	means the ASX Settlement Operating Rules, being the operating rules of the Settlement Facility for the purposes of the Corporations Act.
ATO	means the Australian Taxation Office.
AUD	means Australian dollars, the lawful currency of the Commonwealth of Australia.
Board or **Board of Directors**	means the board of directors of the Company.
BRCA	means breast cancer gene.
Broker Firm Offer	means the offer open to Australian resident retail investors and sophisticated investors who have received a firm allocation from their broker.
CAGR	means compound annual growth rate.
CHESS	means Clearing House Electronic Subregister System, operated by ASX Settlement.
CLIA	means Clinical Laboratory Improvement Amendments of 1988.
Closing Date	means the date on which the Offer closes, being 2 July 2021, or another date nominated by the Company in consultation with the Lead Manager.

Appendix C: Glossary continued

Term	Definition
Company or **BCAL**	means BCAL Diagnostics Limited (ACN 142 051 223).
Completion	means the completion of the Offer, being the date upon which commencement of official quotation of the Company's Shares begins on the ASX.
Constitution	means BCAL's constitution adopted on 5 February 2021.
Corporations Act	means the *Corporations Act 2001* (Cth), as in force from time to time.
COVID-19	means the COVID-19 pandemic.
Director	means a director of the Company and **Directors** means all of them.
DNA	means deoxyribonucleic acid.
Equity Incentive Plan	means the equity plan rules adopted by the Company on 31 May 2021.
EU	means the European Union.
EV	means extracellular vesicles.
Executive Director	means an executive director of the Company.
Existing Shareholders	means the holders of Shares before the date of this Prospectus.
FDA	means the Food and Drug Administration of the United States of America.
Former ESOP	means the BCAL Employee Share Option Plan 2019 adopted by resolution of Shareholders in December 2019.
HIN	means the holder identification number issued by ASX.
IDC	means invasive ductal carcinoma.
Investigating Accountant's Report	means the report prepared by Pitcher Partners and provided at Section 8.
IP	means intellectual property.
IP Report	means the intellectual property report prepared by Shelston IP and provided at Appendix B.
IVD	means *in vitro* diagnostic.
LDT	means laboratory developed test.
Lead Manager or **PAC Partners**	means PAC Partners Securities Pty Ltd (ACN 623 653 912).
Lead Manager Securities	has the meaning given in Section 6.5.
License Agreement	means the agreement between BCAL and ULRF entered into in 2013, as amended from time to time.

Term	Definition
Mills Oakley	means Mills Oakley (ABN 51 493 069 734).
Minimum Subscription Amount	means $8,000,000.
MRI	means magnetic resonance imaging.
Non-Executive Director	means a non-executive director of the Company.
NSW	means the state of New South Wales, Australia.
Offer	means the offer of Shares under this Prospectus, as described in Section 7.
Offer Period	means the period expected to be from 14 June 2021 to 2 July 2021 during which investors may subscribe for Shares under the Offer.
Offer Price	means $0.25 per Share.
Official List	means the official list of ASX.
Official Quotation	means official quotation of securities by ASX.
Officer	means an officer of the Company, within the meaning of the Corporations Act, and **Officers** means all of them.
Opening Date	means the date that the Offer opens, being 14 June 2021.
Oversubscription	means the ability of the Company to accept subscriptions over 32,000,000 Shares, up to an additional 16,000,000 Shares.
Pitcher Partners or **Investigating Accountant**	means Pitcher Partners Sydney Corporate Finance Pty Limited (ACN 122 561 184).
Pitcher Partners Sydney Partnership or **Independent Auditor**	means Pitcher Partners Sydney (ABN 17 795 780 962).
PMA	means pre-market approval application to FDA.
Prospectus	means this prospectus.
Prospectus Date	means 4 June 2021.
RNA	means ribonucleic acid.
Scientific Advisory Board	means the scientific advisory board appointed by the Board from time to time.
sensitivity	means the ability of a diagnostic test to correctly identify those with the disease (true positive rate).
Settlement Facility	has the meaning specified in the ASX Settlement Operating Rules.

Appendix C: Glossary continued

Term	Definition
Share Registry or **Automic**	means Automic Pty Ltd (ACN 152 260 814).
Shareholders	means holders of shares in BCAL.
Shares	means fully paid ordinary shares in BCAL.
Shelston IP	means Shelston IP Pty Ltd (ACN 608 104 070), Patent and Trade Mark Attorneys, and Shelston IP Lawyers Pty Ltd (ACN 607 899 758).
specificity	means the ability of a diagnostic test to correctly identify those without the disease (true negative rate).
SRN	means the securityholder reference number in relation to an issuer sponsored holding.
TGA	means the Australian Therapeutic Goods Administration.
ULRF	means the University of Louisville Research Foundation.
USA	means the United States of America.
US Securities Act	means the US Securities Act of 1933, as amended.
US$	means the lawful currency of the USA.
You	means the investors under this prospectus.

Corporate directory

Company

Suite 506, Level 5
50 Clarence Street
Sydney NSW 2000
www.bcaldiagnostics.com

Officeholders

Directors:

Jayne Shaw
Ron Phillips AO
Jonathan Trollip
Merilyn Sleigh
Mark Burrows

Company Secretary:

Guy Robertson

Share Registry

Automic Pty Ltd

Deutsche Bank Tower
Level 5
126 Phillip Street
Sydney NSW 2000

Registered Office

Suite 506, Level 5
50 Clarence Street
Sydney NSW 2000

Lead Manager

PAC Partners Securities Pty Ltd

Level 10
330 Collins Street
Melbourne VIC 3000
www.pacpartners.com.au

Legal Adviser

Mills Oakley

Level 7
151 Clarence Street
Sydney NSW 2000
www.millsoakley.com.au

Investigating Accountant

Pitcher Partners Sydney Corporate Finance Pty Limited

Level 16, Tower 2, Darling Park
201 Sussex Street
Sydney NSW 2000
www.pitcher.com.au

IP Lawyers

Shelston Intellectual Property

Level 9
60 Margaret Street
Sydney NSW 2000
www.shelstonip.com


BCAL diagnostics
Breast cancer blood screening. For every woman, everywhere.