

For personal use only



Cleo Diagnostics Ltd
ACN 655 717 169

PROSPECTUS

For an offer of up to 60,000,000 Shares at an issue price of \$0.20 each to raise up to \$12,000,000 (before costs).

This Prospectus also includes the Conversion Offer and the Lead Manager Offer detailed in Sections 1.1(b) and 1.1(c), respectively.

ASX Code

COV

IMPORTANT NOTICES

This is an important document and requires your immediate attention. It should be read in its entirety. Please consult your professional adviser(s) if you have any questions about this Prospectus. The Securities offered pursuant to this Prospectus should be considered as speculative.



Table of contents

Important information	2
Corporate directory	7
Letter from the Chair	8
Key details of the Offers	10
Indicative timetable	11
Investment overview	12
1. Details of the Offers	27
2. Company overview	41
3. Industry overview	58
4. Risk factors	65
5. Financial information	73
6. Board, management and corporate governance	85
7. Material contracts	100
8. Additional information	106
9. Authorisation	120
10. Glossary of terms	121
Annexure A – Intellectual Property Report	125
Annexure B – Independent Limited Assurance Report	126



For personal use only

Important information

The Offers

This Replacement Prospectus is issued by Cleo Diagnostics Ltd (ACN 655 717 169) (**Company**) for the purpose of Chapter 6D of the *Corporations Act 2001* (Cth) (**Corporations Act**). The Offers in this Prospectus comprise: (i) an initial public offering of up to 60,000,000 Shares at an issue price of \$0.20 each to raise up to \$12,000,000 (before costs) (**Public Offer**); (ii) a separate offer to the Noteholders (or their respective nominees) comprising the issue of up to 16,000,000 Conversion Shares (**Conversion Offer**); and (iii) a separate offer to the Lead Manager (or its nominees) of up to 5,000,000 Options as part consideration for the provision of lead manager and bookrunner services provided to the Company (**Lead Manager Offer**).

Lodgement and listing

This Replacement Prospectus is dated and was lodged with the Australian Securities and Investments Commission (**ASIC**) on 6 July 2023 (**Prospectus Date**). This Replacement Prospectus replaces the Original Prospectus dated 23 June 2023 (**Original Prospectus Date**) that was issued by the Company and lodged with ASIC on that date. Neither ASIC nor ASX (or their respective officers) take any responsibility for the contents of this Prospectus or the merits of the investment to which this Prospectus relates.

For the purposes of this document this Replacement Prospectus will be referred to as either the "Replacement Prospectus" or the "Prospectus". ASIC, ASX and their respective officers do not take any responsibility for the contents of this Replacement Prospectus or the merits of the investment to which this Replacement Prospectus relates.

This Replacement Prospectus has been issued to provide further disclosure in respect of:

- the ownership of the intellectual property underpinning the Tests;
- the Company's business model and, in particular, the software program for the ELISA kit;
- the underlying sources in respect to key medical statements and statistics;
- the Seed Raising Convertible Note Agreement with Dr Andrew Stephens (Chief Scientific Officer and Executive Director);

- the risk to investors if the Hudson Licence Agreement is terminated;
- the relevance of the Research Services Agreement to the Company's operations following Admission;
- to include Professor Tom Jobling's consent to be named as a supporter of the Licenced Technology; and
- Figure 3, Figure 9 and Figure 10.

Application was made to ASX within seven days of the Original Prospectus Date for Official Quotation of the Shares the subject of the Public Offer.

Expiry Date

This Prospectus expires on the date which is 13 months after the Original Prospectus Date (**Expiry Date**). No Securities will be issued on the basis of this Prospectus after the Expiry Date.

Not investment advice

The information in this Prospectus is not investment or financial product advice and does not take into account your investment objectives, financial situation or particular needs. It is important that you read this Prospectus carefully and in its entirety before deciding whether to invest in the Company.

In particular, you should consider the risk factors that could affect the performance of the Company. 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 or other professional adviser before deciding whether to invest in the Company. See Section 4 for the key risks relating to an investment in the Company, noting there may be other risks relevant to your personal circumstances.

Except as required by law, and only to the extent required, no person named in this Prospectus, nor any other person, warrants or guarantees the performance of the Company, the repayment of capital by the Company or any return on investment in Securities made pursuant to this Prospectus.

No person is authorised to give any information or to make any representation in connection with the Offers, 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 Offers.



Taylor Collison Limited (ACN 008 172 450) (the **Lead Manager**), has acted as the Lead Manager to the Public Offer. To the maximum extent permitted by law, the Lead Manager and its affiliates, officers, employees and advisers expressly disclaim all liabilities in respect of, make no representations regarding, and take no responsibility for, any part of this Prospectus other than references to their name and make no representation or warranty as to the currency, accuracy, reliability or completeness of this Prospectus.

The Company, the Share Registry and the Lead Manager disclaim all liability, whether in negligence or otherwise, to persons who trade Shares before receiving their holding statement.

Exposure Period

The Corporations Act prohibits the Company from processing Applications in the seven day period after the Original Prospectus Date (**Exposure Period**). The Exposure Period may be extended by ASIC by up to a further seven days. The purpose of the Exposure Period is to enable this Prospectus to be examined by market participants prior to the raising of funds. You should be aware that this examination may result in the identification of deficiencies in this Prospectus. In such circumstances, any Application that has been received may need to be dealt with in accordance with section 724 of the Corporations Act. Applications under this Prospectus will not be processed by the Company until after the Exposure Period. No preference will be conferred upon Applications received during the Exposure Period.

No cooling-off rights

Cooling-off rights do not apply to an investment in the Securities issued under this Prospectus. This means that, in most circumstances, you cannot withdraw your Application once it has been accepted.

Conditional Offers

The Offers contained in this Prospectus are conditional on certain events occurring. If these events do not occur, the Offers will not proceed and Applicants will be refunded their Application Monies (without interest). See Section 1.3 for further details on the conditions attaching to the Offers.

Target Market Determination

In accordance with the design and distribution obligations under the Corporations Act, the Company has determined the target market for the offer of the Lead Manager Options issued under this Prospectus. The Company and the Lead Manager will only make available the Lead Manager Offer to those investors who fall within the target market

determination (**TMD**) as set out on the Company's website (www.cleodx.com). By making an application under the Lead Manager Offer, you warrant that you have read and understood the TMD and that you fall within the target market set out in the TMD.

Electronic Prospectus and Application Forms

During the Exposure Period, an electronic version of this Prospectus (without an Application Form) will be available at www.cleodx.com. Application Forms will not be made available until after the Exposure Period has expired.

Any person accessing the electronic version of this Prospectus for the purpose of making an investment in the Company must be resident in Australia and must only access this Prospectus from within Australia.

The Prospectus is not available to persons in other jurisdictions in which it may not be lawful to make such an invitation or offer to apply for Securities. If you access the electronic version of this Prospectus, you should ensure that you download and read the Prospectus in its entirety.

Persons having received a copy of this Prospectus in its electronic form may obtain an additional paper copy of this Prospectus and the Application Form (free of charge) from the Company (see the Corporate Directory for contact details).

Applications will only be accepted on the Application Form attached to, or accompanying, this Prospectus. The Corporations Act prohibits any person from passing on to another person the Application Form unless it is attached to a paper copy of the Prospectus or the complete and unaltered electronic version of this Prospectus.

Prospective investors wishing to subscribe for Securities under the Offers should complete the relevant Application Form. If you do not provide the information required on the Application Form, the Company may not be able to accept or process your Application.

Foreign jurisdictions

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

No action has been taken to register or qualify the Securities the subject of this Prospectus or the Offers, or otherwise to permit the offering of the Securities, in any jurisdiction outside Australia.



Subject to the provisions outlined in Section 1.16, certain investors in New Zealand, Hong Kong and Singapore are eligible to participate in the Public Offer.

The distribution of this Prospectus in jurisdictions outside of Australia (including electronically) may be restricted by law and persons who come into possession of this Prospectus outside of Australia should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

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 Securities 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:

1. is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
2. meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
3. is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
4. is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
5. is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

Hong Kong

WARNING: This document 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**). Accordingly, this document may not be distributed, and the Securities may 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 Securities 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

Securities that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares 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 document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offers. If you are in doubt about any contents of this document, you should obtain independent professional advice.

Singapore

This document and any other materials relating to the Securities have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of Securities, 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 13 of the Securities and Futures Act 2001 of Singapore (the **SFA**) or another exemption under the SFA.

This document has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, 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 Securities being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire Securities. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

Taxation

The acquisition and disposal of Securities under the Offers will have tax consequences, which will differ depending on the individual financial affairs of each investor. All potential investors in the Company are urged to obtain independent financial advice about the consequences of acquiring Securities from a taxation viewpoint and generally.

The Company does not propose to give any taxation advice and, to the maximum extent



permitted by law, the Company, its Directors and other officers and each of their respective advisers accept no responsibility or liability for any taxation consequences of subscribing for Securities under this Prospectus. You should consult your own professional tax advisers in regard to tax implications of the Offers.

Past performance

This Prospectus includes information regarding the past performance of the Company. Investors should be aware that past performance should not be relied upon as being indicative of future performance.

Forward-looking statements

This Prospectus contains forward-looking statements which are identified by words such as 'believes', 'estimates', 'expects', 'targets', 'intends', 'may', 'will', 'would', 'could', or 'should' and other similar words that involve risks and uncertainties.

These statements are based on an assessment of present economic and operating conditions, and on a number of assumptions regarding future events and actions that, as at the Prospectus Date, are expected to take place.

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

Any forward-looking statements are subject to various risks that could cause the Company's actual results to differ materially from the results expressed or anticipated in these statements. Forward-looking statements should be read in conjunction with, and are qualified by reference to, the risk factors as set out in Section 4. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of the Company, the Directors and the Company's management.

The Company, the Directors, the Company's management and the Lead Manager cannot and do not give assurances that the results, performance or achievements expressed or implied in the forward-looking statements contained in this Prospectus will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.

Financial information presentation

Historical financial information, including the pro forma financial information, has been prepared and presented in accordance with the recognition and measurement principles prescribed by the Australian Accounting Standards (as adopted by the Australian Accounting Standards Board (**AASB**)). The historical financial information also complies with the Australian equivalents to the recognition and measurement principles of the International Financial Reporting Standards and interpretations adopted by the International Accounting Standards Board.

Company website

Any references to documents included on the Company's website are for convenience only, and none of the documents or other information available on the Company's website is incorporated into this Prospectus by reference.

Third party statements

This Prospectus includes attributed statements from books, journals and comparable publications that are not specific to, and have no connection with the Company. 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 such consent having been obtained.

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 shown endorses this Prospectus or its contents or that the assets shown in them are owned by the Company. Diagrams used in this Prospectus are illustrative only and may not be drawn to scale.

Disclaimer

Except as required by law, and only to the extent so required, none of the Company, the Directors, the Company's management, the Lead Manager or any other person warrants or guarantees the future performance of the Company, or any return on any investment made pursuant to this Prospectus.

Currency

All financial amounts contained in this Prospectus are expressed in Australian dollars unless otherwise stated. Any discrepancies between totals and sums and components in tables, figures and diagrams contained in this Prospectus are due to rounding.



For personal use only

Time

All references to time in this Prospectus are references to AEST, being the time in Melbourne, Victoria, unless otherwise stated.

Governing law

The Prospectus and the contracts that arise from the acceptance of the Applications under this Prospectus are governed by the law applicable in Victoria and each Applicant submits to the exclusive jurisdiction of the courts of Victoria.

Defined terms and interpretation

Defined terms and abbreviations used in this Prospectus are detailed in the glossary in Section 10.

For personal use only



Corporate directory

Directors

Adrien Wing	Chair and Non-Executive Director
Dr Richard Allman	Chief Executive Officer and Executive Director
Dr Andrew Stephens	Chief Scientific Officer and Executive Director
Professor Tom Jobling	Non-Executive Director and Lead Medical Advisor
Lucinda Nolan	Non-Executive Director

Company Secretary

Pauline Moffatt

Registered and Principal Office

Level 2, 480 Collins Street
Melbourne Victoria 3000

Phone: +61 3 9614 0600
Email: office@cleodx.com
Website: www.cleodx.com

Share Registry*

XCEND Pty Ltd
C/- Level 2, 145 William Street
Darlinghurst NSW 2010
Phone (within Australia): (02) 7208 8033
Phone (outside Australia): +61 (2) 7208 8033
Website: <https://www.xcend.co/>

Corporate Lawyers

Hamilton Locke Pty Ltd
Level 48, 152-158 St Georges Terrace
Perth WA 6000

Lead Manager

Taylor Collison Limited
Level 16, 211 Victoria Square
Adelaide SA 5000

Auditor*

BDO Audit Pty Ltd
Level 18, 727 Collins Street
Melbourne VIC 3008

Investigating Accountant

BDO Corporate Finance (East Coast) Pty Ltd
Level 18, 727 Collins Street
Melbourne VIC 3008

Intellectual Property Expert

FB Rice Pty Ltd
Level 12/197 St Georges Terrace
Perth WA 6000

Proposed Stock Exchange Listing

Australian Securities Exchange (**ASX**)
Proposed ASX Code: COV

* These entities are included for information purposes only. They have not been involved in the preparation of this Prospectus.



Letter from the Chair

Dear Investors

On behalf of the Directors, I am pleased to present you with this opportunity to become a shareholder of Cleo Diagnostics Limited (**Cleo** or the **Company**). Cleo is bringing to market a simple blood test which aims to accurately detect early stages of ovarian cancer.

Why is this important? Ovarian cancer is the most lethal gynaecological cancer affecting women. Currently, the five-year survival rate after a diagnosis of ovarian cancer is 50.8% - that's half of all women that are diagnosed will die within 5 years.¹ Current treatment involves expensive, invasive surgery and intensive chemotherapy – each with their own risk of complications.

There is no accurate, pre-surgical method to diagnose ovarian cancer, or to accurately differentiate between cancerous versus much more common non-cancerous (benign) disease.

This is simply not good enough. If accurately detected early, 94% of patients live longer than 5 years after diagnosis.² When it comes to other female cancers such as cervical and breast, where early detection testing is available, survivability rates are now at 74% and 92% respectively.³

Pursuant to a licence agreement with the Hudson Institute of Medical Research (refer to Section 7.1 of the Prospectus for further information), the Company has a worldwide exclusive licence to use, sub-licence, develop, modify and commercialise the intellectual property which underpins its operations and the ovarian cancer Tests.

The novel patented ovarian cancer blood test licenced by Cleo from Hudson measures the CXCL10 biomarker, produced early and at high levels by ovarian cancers but not in non-malignant disease. The Tests aim to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by diagnostic laboratories worldwide.

The Tests are backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted with over 500 patients, as well as in excess of \$5,000,000 funding from the National Health and Medical Research Council (**NHMRC**) and Ovarian Cancer Research Foundation (**OCRF**). Our licenced ovarian cancer Tests are strongly supported by Professor Tom Jobling OAM (OCRF Founder).

Cleo has:

- (a) licensed a blood test for the detection of ovarian cancer, with potential to substantially improve existing standard of care;
- (b) a strong body of supporting scientific evidence, developed over 10 years of research and development at Hudson Institute of Medical Research and two clinical studies;
- (c) IP protection in place and a global exclusive licence;
- (d) a staged execution strategy with a clear, achievable pathway to target markets; and
- (e) an experienced leadership team with credentials to execute.

The Company is seeking to raise up to \$12,000,000 (before costs) through the issue of up to 60,000,000 Shares at \$0.20 each to support the Licenced Technology development activities. The proceeds from the Public Offer will be used to:

¹ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.

² <https://www.cancer.org/content/dam/CRC/PDF/Public/8775.00.pdf>. The author has not provided their consent for the statement to be included in this Prospectus.

³ <https://pubmed.ncbi.nlm.nih.gov/11240691/>. [https://www.clinical-breast-cancer.com/article/S1526-8209\(18\)30780-8/fulltext](https://www.clinical-breast-cancer.com/article/S1526-8209(18)30780-8/fulltext). The authors have not provided their consent for the statements to be included in this Prospectus.



- For personal use only
- (a) fund the test performance work and regulatory compliance work to achieve FDA compliance for the Triage Test (a pre-surgical test to determine the likelihood that a pre-surgical ovarian mass in a patient not yet referred to an oncologist, is malignant);
 - (b) fund further research and development for the Screening Test (a test to identify early-stage ovarian cancer in patients who do not present any symptoms consistent with ovarian cancer) and the Recurrence Test (a post-surgical test to identify whether a cancer is recurring following surgical removal and chemotherapy of cancerous tissue);
 - (c) fund the Company's general working capital requirements; and
 - (d) pay corporate and administration costs and the costs of the Offers.

It is estimated that by 2040, the number of women around the world diagnosed with ovarian cancer will rise almost 42% to 445,721 each year.⁴ The number of women dying from ovarian cancer each year is further projected to reach 313,617 an increase of over 50% from 2020.⁵

The Directors believe the opportunity presented to address ovarian cancer is urgent and we cannot wait any longer to act on the unmet need to potentially save the lives of millions of women around the world. An accurate and early detection blood test could shift survivability for ovarian cancer significantly as seen with other cancers.

This Prospectus contains detailed information about the Offers and the current and proposed operations of the Company, as well as the risks pertaining to an investment in the Company. Potential investors in the Company should carefully consider those risks (see Section 4). Before deciding on whether to invest in the Company, you should read this Prospectus carefully and in its entirety and consult with your accountant, financial adviser, stockbroker, lawyer or other professional adviser.

We look forward to welcoming you as a Shareholder should you decide to take up Shares pursuant to the Public Offer.

Yours faithfully



Adrien Wing
Non-Executive Chair
Cleo Diagnostics Ltd

⁴ <https://worldovariancancercoalition.org/about-ovarian-cancer/key-stats/>. The author has not provided their consent for the statement to be included in this Prospectus.

⁵ <https://worldovariancancercoalition.org/about-ovarian-cancer/key-stats/>. The author has not provided their consent for the statement to be included in this Prospectus.

Key details of the Offers

	Shares	Options	Convertible Notes
Securities on issue prior to Admission			
Securities on issue at Prospectus Date ¹	45,000,001	Nil	16,000,000
Securities on issue at Admission			
Hudson Consideration Shares ²	7,500,000	Nil	Nil
Public Offer Shares	60,000,000	Nil	Nil
Conversion Shares ³	16,000,000	Nil	Nil
Lead Manager Options ⁴	Nil	5,000,000	Nil
Advisor Options ⁵	Nil	1,500,000	Nil
Director and employee Options ⁶	Nil	7,500,000	Nil
Total on Admission⁷	128,500,001	14,000,000	Nil
Indicative market capitalisation⁸	~\$25.7 million		

Notes:

- Comprising:
 - 1 Share issued upon incorporation of the Company;
 - 45,000,000 Shares issued on conversion of convertible notes issued to founders of the Company; and
 - 16,000,000 Seed Raising Convertible Notes convertible to an equivalent number of Shares in accordance with the Seed Raising Convertible Note Agreements summarised in Section 7.4. The Seed Raising Convertible Notes are expected to convert on the business day immediately prior to Admission.
- Consideration to be issued to Hudson in accordance with the Hudson Licence Agreement summarised in Section 7.1.
- Shares to be issued to the Noteholders (or their respective nominees) upon conversion of the Seed Raising Convertible Notes summarised in Section 7.4.
- Options to be issued in accordance with the Lead Manager Mandate summarised in Section 7.3. See Section 8.3 for the terms and conditions of the Lead Manager Options.
- Options to be issued to IRX Advisors (or its nominees) as consideration for the provision of investor relations and marketing services provided to the Company. See Section 8.3 for the terms and conditions of the Advisor Options.
- Options to be issued to Directors and employees of the Company (or their respective nominees) as part of their remuneration packages or as fees for services. See Section 8.2 for the terms and conditions of the Options.
- Assumes that the Seed Raising Convertible Notes are converted into Shares and that no further Securities are issued and no Options are converted into Shares.
- Based on the Offer Price multiplied by the number of Shares on issue on Admission. There is no guarantee that the Shares will trade at the Offer Price on or after Admission.



For personal use only

Indicative timetable

Event	Date
Lodgement of Prospectus with ASIC	6 July 2023
Opening Date of Offers	8 July 2023
Closing Date of Offers	4 August 2023
Settlement date of the Offers	11 August 2023
Issue of Securities under the Offers	17 August 2023
Despatch of holding statements for Securities issued under the Offers	
Expected date for Official Quotation	18 August 2023

Note: The dates shown in the table above are indicative only and may vary subject to the Corporations Act, the Listing Rules and other applicable laws. The Company reserves the right to vary the dates and times of the Offers (including, to vary the Opening Date and Closing Date) to accept late Applications, either generally or in particular cases, or to cancel or withdraw the Offers before the allocation of Securities in each case without notifying any recipient of this Prospectus or any Applicants, which may have a consequential effect on other dates. If the Offers are cancelled or withdrawn before the allotment of Securities, then all Application Monies will be refunded in full (without interest) in accordance with the requirements of the Corporations Act. Applicants are encouraged to lodge their Application Form and deposit the Application Monies as soon as possible after the Opening Date if they wish to invest in the Company. The Company's Admission and commencement of Official Quotation of its Securities are subject to confirmation from ASX.



For personal use only

Investment overview

This investment overview is not intended to provide full information for investors intending to apply for Securities offered pursuant to this Prospectus. This Prospectus should be read and considered in its entirety. The Securities offered pursuant to this Prospectus carry no guarantee in respect of return of capital, return on investment, payment of dividends or the future value of the Securities.

Topic	Summary	More information
The Company, its business model and strategy		
Who is the issuer of the Prospectus?	Cleo Diagnostics Ltd (ACN 655 717 169) (Cleo or the Company).	Section 2.1
Who is the Company and what does it do?	<p>Cleo is a medical diagnostics/devices entity focussed on the development of non-invasive blood based IVD tests to detect the presence, and recurrence, of ovarian cancer.</p> <p>The Company has developed a three-phased product development strategy that will deliver three related tests for ovarian cancer detection:</p> <ul style="list-style-type: none"> (a) Triage Test – a pre-surgical test to determine the likelihood that a pre-surgical ovarian mass in a patient not yet referred to an oncologist, is malignant. (b) Recurrence Test – a post-surgical test to identify whether a cancer is recurring following surgical removal and chemotherapy of cancerous tissue. (c) Screening Test – a screening test to identify early-stage ovarian cancer in patients who do not present any symptoms consistent with ovarian cancer. <p>Each of the three tests are non-invasive and are performed using a sample of the patient’s blood. They are specifically designed to be low-cost and fit within existing pathology lab infrastructure.</p> <p>Upon Admission, the Company’s primary focus will be to bring the Triage Test to market which has to date produced strong results to accurately differentiate patients with malignant ovarian cancer from those with benign gynaecological conditions.</p>	Sections 2.1, 2.2 and 2.3
What is the Company’s business model, growth strategy and key objectives?	<p>The Licenced Technology development strategy is centred around three key pillars:</p> <ul style="list-style-type: none"> (a) <i>Detect effectively</i> - enhance the accuracy of ovarian cancer detection, particularly at early stages of development and thereby reduce the rate of false positives and false negatives; (b) <i>Detect earlier</i> – providing improved ability to identify and triage patients more effectively, and pave the way towards earlier diagnosis of malignancy with the aim of allowing earlier intervention in the treatment of patients with ovarian cancer; and (c) <i>Treat efficiently</i> - improve the referral process and better inform clinical decision-making workflows. 	Sections 2.3 and 3



For personal use only

Topic	Summary	More information
	<p>The Company has implemented a commercialisation strategy, which focuses on bringing the Triage Test to market as the Company's first product. The proposed strategy enables the Company to deliver a commercial product whilst ongoing development and regulatory activities for the Screening Test and the Recurrence Test remain on foot.</p> <p>The Triage Test is intended to take the form of an immunoassay. The antibodies, control proteins and the algorithm linking blood concentrations of the target biomarker proteins to an ovarian cancer risk score, are intended to form the key components of the three Tests.</p> <p>A summary of the key steps to achieve commercialisation of the Triage Test is detailed in Section 2.3(a)(iv).</p> <p>While the Company's immediate focus will be on the Tests, it may pursue and assess other new business opportunities in the biotechnology and medtech sectors over time which complement its business. These new business opportunities may take the form of direct or passive investments. At present, the Company is not pursuing any such acquisitions.</p>	
Where does the Company operate and what are its main business activities?	<p>The Company's main business activities, being medical diagnostics/devices development and commercialisation, will be conducted in Melbourne, Victoria.</p> <p>A summary of the Company's proposed activities following Admission is detailed in the following Sections:</p> <p>(a) Triage Test – see Section 2.3(a)(iii).</p> <p>(b) Recurrence Test – see Section 2.3(b)(iii).</p> <p>(c) Screening Test – see Section 2.3(c)(iii).</p> <p>The Company's intended use of funds following Admission is set out in Section 1.5. The use of funds is a statement of current intentions as at the Prospectus Date. Prospective investors should note that, as with any budget, the allocation of funds set out in the above table may change depending on a number of factors, including market conditions, the development of new opportunities and/or any number of other factors (including the risk factors outlined in Section 4), and actual expenditure levels, may differ significantly from the above estimates.</p> <p>The funds raised from the Offers, assuming the Minimum Subscription is raised, will provide the Company with sufficient working capital to carry out its stated objectives in this Prospectus for approximately the 24-month period following Admission.</p>	Section 2.3
How does the Company propose to achieve its objectives?	<p>The Company intends to achieve its objectives by executing a strategic plan covering, but not limited to:</p> <p>(a) the raising of sufficient capital to fund its stated objectives as set out in Sections 1.5 and 2. Investors should also refer to Section 4.1(a) regarding the Company's future capital requirements;</p>	Section 2.3



Topic	Summary	More information
	<p>(b) test evaluation to ensure that the Triage Test is robust, scalable, meets the performance expectations of patients, clinicians, and testing laboratories, as well as demonstrating safety and efficacy to the relevant regulatory bodies;</p> <p>(c) identification and execution of the regulatory testing required in the United States to achieve FDA compliance for the Triage Test;</p> <p>(d) maintenance and protection of the Licenced Technology;</p> <p>(e) the successful in-house development of protein reagents and monoclonal antibodies for each of the target biomarker proteins which is anticipated to reduce reliance on commercial assays;</p> <p>(f) successful registration with the FDA for clinical use of the Triage Test; and</p> <p>(g) subject to the satisfaction of the milestones in Section 2.3(a)(iv), creation of sales, distribution and marketing capabilities for the Triage Test to ensure entry into the proposed key geographic markets in the future.</p> <p>Although the Company's immediate focus will be on the Tests, the Company may pursue and assess other new business opportunities in the biotechnology and medtech sectors over time which complement its business. These new business opportunities may take the form of direct or passive investments. At present, the Company is not pursuing any such acquisitions.</p>	
<p>What are the key dependencies of the Company's business model?</p>	<p>The key dependencies of the Company's business model include (amongst others):</p> <p>(a) sufficient market awareness and industry adoption;</p> <p>(b) being able to continue to maintain the Hudson Licence Agreement and to maintain, protect and develop the Licenced Technology;</p> <p>(c) further product development to increase the functionality and performance of the Licenced Technology;</p> <p>(d) sufficient funding to ensure the Company is able to complete development;</p> <p>(e) future access to additional capital, should it be required to fund potential future growth;</p> <p>(f) the ability to continually protect and advance the Company's existing knowledge, licenced intellectual property rights and trade secrets; and</p> <p>(g) attracting and retaining key staff and personnel.</p>	<p>Section 2.7</p>
<p>How was the value of the consideration under the Hudson Licence Agreement determined?</p>	<p>In determining the consideration for the Hudson Licence Agreement, the Company did not undertake a formal valuation of the Licenced Technology, but took into account the following considerations:</p>	<p>Section 2.1</p>



Topic	Summary	More information
	<p>(a) the Company’s assessment of the costs incurred by Hudson in the development of the Licenced Technology;</p> <p>(b) the exclusivity and other material terms of the Hudson Licence Agreement, which are set out in Section 7.1;</p> <p>(c) the “at-risk” nature of the payments to be made to Hudson in the event that a regulatory approval is obtained in the US, Australia, Europe or Japan (see Section 7.1(e) for further information); and</p> <p>(d) the Company’s assessment of the future prospects of the Licenced Technology based on the level of development of the Licenced Technology and the ability of the Company to protect and potentially commercially exploit the underlying intellectual property.</p> <p>The Board is of the opinion that the opportunity presented under the Hudson Licence Agreements represents an opportunity that is in the best interests of current Shareholders of the Company and was involved in a negotiation process prior to executing the Hudson Licence Agreement.</p>	
<p>Will the Company require more capital?</p>	<p>The Company’s planned activities following Admission will initially be funded by the funds raised by the Offers, as further detailed in Section 1.5.</p> <p>However, the Directors anticipate the Company will in the future require additional capital to further its proposed business strategy. The amount and nature of any such additional funding will be determined based on market conditions and the needs of the business at the relevant time.</p>	<p>Section 1.5</p>
<p>Key risks</p>		
<p>Additional capital requirements</p>	<p>The Company has no operating revenue and is unlikely to generate any operating revenue unless and until the Triage Test is successfully developed and commercialised. The future capital requirements of the Company will depend on many factors including its business development activities. The Company believes its available cash and the net proceeds of the Public Offer should be adequate to fund its activities and objectives for the two-year period following Admission.</p> <p>The Company’s proposed activities following Admission involve significant financial risk and capital investment. The Company may never generate revenue or achieve profitability.</p> <p>The Company will require further financing in the future, in addition to amounts raised pursuant to the Public Offer. The Company also has an obligation to pay \$1,500,000 (excluding GST) to Hudson upon the satisfaction of the first regulatory approval of the Licenced Technology in the USA, Australia, Europe or Japan. The Company has not set aside funds for the payment of the \$1,500,000 in its current use of funds and may be required to raise capital through the issue of further Shares prior to paying the \$1,500,000, which will have a dilutionary impact on Shareholders. It is also possible further capital may be required at an earlier stage if any risks,</p>	<p>Section 4.1(a)</p>



Topic	Summary	More information
	<p>including those described in this Section 4 materialise. Any additional equity financing may be dilutive to Shareholders, may be undertaken at lower prices than the then market price (or Offer Price) or may involve restrictive covenants which limit the Company's operations and business strategy. Debt financing, if available, may involve restrictions on financing and operating activities or the registering of security interests over the Company's assets. Although the Directors believe that additional capital can be obtained, no assurances can be made that appropriate capital or funding, if and when needed, will be available on terms favourable to the Company or at all.</p> <p>The Company may undertake additional offerings of Securities in the future. The increase in the number of Shares issued and outstanding and the possibility of sales of such Shares may have a depressive effect on the price of Shares. In addition, as a result of the offering of such additional Shares, the voting power of the Company's existing Shareholders will be diluted.</p>	
Intellectual property risks	<p>The Company's success, in part, depends on its ability to obtain patents, maintain trade secret protection, and operate without infringing the intellectual proprietary rights of third parties. If patents are not granted, or granted only for limited claims, the Company's licenced intellectual property may not be adequately protected and may be able to be copied, reproduced or otherwise circumvented by third parties.</p> <p>There is no guarantee that the Company's licenced intellectual property comprises all the rights that the Company may require to commercialise its products. There can also be no assurance that any patents which the Company may own, access or control will afford the Company commercially significant protection of its Licenced Technology or its products.</p> <p>The Company's existing intellectual property includes the Company's licencing rights under the Hudson Licence Agreement (see Section 7.1 for further information). The Company has, under the Hudson Licence Agreement, acquired (amongst other things) the rights to various patent applications pending in a number of countries based on international (PCT) application no PCT/AU2020/051403. On 23 March 2023, the patent in Australia was granted (as patent number 2020404453). The patent in the United States is expected to be granted in the next three months.</p> <p>Patent applications are currently pending in China, Europe, Israel, India, Japan, Korea, New Zealand and Singapore. Refer to section 1.4.2 of the Intellectual Report at Annexure A for further details.</p> <p>Although the patent in Australia has been granted, investors should be aware that the granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid the Company's patented technology. Moreover, 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 also possible that a court may</p>	Section 4.1(b)



Topic	Summary	More information
	<p>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.</p> <p>There is a risk that the Company's licenced intellectual property rights, including its patents (granted and applications), may be challenged (or threatened to be) by a third party at any time. If any of the Company's licenced intellectual property rights are challenged, the Company would need to defend such claims, which is costly and may result in the Company incurring significant costs, management time and reputational damage, any of which would be adverse to the Company's financial performance.</p> <p>The Company is aware that in the US diagnostic methods generally are becoming increasingly difficult to patent. If the Company's US patent application is ultimately not granted by the United States Patent and Trademark Office (USPTO), although the Company's patent application would constitute prior art, competitors may seek to utilise the information contained in the Company's US patent application to develop competing products which could adversely impact the Company's ability to commercialise its products in the US or otherwise substantially dilute its market share.</p>	
Licencing risk	<p>Pursuant to the Hudson Licence Agreement, the Company has a worldwide exclusive licence to use, sub-licence, develop, modify and commercialise the Licenced Technology which underpins its operations, rather than having ownership of that intellectual property. Termination of the Hudson Licence Agreement would have an adverse effect on the operations and financial position of the Company.</p> <p>Hudson has a right to terminate the Hudson Licence Agreement if the Company commits a material breach, and that breach is not remedied within 30 days after notice to do so (see Section 7.1 for further details). If the Hudson Licence Agreement is terminated this will have a material adverse effect on the Company's operations, its ability to continue to commercialise the Tests and, in this regard, maintain a listing on ASX. The Company may pursue and assess other new business opportunities in the biotechnology and medtech sectors over time which complement its business. These new business opportunities may take the form of direct or passive investments. At present, the Company is not pursuing any such acquisitions.</p> <p>As at the Prospectus Date, the Directors confirm that the Company is not in breach of the Hudson Licence Agreement, and they are not aware of any facts or circumstances that may give Hudson a right to terminate the Hudson Licence Agreement.</p>	Section 4.1(c)
Intellectual property infringement	The Company has engaged FB Rice to develop and implement an intellectual property strategy to seek to establish patent protection in its proposed key markets as a means of enabling the Company to guard its exclusivity,	Section 4.1(d)



Topic	Summary	More information
	<p>maintain an advantage over competitors and provide it with a basis for enforcement in the event of infringement (or potential infringement) of the Company’s licenced intellectual property rights by third parties. Notwithstanding this strategy, there is always a risk of third parties claiming an involvement in medical discoveries and, if disputes arise, such claims or disputes can adversely affect the Company, its reputation and financial performance. Further, competition in retaining and sustaining protection of intellectual property, and the complex nature of intellectual property and its protection, can lead to expensive and lengthy disputes for which there can be no guaranteed outcome.</p> <p>In the event of a dispute, the Company’s potential competitors may potentially be able to sustain costs of litigation or proceedings more effectively than the Company because of comparatively greater financial resources. In addition, parties making claims against the Company may obtain injunctive or other relief to prevent the Company from further developing or commercialising its products. In the event a successful claim of infringement is made 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 such licences at a reasonable cost, or at all, it may encounter delays and lose substantial resources while seeking to develop alternative products.</p> <p>The Company is unable to state with certainty that another party will not claim (or threaten) its rights are infringed or, if litigation claiming that the Company is infringing the intellectual property rights of a third party is launched, what the result of any such litigation will be.</p> <p>The enforcement of intellectual property rights is dependent on a strong and impartial rule of law. In the event that intellectual property infringement occurs in a jurisdiction without a strong and impartial judicial system that recognises the Company’s licenced intellectual property rights, infringement of the Company’s licenced intellectual property may occur and the Company may be unable to successfully enforce its rights.</p>	
Development and uncertainty of research	<p>The development and commercialisation of medical diagnostic products is subject to an inherent and high risk of failure. The key steps in the Company’s development strategy for the Triage Test include:</p> <ul style="list-style-type: none"> (a) (antibody development): the successful in-house development of protein reagents and monoclonal antibodies for each of the target biomarker proteins which is anticipated to reduce reliance on commercial assays; (b) (test performance evaluation): test evaluation to ensure that the product is robust, scalable, meets the performance expectations of patients, clinicians, and testing laboratories, as well as demonstrating safety and efficacy to the relevant regulatory bodies; and 	Section 4.1(f)



Topic	Summary	More information
	<p>(c) (regulatory submissions): subject to the foregoing, the initial FDA 510(k) application and subsequent Australian and European regulatory approvals.</p> <p>The Company's efforts to develop in-house reagents for its Triage Test may be unsuccessful resulting in a reliance on commercially available reagents, which may increase supply and quality control risks. On the other hand, in-house reagents may have different performance characteristics from those commercially available reagents used in earlier clinical trials for the Triage Test, giving rise to additional research and development and the potential for greater than anticipated complexity, cost and delays in commercialisation of the Triage Test.</p> <p>Success in commercialisation of the Triage Test is dependent upon the satisfaction of the milestones set out in Section 2.3(a)(iv). Failure to achieve any one or more of these milestones could have an adverse effect on the Company's development activities and financial position.</p> <p>Related to the above, the Company is and will continue to be reliant on the results received from the research and development it undertakes on its Screening Test and Recurrence Test, including, for example, the results of clinical studies. While the Company is encouraged by trial results to date and will conduct or participate in future clinical trials on the advice of management and consultants with considerable industry experience, as it seeks to move to commercialisation of its Screening Test and Recurrence Test in the long term, those trials can be expensive, time consuming and involve potential delay. There is no certainty the results of those trials will demonstrate any material benefit or advancement in efficacy over existing alternatives or potential new products, and there is the potential for the product to be found to be ineffective or unsafe for public use. Further, the success of clinical trials may be impacted by the ability to recruit patients to participate, lack of product effectiveness in trials, compliance with ethics protocols, modifications or adaptations to trial protocols, failure to meet trial end points, and changes to regulations governing the conduct of trials.</p> <p>Separately, there is the potential that the results of clinical trials for the Screening Test and the Recurrence Test may deliver results which requires a change in strategy (see also Section 4.1(m) below) which, in particular may result in a decision to remove existing, and/or add additional, target biomarker proteins to the current prototype biomarker panel resulting in additional research and development and greater than anticipated complexity and cost in commercialisation.</p>	
Regulatory approvals	<p>Product commercialisation and development involves lengthy processes that are dependent on the evaluation by external groups such as the FDA (in the US), 'CE marking' (in the European Union) and approval from the TGA (in Australia). There is no guarantee the Company will meet the relevant regulator's benchmarks for its Triage Test, which may require the Company to conduct further clinical studies, resulting in significant cost and delay, and which may ultimately result in a</p>	Section 4.1(g)



Topic	Summary	More information																		
	failure to receive the necessary regulatory approvals in one, or multiple, key markets for the Company's Triage Test.																			
Product risks and liability	As with all new public health products, even if the Company was successful in development of its products and obtains regulatory approvals, there is no assurance unforeseen adverse events or manufacturing defects will not arise. Adverse events could expose the Company to product liability claims in litigation, potentially resulting in any regulatory approval (when/if obtained) being removed and damages being awarded against the Company. In such event, the Company's liability may exceed the Company's insurance coverage (if any). The efficacy and results of trials relating to future products will rely on the proper implementation of use/testing protocols which may include requirements for clinicians and diagnostic labs to adhere to standard operating procedures for collection and processing of blood samples. While none of the anticipated requirements of the proposed Cleo products are expected to be onerous or unusual, a failure to adhere to these requirements may adversely affect the efficacy and reliability of test results.	Section 4.1(l)																		
Directors, key managers, interests, benefits and related party transactions																				
Who are the Company's Directors and key management personnel?	The Company's Directors and key management personnel is comprised of: (a) Adrien Wing - Chair and Non-Executive Director; (b) Dr Richard Allman - Chief Executive Officer and Executive Director; (c) Dr Andrew Stephens - Chief Scientific Officer and Executive Director; (d) Professor Tom Jobling - Non-Executive Director and Lead Medical Advisor; and (e) Lucinda Nolan - Non-Executive Director.	Sections 6.1 and 6.2																		
What interests do the Directors and key management personnel have in the Securities of the Company?	As at the Prospectus Date, the Directors and key management personnel have the following interests in the Company's Securities: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #d3d3d3;">Person</th> <th style="background-color: #d3d3d3;">Shares</th> <th style="background-color: #d3d3d3;">Voting power (%)</th> </tr> </thead> <tbody> <tr> <td>Adrien Wing</td> <td>13,000,000</td> <td>28.89</td> </tr> <tr> <td>Dr Richard Allman</td> <td>1,500,000</td> <td>3.33</td> </tr> <tr> <td>Dr Andrew Stephens</td> <td>Nil</td> <td>Nil</td> </tr> <tr> <td>Professor Tom Jobling</td> <td>1,000,000</td> <td>2.22</td> </tr> <tr> <td>Lucinda Nolan</td> <td>Nil</td> <td>Nil</td> </tr> </tbody> </table> Based on the intentions of the Directors and key management personnel as at the Prospectus Date in relation to the Offers,	Person	Shares	Voting power (%)	Adrien Wing	13,000,000	28.89	Dr Richard Allman	1,500,000	3.33	Dr Andrew Stephens	Nil	Nil	Professor Tom Jobling	1,000,000	2.22	Lucinda Nolan	Nil	Nil	Sections 6.3 and 6.4
Person	Shares	Voting power (%)																		
Adrien Wing	13,000,000	28.89																		
Dr Richard Allman	1,500,000	3.33																		
Dr Andrew Stephens	Nil	Nil																		
Professor Tom Jobling	1,000,000	2.22																		
Lucinda Nolan	Nil	Nil																		



Topic	Summary	More information																								
	<p>the Directors and key management personnel and their related entities will have the following interests in Securities on Admission:</p> <table border="1"> <thead> <tr> <th>Person</th> <th>Shares¹</th> <th>Voting power (%)²</th> <th>Options³</th> </tr> </thead> <tbody> <tr> <td>Adrien Wing</td> <td>14,250,000</td> <td>11.09</td> <td>Nil</td> </tr> <tr> <td>Dr Richard Allman</td> <td>1,500,000</td> <td>1.17</td> <td>2,500,000</td> </tr> <tr> <td>Dr Andrew Stephens</td> <td>500,000</td> <td>0.39</td> <td>1,500,000</td> </tr> <tr> <td>Professor Tom Jobling</td> <td>1,250,000</td> <td>0.97</td> <td>1,500,000</td> </tr> <tr> <td>Lucinda Nolan</td> <td>Nil</td> <td>Nil</td> <td>1,500,000</td> </tr> </tbody> </table> <p>Notes</p> <ol style="list-style-type: none"> The above Shareholding is based on the intentions of each of the Directors as at the Prospectus Date in relation to the Offers. This number is indicative only and is otherwise subject to the allocation policy set out in Section 1.2. Assumes the Minimum Subscription is raised and that no further Shares are issued. See Section 8.2 for the terms and conditions of the Options. 	Person	Shares ¹	Voting power (%) ²	Options ³	Adrien Wing	14,250,000	11.09	Nil	Dr Richard Allman	1,500,000	1.17	2,500,000	Dr Andrew Stephens	500,000	0.39	1,500,000	Professor Tom Jobling	1,250,000	0.97	1,500,000	Lucinda Nolan	Nil	Nil	1,500,000	
Person	Shares ¹	Voting power (%) ²	Options ³																							
Adrien Wing	14,250,000	11.09	Nil																							
Dr Richard Allman	1,500,000	1.17	2,500,000																							
Dr Andrew Stephens	500,000	0.39	1,500,000																							
Professor Tom Jobling	1,250,000	0.97	1,500,000																							
Lucinda Nolan	Nil	Nil	1,500,000																							
What are the remuneration arrangements and benefits of the Directors and key management personnel?	<p>Since incorporation of the Company, the Directors have received remuneration (including superannuation) / directors' fees, as set out below:</p> <table border="1"> <thead> <tr> <th>Person</th> <th>Remuneration / directors' fees</th> </tr> </thead> <tbody> <tr> <td>Adrien Wing</td> <td>\$80,080</td> </tr> <tr> <td>Dr Richard Allman</td> <td>\$145,228</td> </tr> <tr> <td>Dr Andrew Stephens</td> <td>\$94,025</td> </tr> <tr> <td>Professor Tom Jobling</td> <td>Nil</td> </tr> <tr> <td>Lucinda Nolan</td> <td>Nil</td> </tr> </tbody> </table> <p>From Admission, the Directors will be entitled to the following annual remuneration / directors' fees:</p> <table border="1"> <thead> <tr> <th>Person</th> <th>Remuneration / directors' fees</th> </tr> </thead> <tbody> <tr> <td>Adrien Wing</td> <td>\$90,000 (plus GST)</td> </tr> <tr> <td>Dr Richard Allman</td> <td>\$180,000 (excluding superannuation)</td> </tr> </tbody> </table>	Person	Remuneration / directors' fees	Adrien Wing	\$80,080	Dr Richard Allman	\$145,228	Dr Andrew Stephens	\$94,025	Professor Tom Jobling	Nil	Lucinda Nolan	Nil	Person	Remuneration / directors' fees	Adrien Wing	\$90,000 (plus GST)	Dr Richard Allman	\$180,000 (excluding superannuation)	Section 6.6						
Person	Remuneration / directors' fees																									
Adrien Wing	\$80,080																									
Dr Richard Allman	\$145,228																									
Dr Andrew Stephens	\$94,025																									
Professor Tom Jobling	Nil																									
Lucinda Nolan	Nil																									
Person	Remuneration / directors' fees																									
Adrien Wing	\$90,000 (plus GST)																									
Dr Richard Allman	\$180,000 (excluding superannuation)																									



Topic	Summary	More information												
	<table border="1"> <tr> <td>Dr Andrew Stephens</td> <td>\$180,000 (excluding superannuation) pro-rated for three business days a week (being \$108,000)</td> </tr> <tr> <td>Professor Tom Jobling</td> <td>\$48,000 (plus GST)</td> </tr> <tr> <td>Lucinda Nolan</td> <td>\$48,000 (plus GST)</td> </tr> </table> <p>The Directors may participate in the Company's Employee Incentive Plan, subject to the receipt of any required Shareholder approvals.</p>	Dr Andrew Stephens	\$180,000 (excluding superannuation) pro-rated for three business days a week (being \$108,000)	Professor Tom Jobling	\$48,000 (plus GST)	Lucinda Nolan	\$48,000 (plus GST)							
Dr Andrew Stephens	\$180,000 (excluding superannuation) pro-rated for three business days a week (being \$108,000)													
Professor Tom Jobling	\$48,000 (plus GST)													
Lucinda Nolan	\$48,000 (plus GST)													
What important contracts and/or arrangements with related parties is the Company a party to?	<p>As at the Prospectus Date, the Company is a party to the following important contracts and related party arrangements:</p> <ul style="list-style-type: none"> (a) Hudson Licence Agreement (see Section 7.1); (b) Research Services Agreement (see Section 7.2); (c) Seed Raising Convertible Note Agreements with Dr Andrew Stephens and various other unrelated parties (see Section 7.4); (d) executive services agreement with Dr Richard Allman and Dr Andrew Stephens (see Section 7.5); (e) letters of appointment with each of its Directors on standard terms (see Section 7.5); and (f) deeds of indemnity, insurance and access with each of its Directors on standard terms (see Section 7.6). 	Section 7												
Who will be the substantial holders of the Company?	<p>Based on the information known as at the Prospectus Date, on Admission the following persons will have an interest in 5% or more of the Shares on issue:</p> <table border="1"> <thead> <tr> <th>Person</th> <th>Shares</th> <th>Voting power (%)</th> </tr> </thead> <tbody> <tr> <td>Adrien Wing</td> <td>14,250,000</td> <td>11.09</td> </tr> <tr> <td>Richard Vom</td> <td>8,850,000</td> <td>6.89</td> </tr> <tr> <td>Hudson Institute of Medical Research</td> <td>7,500,000</td> <td>5.84</td> </tr> </tbody> </table> <p>Note: 1. Assumes that no further Shares are issued.</p>	Person	Shares	Voting power (%)	Adrien Wing	14,250,000	11.09	Richard Vom	8,850,000	6.89	Hudson Institute of Medical Research	7,500,000	5.84	Section 8.5
Person	Shares	Voting power (%)												
Adrien Wing	14,250,000	11.09												
Richard Vom	8,850,000	6.89												
Hudson Institute of Medical Research	7,500,000	5.84												
What are the Lead Manager's interests in the Securities of the Company?	<p>As at the Prospectus Date, the Lead Manager and its associates have a relevant interest in 150,000 Shares (representing approximately 0.1% of the Shares on issue at Admission).</p> <p>The Lead Manager is expected to be issued 5,000,000 Lead Manager Options in connection with the Lead Manager Mandate. A summary of the terms and conditions of the Lead Manager Options is in Section 8.3.</p>	Section 1.8												



Topic	Summary	More information
Financial information		
What is the Company's financial position?	<p>The pro forma statement of financial position of Cleo as at 31 December 2022 is set out in Section 5.5.</p> <p>Investors are encouraged to read in full the Financial Information in Section 5 and the Independent Limited Assurance Report in Annexure B as well as the risk factors set out in Section 4.</p>	Section 5 and Annexure B
Are there any forecasts of future earnings?	<p>There are significant uncertainties associated with forecasting future revenues and expenses of the Company. In light of uncertainty as to timing and outcome of the Company's growth strategies and the general nature of the industry in which the Company will operate, as well as uncertain macro market and economic conditions in the Company's markets, the Company's performance in any future period cannot be reliably estimated. On these bases and after considering ASIC Regulatory Guide 170, the Directors do not believe they have a reasonable basis to reliably forecast future earnings and accordingly forecast financials are not included in this Prospectus.</p>	Section 5.1
Will the Company have sufficient funds for its stated objectives?	<p>The Company will have sufficient working capital at the time of Admission to carry out its stated objectives.</p>	Section 1.5
What is the Company's dividend policy?	<p>The Company does not expect to pay dividends in the near future as its focus will primarily be on growing the existing business.</p> <p>Any future determination as to the payment of dividends by the Company will be at the discretion of the Directors and will depend on the availability of distributable earnings, operating results, the financial condition of the Company, future capital requirements and other factors considered relevant by the Directors. The Company cannot give any assurances in relation to the payment of dividends or franking credits.</p>	Section 2.9
Summary of the Offers		
What are the Offers?	<p>The Offers comprise:</p> <p>(a) the Public Offer – comprising the issue of up to 60,000,000 Shares which is made to the general public in Australia and, subject to the restrictions set out in Section 1.16, certain investors in New Zealand, Hong Kong and Singapore;</p> <p>(b) the Conversion Offer – comprising the issue of up to 16,000,000 Shares which is made to the Noteholders (or their respective nominees) pursuant to the Seed Raising Convertible Note Agreement, a summary of which is in Section 7.4; and</p> <p>(c) the Lead Manager Offer – comprising the issue of up to 5,000,000 Options (Lead Manager Options) as part consideration for the provision of lead manager and</p>	Section 1.1



Topic	Summary	More information
	bookrunner services provided to the Company which is made to the Lead Manager (or its nominees), in accordance with the Lead Manager Mandate summarised in Section 7.3.	
What is the Public Offer Price?	\$0.20 per Share.	Section 1.1
Is there a Minimum Subscription?	<p>Yes, the minimum subscription is \$12,000,000 (before costs) (being the issue of a minimum of 60,000,000 Shares) under the Public Offer (Minimum Subscription).</p> <p>If the Minimum Subscription is not raised within four months of the Original Prospectus Date (or such period as varied by ASIC), the Company will not proceed with the Offers and will either repay the Application Monies (without interest) to Applicants or issue a supplementary prospectus or replacement prospectus and allow Applicants one month to withdraw their Applications and have their Application Monies refunded to them (without interest).</p>	Section 1.4
What are the conditions of the Offers?	<p>Completion of the Offers is subject to the following conditions:</p> <ul style="list-style-type: none"> (a) ASX granting conditional approval for the Company's Admission on conditions satisfactory to the Company; (b) the Company raising the Minimum Subscription; and (c) to the extent required by ASX or the Listing Rules, certain persons entering into a restriction agreement imposing such restrictions on trading on the Company's Securities as mandated by the Listing Rules. <p>If any of the conditions to the Offers are not met or waived, the Company will not proceed with the Offers.</p>	Section 1.3
Why are the Offers being conducted and what are the proposed use of funds?	<p>The purpose of the Offers and proposed use of funds is to:</p> <ul style="list-style-type: none"> (a) position the Company to achieve its strategy and objectives as set out in Section 2; (b) assist the Company to meet the requirements of ASX and satisfy Chapters 1 and 2 of the Listing Rules, as part of the Company's application for Admission; (c) provide the Company with access to capital markets to improve financial flexibility; (d) provide the Company with the benefits of an increased profile that arises from being a listed entity; and (e) provide working capital and pay the costs of the Offers. <p>The Company's source of funds and intended use of the funds, is set out in Section 1.5. The allocation of funds may change depending on several factors, including market conditions, the development of new opportunities and materialisation of any risks described in Section 4, and actual expenditure levels may differ significantly from the above estimates.</p>	Section 1.5



Topic	Summary	More information																												
What is the effect of the Offers on the capital structure of the Company?	<p>The Company's capital structure upon Admission will be as follows:</p> <table border="1"> <thead> <tr> <th></th> <th>Shares</th> <th>Options</th> <th>Convertible Notes</th> </tr> </thead> <tbody> <tr> <td>Securities on issue at Prospectus Date</td> <td>45,000,001</td> <td>Nil</td> <td>16,000,000</td> </tr> <tr> <td>Hudson Consideration Shares</td> <td>7,500,000</td> <td>Nil</td> <td>Nil</td> </tr> <tr> <td>Director and employee Options</td> <td>Nil</td> <td>7,500,000</td> <td>Nil</td> </tr> <tr> <td>Advisor Options</td> <td>Nil</td> <td>1,500,000</td> <td>Nil</td> </tr> <tr> <td>Total Securities to be issued under the Offers</td> <td>76,000,000</td> <td>5,000,000</td> <td>Nil</td> </tr> <tr> <td>Total on Admission</td> <td>128,500,001</td> <td>14,000,000</td> <td>Nil</td> </tr> </tbody> </table> <p>The Company's free float at the time of Admission will be not less than 20%.</p>		Shares	Options	Convertible Notes	Securities on issue at Prospectus Date	45,000,001	Nil	16,000,000	Hudson Consideration Shares	7,500,000	Nil	Nil	Director and employee Options	Nil	7,500,000	Nil	Advisor Options	Nil	1,500,000	Nil	Total Securities to be issued under the Offers	76,000,000	5,000,000	Nil	Total on Admission	128,500,001	14,000,000	Nil	Section 1.6
	Shares	Options	Convertible Notes																											
Securities on issue at Prospectus Date	45,000,001	Nil	16,000,000																											
Hudson Consideration Shares	7,500,000	Nil	Nil																											
Director and employee Options	Nil	7,500,000	Nil																											
Advisor Options	Nil	1,500,000	Nil																											
Total Securities to be issued under the Offers	76,000,000	5,000,000	Nil																											
Total on Admission	128,500,001	14,000,000	Nil																											
How do I apply for Securities under the relevant Offer?	<p>Applications for Securities under the Offers must be made by using the relevant Application Form as follows:</p> <p>(a) using an online Application Form at https://xcend.app/cleodiagnosticsipo and pay the Application Monies electronically; or</p> <p>(b) completing a paper-based application using the relevant Application Form attached to, or accompanying, this Prospectus or a printed copy of the relevant Application Form attached to the electronic version of this Prospectus.</p>	Section 1.9																												
When will I know if my Application was successful?	It is expected that holding statements will be sent to successful applicants on or about 17 August 2023 (subject to any extension of the Offers).	Indicative timetable																												
What are the terms of the Securities offered under the Offers?	<p>All Shares issued under the Public Offer and the Conversion Offer will rank equally with existing Shares on issue. The rights and liabilities attaching to the Shares are further described in Section 8.1.</p> <p>The terms and conditions of the Lead Manager Options are in Section 8.3. If the Lead Manager Options are exercised, the resultant Shares will be of the same class and will rank equally in all respects with the Company's existing Shares on issue in the Company at the Prospectus Date.</p>	Sections 8.1 and 8.3																												

Topic	Summary	More information
Is there a cooling off period?	No.	-
Can the Offers be withdrawn?	Yes. The Company may withdraw the Offers at any time before the issue of Securities to successful Applicants under the Offers. If the Offers, or any part of them, does not proceed, all relevant Application Monies will be refunded (without interest).	Section 1.12
Who is the Lead Manager?	The Lead Manager is Taylor Collison Limited.	Section 1.8
Is the Public Offer underwritten?	No.	Section 1.7
Will the Shares be quoted?	Application was made to ASX within seven days of the Original Prospectus Date for Admission and Official Quotation of its Shares. If ASX does not grant permission within three months after the Original Prospectus Date (or any longer period permitted by law), the Offers will be withdrawn and all Application Monies will be refunded to Applicants (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.	Section 1.11
Are there any escrow arrangements?	None of the Shares issued pursuant to the Public Offer will be subject to escrow arrangements. The Company anticipates that: (a) up to 54,650,000 Shares and 14,000,000 Options will be subject to escrow for 24 months commencing on the date of quotation of the Company's Shares on the Official List; and (b) up to 5,850,000 Shares will be subject to escrow for 12 months commencing on the Relevant Issue Date.	Section 1.17
Is there any brokerage, commission or stamp duty payable by Applicants?	No brokerage, commission or stamp duty should be payable by Applicants on acquisition of Securities under the Offers.	-
How can I find out more about the Prospectus or the Offers?	Questions relating to the Offers and the completion of an Application Form can be directed to the Share Registry, XCEND Pty Ltd on (02) 7208 8033 (within Australia) or +61 (2) 7208 8033 (Outside Australia) 8:30am to 5:00pm (AEST) Monday to Friday during the offer period.	-



1. Details of the Offers

1.1 The Offers

This Prospectus invites investors to subscribe for up to 60,000,000 Shares to be issued at \$0.20 per Share (**Offer Price**) to raise up to \$12,000,000 (before costs) (**Public Offer**).

The Offers comprise:

- (a) the **Public Offer** – comprising the issue of up to 60,000,000 Shares which is made to the general public in Australia and, subject to the restrictions set out in Section 1.16, certain investors in New Zealand, Hong Kong and Singapore;
- (b) the **Conversion Offer** – comprising the issue of up to 16,000,000 Shares which is made to the Noteholders (or their respective nominees) pursuant to the Seed Raising Convertible Note Agreement, a summary of which is in Section 7.4; and
- (c) the **Lead Manager Offer** – comprising the issue of up to 5,000,000 Options (**Lead Manager Options**) as part consideration for the provision of lead manager and bookrunner services provided to the Company which is made to the Lead Manager (or its nominees), in accordance with the Lead Manager Mandate summarised in Section 7.3.

The Offers are made with disclosure under this Prospectus and are made on the terms, and are subject to the conditions, set out in this Prospectus.

(a) **Public Offer**

Subject to the restrictions set out in Section 1.16, the Public Offer is open to the general public in Australia and certain investors in New Zealand, Hong Kong and Singapore.

The Public Offer invites investors to apply for up to 60,000,000 Shares to be issued at the Offer Price to raise up to \$12,000,000 (before costs).

The Shares to be issued by the Company pursuant to the Public Offer, are of the same class and will rank equally with the Company's existing Shares on issue. The rights and liabilities attaching to the Shares are further described in Section 8.1.

The Public Offer is not underwritten.

(b) **Conversion Offer**

The Conversion Offer is a separate offer made under this Prospectus.

The Conversion Offer is comprised of an offer of up to 16,000,000 Shares (**Conversion Shares**) to the holders of the Seed Raising Convertible Notes (**Noteholders**).

The Shares to be issued by the Company pursuant to the Conversion Offer, are of the same class and will rank equally with the Company's existing Shares on issue. The rights and liabilities attaching to the Conversion Shares are further described in Section 8.1.

The purpose of the Conversion Offer is to remove any secondary on-sale restrictions and facilitate future secondary trading of the Conversion Shares to be issued by the Company on conversion of the Seed Raising Convertible Notes, without disclosure under Chapter 6D of the Corporations Act.



The Seed Raising Convertible Notes will convert following completion of the Offers.

A summary of the terms and conditions of the Seed Raising Convertible Notes is in Section 7.4.

(c) **Lead Manager Offer**

The Lead Manager Offer is a separate offer made under this Prospectus.

The Company has agreed to issue the Lead Manager Options under the Lead Manager Offer to the Lead Manager (or its nominees) upon the successful completion of the Public Offer.

The Lead Manager Options will be issued for nil or nominal consideration as part payment to the Lead Manager for the provision of lead manager and bookrunner services provided to the Company in connection with the Public Offer.

The terms and conditions of the Lead Manager Options are in Section 8.3. If the Lead Manager Options are exercised, the resultant Shares will be of the same class and will rank equally in all respects with the Company's existing Shares on issue in the Company at the Prospectus Date.

Only the Lead Manager (or its nominees) may accept the Lead Manager Offer. An Application Form in relation to the Lead Manager Offer will be issued to the Lead Manager (or its nominees) together with a copy of this Prospectus.

The Lead Manager Offer is being made under this Prospectus to remove the need for an additional disclosure document to be issued upon the sale or transfer of any Shares issued upon exercise of Lead Manager Options.

1.2 Allocation policy

The Directors reserve the right to determine the allocation of Shares under the Public Offer, including to reject any Application or to allocate any Applicant fewer Shares than the number applied for. Where the number of Shares issued is less than the number applied for, or where no allotment is made, surplus Application Monies will be refunded, without interest, to the Applicant as soon as practicable after the Closing Date.

No Applicant under the Public Offer has any assurance of being allocated all or any Shares applied for. The allocation of Shares by Directors will be influenced by the following factors:

- (a) the number of Shares applied for;
- (b) the overall level of demand for the Public Offer;
- (c) the timeliness of the bid by particular Applicants;
- (d) the desire for a spread of investors;
- (e) the likelihood that particular Applicants will be long-term Shareholders;
- (f) the desire for an informed and active market for trading Shares following listing;
- (g) ensuring an appropriate Shareholder base for the Company going forward; and
- (h) any other factors that the Company consider appropriate.

The Company will not be liable to any person not allocated Shares or not allocated the full amount applied for.

1.3 Conditions to the Offers

Completion of the Offers is subject to the following conditions:

- (a) ASX granting conditional approval for the Company's Admission on conditions satisfactory to the Company;
- (b) the Company raising the Minimum Subscription; and
- (c) to the extent required by ASX or the Listing Rules, certain persons entering into a restriction agreement imposing such restrictions on trading on the Company's Securities as mandated by the Listing Rules.

If any of these conditions are not satisfied or waived (as applicable), the Company will not proceed with the Offers and the Company will repay all Application Monies received under the Offers to the Applicants (without interest) in accordance with the Corporations Act.

1.4 Minimum Subscription

The minimum subscription under the Offers is \$12,000,000 (before costs) (being the issue of a minimum of 60,000,000 new Shares) under the Public Offer (**Minimum Subscription**).

None of the Securities offered under this Prospectus will be issued if Applications are not received for the Minimum Subscription. If the Minimum Subscription is not raised within four months of the Original Prospectus Date (or such period as varied by ASIC), the Company will not proceed with the Offers and will either repay the Application Monies (without interest) to Applicants or issue a supplementary prospectus or replacement prospectus and allow Applicants one month to withdraw their Applications and have their Application Monies refunded to them (without interest).

1.5 Purpose of the Offers and proposed use of funds

The purpose of the Offers and proposed use of funds is to:

- (a) position the Company to achieve its strategy and objectives as set out in Section 2;
- (b) assist the Company to meet the requirements of ASX and satisfy Chapters 1 and 2 of the Listing Rules, as part of the Company's application for Admission;
- (c) provide the Company with access to capital markets to improve financial flexibility;
- (d) provide the Company with the benefits of an increased profile that arises from being a listed entity; and
- (e) provide working capital and pay the costs of the Offers.

Following Admission, the Company intends to apply the funds raised from the Offers as follows:

Source of funds	\$
Existing cash as at the Prospectus Date	367,794
Proceeds from the Offers	12,000,000
Total funds available	12,367,794



Item	Year 1		Year 2	
	\$	%	\$	%
Triage Test				
Stage gate development, data science, internal trials, verification, usability and validation	786,000	6.4	870,000	7.0
Test Performance Evaluation (FDA Compliance)	640,000	5.2	1,300,000	10.5
Regulatory support and submission	60,000	0.5	240,000	1.9
Screening Test and Recurrence Test				
Stage gate development, data science, internal trials, verification, usability and validation	-	-	554,000	4.5
Clinical trials	200,000	1.6	1,500,000	12.1
Regulatory support and submission	-	-	100,000	0.8
General				
Quality system establishment ISO13485	50,000	0.4	50,000	0.4
Antibody manufacturing establishment including 3 batches	2,000,000	16.2	-	-
Patent and associated legal costs	75,000	0.6	150,000	1.2
General administration	1,045,000	8.5	1,186,000	9.7



and working capital ¹				
Costs of the Offers ²	1,082,000	8.7	-	
Infrastructure, equipment, lab space	240,000	1.9	240,000	1.9
TOTAL	6,178,000	50.0	6,190,000	50.0

Notes:

1. *Working capital expenditure is to be applied towards funds required to expand the business and towards administration costs associated with the Company. These costs include costs for wages and salaries, occupancy costs, professional consultants' fees, compliance and reporting costs associated with running an ASX listed company, as well as other typical administration costs. Working capital also includes surplus funds and funds that may be applied to future acquisitions.*
2. *The expenses paid or payable by the Company in relation to the Offers are summarised in Section 8.8.*

The above table is a statement of current intentions as at the Prospectus Date. Prospective investors should note that, as with any budget, the allocation of funds set out in the above table may change depending on a number of factors, including market conditions, the development of new opportunities and/or any number of other factors (including the risk factors outlined in Section 4), and actual expenditure levels, may differ significantly from the above estimates.

The funds raised from the Offers, assuming the Minimum Subscription is raised, will provide the Company with sufficient working capital to carry out its stated objectives in this Prospectus.

The use of further equity funding may be considered by the Company where it is appropriate to accelerate a specific project or strategy.

Although the Company's immediate focus will be on the Tests, it may pursue and assess other new business opportunities in the biotechnology and medtech sectors over time which complement its business. These new business opportunities may take the form of direct or passive investments. At present, the Company is not pursuing any such acquisitions.

Based on the intended use of funds detailed above, the amounts raised pursuant to the Offers will provide the Company with sufficient funding for approximately the 24-month period following Admission. The future capital requirements of the Company will depend on many factors including the timing and success of the Company's activities and whether any of the risks in Section 4 materialise. The Company believes its available cash and the net proceeds of the Offers should be adequate to fund its business objectives in the short term as stated in this Prospectus, however, the Company will require further financing in the future. The Company expects to obtain additional funding through equity or debt, or a combination of both. See Section 4 for discussion of the risks associated with the Company's future capital requirements.



1.6 Capital structure on Admission

The Company's capital structure upon Admission will be as follows:

	Shares	Options	Convertible Notes
Securities on issue prior to Admission			
Securities currently on issue ¹	45,000,001	Nil	16,000,000
Securities on issue at Admission			
Hudson Consideration Shares ²	7,500,000	Nil	Nil
Public Offer Shares	60,000,000	Nil	Nil
Conversion Shares ³	16,000,000	Nil	Nil
Lead Manager Options ⁴	Nil	5,000,000	Nil
Advisor Options ⁵	Nil	1,500,000	Nil
Director and employee Options ⁶	Nil	7,500,000	Nil
Total on Admission⁷	128,500,001	14,000,000	Nil
Indicative market capitalisation⁸	~\$25.7 million		

Notes:

1. *Comprising:*
 - (a) 1 Share issued upon incorporation of the Company;
 - (b) 45,000,000 Shares issued on conversion of convertible notes issued to founders of the Company; and
 - (c) 16,000,000 Seed Raising Convertible Notes convertible to an equivalent number of Shares in accordance with the Seed Raising Convertible Note Agreements summarised in Section 7.4. The Seed Raising Convertible Notes are expected to convert on the business day immediately prior to Admission.
2. *Consideration to be issued to Hudson in accordance with the Hudson Licence Agreement summarised in Section 7.1.*
3. *Shares to be issued to the Noteholders (or their respective nominees) upon conversion of the Seed Raising Convertible Notes summarised in Section 7.4.*
4. *Options to be issued in accordance with the Lead Manager Mandate summarised in Section 7.3. See Section 8.3 for the terms and conditions of the Lead Manager Options.*
5. *Options to be issued to IRX Advisors (or its nominees) as consideration for the provision of investor relations and marketing services provided to the Company in connection with the Public Offer. See Section 8.3 for the terms and conditions of the Advisor Options.*
6. *Options to be issued to Directors and employees of the Company (or their respective nominees) as part of their remuneration packages or as fees for services. See Section 8.2 for the terms and conditions of the Options.*
7. *Assumes the Seed Raising Convertible Notes are converted into Shares and no further Securities are issued and no Options are converted into Shares.*
8. *Based on the Offer Price multiplied by the number of Shares on issue on Admission. There is no guarantee that the Shares will trade at the Offer Price on or after Admission.*



For personal use only

The Company's free float at the time of Admission will be not less than 20%.

1.7 Underwriting

The Public Offer is not underwritten.

1.8 Interests of Lead Manager

Taylor Collison Limited is the Lead Manager to the Public Offer. A summary of the key terms of the appointment of the Lead Manager is set out in Section 7.3.

(a) Fees payable to the Lead Manager

The Company has or will pay to the Lead Manager certain fees in connection with the Offers as summarised in Section 7.3.

(b) Lead Manager's interests in Securities

As at the Prospectus Date, the Lead Manager and its associates have a relevant interest in 150,000 Shares (representing approximately 0.1% of the Shares on issue at Admission).

(c) Participation in previous placements

The Lead Manager has not participated in a placement of Shares by the Company in the two years preceding lodgement of this Prospectus.

1.9 Applications

(a) General

Applications for Securities under the Offers must be made by using the relevant Application Form as follows:

- (i) using an online Application Form at <https://xcend.app/cleodiagnosicsipo> and pay the Application Monies electronically; or
- (ii) completing a paper-based application using the relevant Application Form attached to, or accompanying, this Prospectus or a printed copy of the relevant Application Form attached to the electronic version of this Prospectus.

By completing an Application Form, each Applicant will be taken to have declared that all details and statements made by them are complete and accurate and that they have personally received the Application Form together with a complete and unaltered copy of the Prospectus.

Applications for Shares under the Public Offer must be for a minimum of \$2,000 worth of Shares (10,000 Shares) and thereafter in multiples of 2,500 Shares and payment for the Shares must be made in full at the Offer Price.

Completed Application Forms and accompanying cheques (if applicable), must be:

- (i) made payable to "Cleo Diagnostics Ltd - IPO";
- (ii) crossed "Not Negotiable"; and



- (iii) mailed or delivered to the address set out on the Application Form by no later than 5:00pm AEST on the Closing Date, which is scheduled to occur on 4 August 2023.

If paying by BPAY® or EFT (Electronic Funds Transfer), please follow the instructions on the Application Form. A unique reference number will be quoted upon completion of the online application. Your BPAY® or EFT reference number will process your payment to your application electronically and you will be deemed to have applied for such Shares for which you have paid. Applicants using BPAY® or EFT should be aware of their financial institution's cut-off time (the payment must be made to be processed overnight) and ensure payment is processed by their financial institution on or before the day prior to the Closing Date. You do not need to return any documents if you have made payment by BPAY® or EFT.

If an Application Form is not completed correctly or if the accompanying payment is the wrong amount, the Company may, in its discretion, still treat the Application Form to be valid. The Company's decision to treat an Application as valid, or how to construe, amend or complete it, will be final.

(b) **Public Offer**

The Public Offer is open to the general public in Australia and, subject to the restrictions set out in Section 1.16, certain investors in New Zealand, Hong Kong and Singapore.

If you wish to apply for Shares under the Public Offer, you should follow the instructions on the Application Form.

Applications under the Public Offer must be for a minimum of 10,000 Shares (\$2,000) and then in increments of 2,500 Shares (\$500).

(c) **Conversion Offer**

The Conversion Offer is open to the Noteholders and only the Noteholders (or their nominees) may apply for the Conversion Shares under the Conversion Offer.

An Application Form will be issued to the Noteholders (or their nominees) together with a copy of this Prospectus.

(d) **Lead Manager Offer**

The Lead Manager Offer is open to the Lead Manager (or its nominees) and only the Lead Manager (or its nominees) may apply for the Lead Manager Options under the Lead Manager Offer.

An Application Form will be issued to the Lead Manager (or its nominees) together with a copy of this Prospectus.

(e) **Acknowledgements**

If you do not provide the exact amount, the Company reserves the right to issue you a lesser number of Securities and (if necessary) return a portion of your funds. No interest will be paid on money returned. No brokerage or stamp duty costs are payable by Applicants. The Application Form and related payment must be completed and received by no later than the Closing Date. The Offers may be closed at an earlier date and time at the discretion of the Directors, without prior notice. Applicants are therefore encouraged to submit their Application Forms as early as possible. However, the Company reserves the right to extend the Offers or accept late Applications.



The return of a completed Application Form with the requisite Application Monies (if applicable) will be taken by the Company to constitute a representation and warranty by the Applicant that all relevant approvals have been obtained and that the Applicant:

- (i) agreed to be bound by the terms of the Offers;
- (ii) agreed to be bound by the terms of the Constitution;
- (iii) irrevocably and unconditionally agree to the terms and conditions of the Offers and the terms and conditions set out in this Prospectus (having read the Prospectus in its entirety) and the Application Form;
- (iv) declares that all details and statements in the Application Form are complete and accurate;
- (v) declares that, if they are an individual, they are over 18 years of age and have full legal capacity and power to perform all its rights and obligations under the Application Form;
- (vi) acknowledged that, once the Company receives an Application Form, it may not be withdrawn;
- (vii) applied for the number of Securities at the Australian dollar amount (where applicable) shown on the front of the Application Form;
- (viii) agreed to being allocated and issued or transferred the number of Securities applied for (or a lower number allocated in a way described in this Prospectus), or no Securities at all;
- (ix) acknowledged that the Company may not pay dividends, or that any dividends paid may not be franked;
- (x) declared that the Applicant(s) is/are a resident of Australia or is otherwise eligible to participate in the Offers under this Prospectus having regard to the restrictions in Section 1.16;
- (xi) authorises the Company and its respective officers or agents, to do anything on their behalf necessary for the Securities to be issued to them, including to act on instructions of the Company's Share Registry upon using the contact details set out in the Application Form;
- (xii) acknowledges that the information contained in, or accompanying, the Prospectus is not investment or financial product advice or a recommendation that the Securities applied for are suitable for them given their investment objectives, financial situation or particular needs;
- (xiii) acknowledges that the Securities have not, and will not be, registered under the securities laws in any other jurisdictions outside Australia, and accordingly, the Securities may not be offered, sold or otherwise transferred except in accordance with an available exemption from, or in a transaction not subject to, the registration requirements of applicable securities laws;
- (xiv) acknowledged and agreed that the Offers may be withdrawn by the Company, or may otherwise not proceed in the circumstances described in this Prospectus; and
- (xv) acknowledged and agreed that if the listing does not occur for any reason, the Offers will not proceed.



1.10 Application Monies to be held in trust

To the extent required by the Corporations Act, until the Securities are issued under the Prospectus, the Application Monies for Securities will be held by the Company on trust on behalf of Applicants in a separate bank account maintained solely for the purpose of depositing Application Monies received pursuant to this Prospectus. However, the Company will be entitled to retain all interest that accrues on the bank account and each Applicant waives the right to claim interest. If the Shares to be issued under the Prospectus are not admitted to Official Quotation within three months after the Original Prospectus Date, no Securities will be issued and Application Monies will be refunded in full without interest in accordance with the Corporations Act.

1.11 ASX listing

Application was made to ASX within seven days of the Original Prospectus Date for Admission and Official Quotation of its Shares. The Company confirms that the issue price of all securities for which the Company will apply for Official Quotation is at least \$0.20 in cash.

Completion is conditional on ASX approving this application for Admission on conditions acceptable to the Company. If ASX does not grant permission within three months after the Original Prospectus Date (or any longer period permitted by law), the Offers will be withdrawn and all Application Monies will be refunded to Applicants (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.

ASX takes no responsibility for the contents of this Prospectus. The fact that ASX may admit the Company to the Official List is not to be taken in any way as an indication of the merits of the Company or the Securities offered pursuant to this Prospectus.

1.12 Discretion regarding the Offers

The Company may withdraw the Offers at any time before the issue of Securities to successful Applicants under the Offers. If the Offers, or any part of them, does not proceed, all relevant Application Monies will be refunded (without interest).

The Company also reserves the right to, subject to the Corporations Act, extend the Offers or any part of them, accept late Applications either generally or in particular cases, reject any Application or allocate to any Applicant fewer Securities than the amount applied for.

1.13 Commencement of trading

It is the responsibility of each person who trades in Shares to confirm their holding before trading in Shares. If you sell Shares before receiving a holding statement, you do so at your 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 holding statement, whether on the basis of a confirmation of allocation provided by any of them, by a broker or otherwise.

1.14 CHES and issuer sponsorship

The Company will apply to participate in CHES. All trading on the ASX will be settled through CHES. ASX Settlement, a wholly owned subsidiary of the ASX, operates CHES in accordance with the Listing Rules and the ASX Settlement Operating Rules. On behalf of the Company, the Share Registry will operate an electronic issuer sponsored sub-register and an electronic CHES sub-register. The two sub-registers together make up the Company's principal register of securities.



Under CHESS, the Company will not issue certificates to Shareholders. Rather, holding statements (similar to bank statements) will be sent to Shareholders as soon as practicable after allotment. Holding statements will be sent either by CHESS (for Shareholders who elect to hold Shares on the CHESS sub-register) or by the Company's Share Registry (for Shareholders who elect to hold their Securities on the issuer sponsored sub-register). The statements will set out the number of existing Securities (where applicable) and the number of new Securities allotted under this Prospectus and provide details of a Shareholder's holder identification number (for Shareholders who elect to hold Shares on the CHESS sub-register) or Shareholder reference number (for Shareholders who elect to hold their Shares on the issuer sponsored sub-register). Updated holding statements will also be sent to each Shareholder at the end of each month in which there is a transaction on their holding, as required by the Listing Rules.

1.15 Overseas applicants

This Prospectus does not, and is not intended to, constitute an offer in any place or jurisdiction, or to any person to whom, it would not be lawful to make such an offer or to issue this Prospectus. The distribution of this Prospectus in jurisdictions outside Australia, may be restricted by law and persons who come into possession of this Prospectus should seek advice on and observe any of these restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

No action has been taken to register or qualify the Securities or otherwise permit an offering of the Securities the subject of this Prospectus in any jurisdiction outside Australia. Applicants who are residents in countries other than Australia, should consult their professional advisers as to whether any governmental or other consents are required or whether any other formalities need to be considered and followed.

If you are outside Australia, it is your responsibility to obtain all necessary approvals for the issue of the Securities pursuant to this Prospectus. The return of a completed Application Form will be taken by the Company to constitute a representation and warranty by you that all relevant approvals have been obtained.

1.16 Notice to foreign investors

(a) **Notice to investors in 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 Securities 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:

- (i) is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- (ii) meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- (iii) is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- (iv) is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- (v) is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

(b) **Notice to investors in Hong Kong**

WARNING: This document 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**). Accordingly, this document may not be distributed, and the Securities may 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 Securities 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 Securities that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares 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 document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offers. If you are in doubt about any contents of this document, you should obtain independent professional advice.

(c) **Notice to investors in Singapore**

This document and any other materials relating to the Securities have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of Securities, 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 13 of the Securities and Futures Act 2001 of Singapore (the **SFA**) or another exemption under the SFA.

This document has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, 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 Securities being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire Securities. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

1.17 Escrow arrangements

ASX will classify certain Securities as being subject to the restricted securities provisions of the Listing Rules. Restricted Securities are required to be held in escrow for up to 24 months and are not allowed to be sold, mortgaged, pledged, assigned or transferred for that period without the prior approval of ASX. During the period in which these Securities are prohibited from being transferred, trading in Shares may be less liquid which may impact a Shareholder's ability to dispose of their Shares in a timely manner.



Prior to the Company's Shares being admitted to Official Quotation, the Company will enter into escrow agreements with certain recipients of Restricted Securities in accordance with Chapter 9 of the Listing Rules, and the Company will announce to ASX full details (quantity and duration) of the Securities required to be held in escrow.

As at the date of this Prospectus, the Company expects that up to 54,650,000 Shares and 14,000,000 Options to be subject to 24 months escrow upon Admission and up to 5,850,000 Shares to be subject to 12 months escrow commencing on the Relevant Issue Date. The Company may, in its discretion, resolve to enter into voluntary restriction agreements.

1.18 Taxation

It is the responsibility of all persons to satisfy themselves of the particular taxation treatment that applies to them in relation to the Offers, by consulting their own professional tax advisers. To the maximum extent permitted by law, neither the Company nor any of its Directors, officers nor any of their respective advisers accepts any liability or responsibility in respect of the taxation consequences of the matters referred to above.

1.19 Privacy disclosure

Persons who apply for Securities pursuant to this Prospectus are asked to provide personal information to the Company, either directly or through the Share Registry. The Company and the Share Registry collect, hold and use that personal information to assess Applications for Shares, to provide facilities and services to security holders, and to carry out various administrative functions. Access to the information collected may be provided to the Company's agents and service providers and to ASX, ASIC and other regulatory bodies on the basis that they deal with such information in accordance with the relevant privacy laws. If you do not provide the information required on the Application Form, the Company may not be able to accept or process your Application.

An Applicant has a right to gain access to the information that the Company holds about that person subject to certain exemptions under law. A fee may be charged for access. Access requests must be made in writing to the Company's registered office.

1.20 Electronic Prospectus

Pursuant to Regulatory Guide 107, ASIC has exempted compliance with certain provisions of the Corporations Act to allow distribution of an electronic Prospectus on the basis of a paper Prospectus lodged with ASIC and the issue of Securities in response to an electronic application form, subject to compliance with certain provisions. If you have received this Prospectus as an electronic Prospectus please ensure that you have received the entire Prospectus accompanied by the Application Form. If you have not, please email the Company and the Company will send to you, for free, either a hard copy or a further electronic copy of this Prospectus or both. The Company reserves the right not to accept an Application Form from a person if it has reason to believe that when that person was given access to the electronic Application Form, it was not provided together with the electronic Prospectus and any relevant supplementary or replacement prospectus or any of those documents were incomplete or altered. In such a case, the Application Monies received will be dealt with in accordance with section 722 of the Corporations Act.

1.21 Paper copies of Prospectus

The Company will provide paper copies of this Prospectus (including any supplementary or replacement document) and the Application Form to investors upon request and free of charge. Requests for a paper copy Prospectus and Application Form should be directed to the Company Secretary on pauline.moffatt@cleodx.com.



1.22 Enquiries

This Prospectus provides information for potential investors in the Company and should be read in its entirety. If, after reading this Prospectus, you have any questions about any aspect of an investment in the Company, please contact your stockbroker, accountant or independent financial adviser.

Questions relating to the Offers and the completion of an Application Form can be directed to the Share Registry, XCEND Pty Ltd on (02) 7208 8033 (within Australia) or +61 (2) 7208 8033 (Outside Australia) 8:30am to 5:00pm (AEDT) Monday to Friday during the offer period.

For personal use only



2. Company overview

2.1 Background

The Company was incorporated on 30 November 2021 for the purpose of undertaking the development and commercialisation of three ovarian cancer Tests (**Tests**), each of which are based on the same underlying core technology (**Licenced Technology**).

The technology underlying the Company's Tests was discovered and developed at the Hudson Institute of Medical Research in Melbourne, Australia (**Hudson**). Under the leadership of Dr Andrew Stephens, the Licenced Technology represents the culmination of over 10 years of scientific research into proteomic biomarkers⁶ for ovarian cancer detection and investigating the relationship between tumour progression and immune evasion in ovarian cancers.

Hudson is a leading Australian medical research institute recognised internationally for discovery science and translational research into cancer, inflammation, reproductive health and pregnancy, and infant and child health. Hudson was formed in 2014 through the merger of Prince Henry's and Monash Institutes of Medical Research. Combined, they have more than 75 years' experience in research discoveries to Australia and beyond. Institute scientists pioneered IVF and stem cell discoveries amongst other discoveries. Hudson is home to 325 staff and 180 students.

The Tests are split into three categories, each of which are specifically designed and targeted to identify, at different points in a patient's lifetime, the presence of, or the likelihood of developing or re-developing, ovarian cancer. See Section 2.3 for a detailed overview of the Company's three Tests.

On 29 August 2022, the Company entered into an exclusive licence agreement with Hudson, pursuant to which Hudson agreed to licence certain technology to the Company relating to the Tests (**Hudson Licence Agreement**). See Section 7.1 for a summary of the Hudson Licence Agreement.

The Company was established to leverage Hudson's research to provide a public platform to raise capital and accelerate the development and commercialisation of the Tests.

In determining the consideration for the Hudson Licence Agreement, the Company did not undertake a formal valuation of the Licenced Technology, but took into account the following considerations:

- (a) Company's assessment of the costs incurred by Hudson in the development of the Licenced Technology;
- (b) the exclusivity and other material terms of the Hudson Licence Agreement, which are set out in Section 7.1;
- (c) the "at-risk" nature of the payments to be made to Hudson in the event that a regulatory approval is obtained in the US, Australia, Europe or Japan (see Section 7.1(e) for further information);

⁶ 'Proteomic biomarker' research describes the global identification, relative quantitation and comparison between disease versus non-disease states of proteins present in biological samples, in this case blood. This information is used to assist in the definition of molecular events associated with cancer formation and progression, and understand how they differ between malignant and non-malignant disease. The proteomic composition of blood provides an accurate and specific 'snapshot' of biological status at any particular time, and when used individually or in combination with other diagnostic approaches can achieve a high degree of sensitivity and specificity for the early diagnosis of diseases such as cancer.



- (d) the Company's assessment of the future prospects of the Licenced Technology based on the level of development of the Licenced Technology and the ability of the Company to protect and potentially commercially exploit the underlying intellectual property.

The Board is of the opinion that the opportunity presented under the Hudson Licence Agreements represents an opportunity that is in the best interests of current Shareholders of the Company and was involved in a negotiation process prior to executing the Hudson Licence Agreement.

A detailed summary of the Company's history is in Section 2.2 below.

2.2 Company history

(a) Research and development timeline

In 2010, researchers at Hudson first identified the small inflammatory molecule 'CXCL10' in ovarian cancer tissue sections. Subsequent research demonstrated the restricted expression of this newly identified CXCL10 form to malignant tissues only, and its presence at very early stages of tumour growth and progression in ovarian cancer patients.

Following these discoveries, researchers at Hudson confirmed the presence of CXCL10 in multiple ovarian cancer samples and demonstrated a mechanism leading to its production in cancer cells *in vitro*. Further investigations targeted the relationship between CXCL10 processing, tumour progression and immune evasion in ovarian cancers using antibodies developed by researchers at Hudson which bind to select biomarkers⁷, including CXCL10 and other known markers of ovarian cancer, to indicate the presence of ovarian cancer. This panel of antibodies proved effective in identifying and differentiating patients with malignant disease from those with benign gynaecological disease and are the foundation of the Tests.

Dr Stephens and his team developed a novel assay, the 'Multiplex Active Ratio Test' (**mART**), for the measurement of Ag-CXCL10 proteoforms in biological samples. mART was validated for use in a range of sample types. Analyses of a limited number of clinical samples using mART suggested the capacity to discriminate between patients with high-grade epithelial ovarian cancer versus benign disease.

(i) Clinical Study 1

In 2020, Dr Andrew Stephens and his team completed their first human Clinical Study 1 using the Triage Test. This study demonstrated the utility of mART measurement (comprising the measurement of CXCL10 forms in plasma, ascites fluid or vaginal swabs) in patients who underwent surgery for suspected ovarian cancers.

In a cohort of ~275 patients, mART accurately differentiated patients with malignant epithelial ovarian cancers from those with benign gynaecological conditions (AUC 0.8617) and significantly outperformed the current clinical standard test (also known as 'CA-125').⁸ Moreover, the prototype significantly increased prognostic performance (AUC 0.9511; Sensitivity 90.0%; Specificity 91.7%; Cohen's $d > 1$) for epithelial ovarian cancer detection.⁹

⁷ A 'biomarker' is a biomolecule or variant biomolecule (e.g., DNA, RNA or protein) that is present at measurably greater or lesser concentrations, or is present in an altered form, in a disease state versus a normal condition.

⁸ <https://www.mdpi.com/2075-4418/11/6/1048>. The author has not provided their consent for the statement to be included in this Prospectus.

⁹ <https://www.mdpi.com/2075-4418/11/6/1048>. The author has not provided their consent for the statement to be included in this Prospectus.



(ii) **Clinical Study 2**

In 2022, Dr Andrew Stephens and his team completed their second human Clinical Study 2 using mART to determine its applicability to the Triage Test. This study was conducted in patients at elevated risk of ovarian cancer, and who underwent prophylactic surgery for known or suspected genetic predisposition to develop disease. This study demonstrated that mART, used as part of a broader multi-biomarker panel, was able to identify malignancy at an early stage; and potentially at a pre-cancerous stage (p53 lesion, the precursor lesion found in the fallopian tube that gives rise to large proportion of ovarian cancers (**p53**)).

In a cohort of 271 patients, selected for increased risk of ovarian cancer (e.g. mutation carriers, or strong familial histories of ovarian cancer in the absence of known mutation) and who underwent prophylactic oophorectomy (surgery to remove ovaries and fallopian tubes), accurate differentiation between benign and malignant samples was confirmed using mART. In addition, mART was able to correctly classify a small number of patients with pre-cancerous p53 lesions as cancerous.

The Company is in the process of undertaking analysis, review and validation of the study and intends to publish the findings once the process is complete. Whilst initial analyses indicated greater than 90% Sensitivity and Specificity for the identification of early stage epithelial ovarian cancers within the cohort, the Company cautions that the results remain subject to further analysis, peer review and validation and should not be relied upon in making an investment decision in the Company.

(iii) **Patent**

In December 2020, Hudson lodged a patent application (PCT/AU2020/051403) titled 'CXCL10 Binding proteins and uses thereof', which covers the production of antibodies to CXCL10 and modified CXCL10, two key biomarkers in the Triage Test, Screening Test and the Recurrence Test, together with their application in ovarian cancer diagnostics.

On 23 March 2023, the patent in Australia was granted (as patent number 2020404453). The patent in the United States is expected to be granted in the next three months. Refer to Section 4.1(b) for a summary of the intellectual property risks affecting the Company. A summary of the status of the patent applications is in Section 2.8 and section 1.4.2 of the Intellectual Property Report at Annexure A.

(iv) **Novel**

The ovarian cancer Tests are considered to be 'novel' because:

- (A) the Tests use CXCL-10 in its prototype biomarker panel; and
- (B) there is no test currently on the market which uses CXCL-10 to detect ovarian cancer.



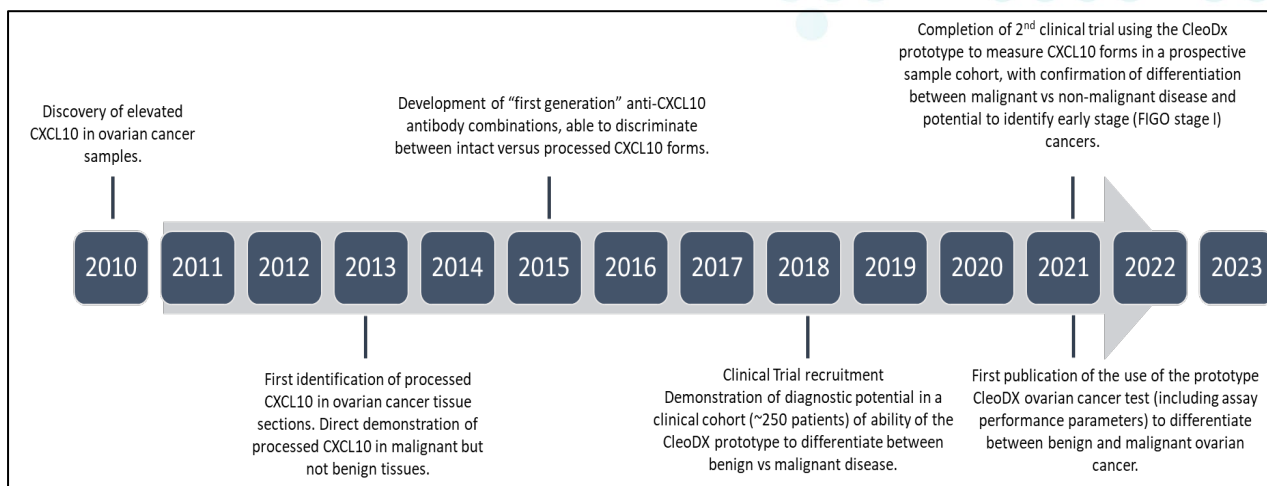


Figure 1: Research and development history of the Licenced Technology

2.3 Overview of the Tests

Cleo has developed a three-phased product development strategy that will deliver three related tests for ovarian cancer detection:

- Triage Test** – a pre-surgical test to determine the likelihood that a pre-surgical ovarian mass in a patient not yet referred to an oncologist, is malignant.
- Recurrence Test** – a post-surgical test to identify whether a cancer is recurring following surgical removal and chemotherapy of a primary tumour.
- Screening Test** – a screening test to identify early-stage ovarian cancer in women who do not present any symptoms consistent with ovarian cancer.

Each of the three tests are non-invasive and are performed using a sample of the patient's blood. They are specifically designed to be low-cost and fit within existing pathology lab infrastructure.

BLOOD TEST

Blood collected via a simple blood draw. Part of a standard panel of tests ordered by a doctor.

RESULT

An easy to understand Report is prepared and sent to the patient's doctor for clinical triage

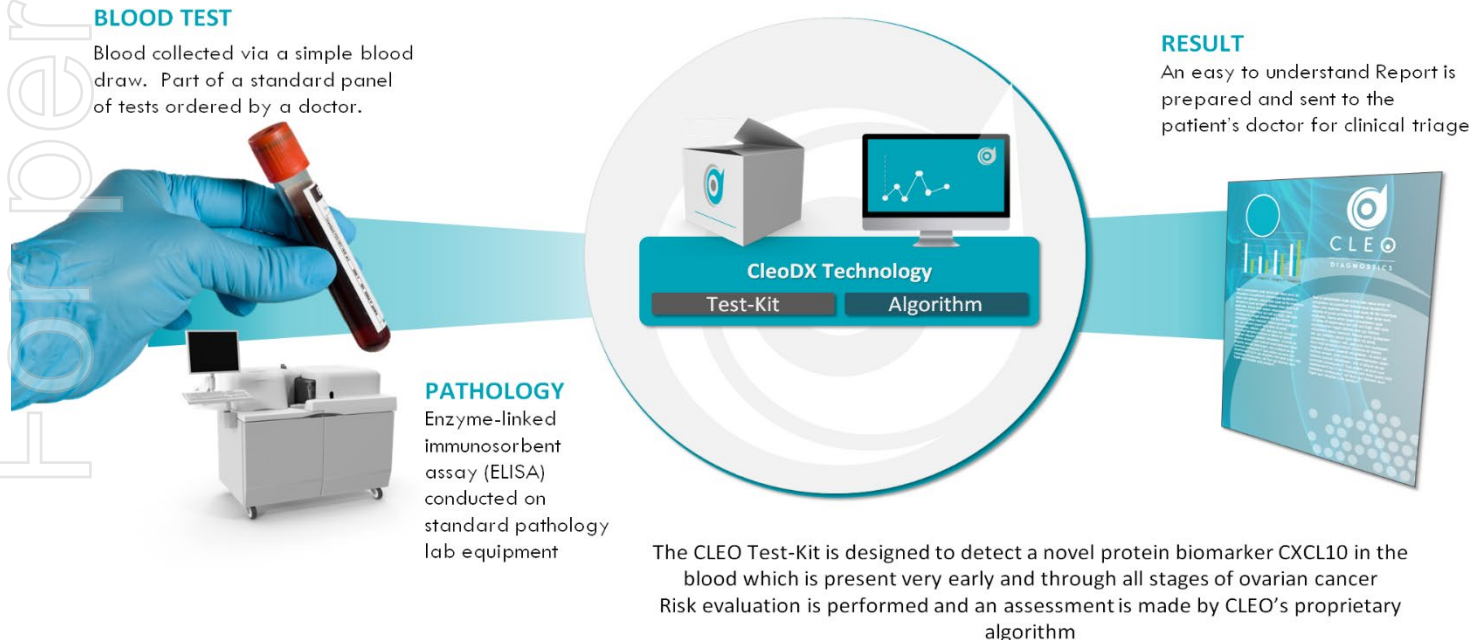


Figure 2: Clinical workflow of the Triage Test

The Company's most progressed Test is the Triage Test. To date, the Company has completed two human clinical studies using the Triage Test which have produced strong results evidencing that the Triage Test can accurately differentiate patients with malignant ovarian cancer from those with benign gynaecological conditions. The Company's prototype has performance characteristics which exceed those of two commercially available, Food and Drug Administration (FDA) approved, surgical triage tests for ovarian cancer (see Section 3.6 for a full discussion of competing products on market or in development).

The Company's next phase of evaluation is intended to strengthen the efficacy of current data and product performance against current leading and comparable tests, primarily the CA-125 test, which has an AUC (Area Under the Curve)¹⁰ of 0.82 (versus the Company's prototype which has an AUC of 0.95).¹¹ To put these numbers into perspective, CA125 correctly identified 52% of malignant cases correctly (at a Specificity of 90%), whereas the Cleo prototype correctly identified 91.7% of malignant cases correctly (at the same Specificity of 90%).¹²

An overview of the Tests is outlined below.

(a) **Triage Test**

(i) **General**

The Triage Test is intended to be the Company's first product to market.

As noted above, the Triage Test is designed to determine the likelihood that a pre-surgical ovarian mass is either benign or malignant prior to referral to an oncologist for surgical intervention.

The Triage Test is expected to be used in conjunction with clinical and radiological evaluation of a patient by physicians, to improve the referral process and better inform clinical decision-making workflows.

Ovarian masses (typically benign cysts) are very common and non-life threatening; around 10% of women will have surgery during their lifetime for investigation of an ovarian mass.¹³ As malignancy has very different clinical management requirements to non-malignant disease, it is important that patients can be accurately diagnosed and triaged prior to surgery. An accurate (e.g. >90% specific) method to pre-surgically triage patients to appropriate tertiary care would greatly improve the clinical management of gynaecological disease.

(ii) **Existing level of operations for the Triage Test**

Phase	Status
Proof of concept studies complete	Completed
Functional requirements and customer needs established	Completed

¹⁰ The AUC is a measure of test discrimination, that is, a measure of how well the model can separate those who do and do not have the disease of interest and incorporates both sensitivity and specificity into a single metric. The results range from a value of 0.5 up to 1.0 for a test with perfect discrimination.

¹¹ <https://www.mdpi.com/2075-4418/11/6/1048>. The author has not provided their consent for the statement to be included in this Prospectus.

¹² <https://www.mdpi.com/2075-4418/11/6/1048>. The author has not provided their consent for the statement to be included in this Prospectus.

¹³ https://www.rcog.org.uk/media/yhujmdvr/gtg_62-1.pdf. The author has not provided their consent for the statement to be included in this Prospectus.



α-prototype identified and evaluated	Completed
β-prototype identified	Completed
β-prototype evaluation	Current status

(iii) **Proposed activities following Admission**

The activities to be undertaken during the two-year period following Admission, include:

- (A) conducting test performance evaluation to confirm the validity of product performance and accuracy in preparation for regulatory approval applications;
- (B) cross-validation of the science in independent study cohorts;
- (C) establishment of an ISO 13485 medical device quality system¹⁴;
- (D) further development of the β-prototype kit, including the development of antibody reagents in a form suitable for commercial distribution;
- (E) development of a medical affairs strategy in preparation for applications to the FDA, Therapeutic Goods Administration (TGA) and CE for regulatory approval; and
- (F) preparation and submission of an 510(k) FDA application for the Triage Test.

An indicative timeline for the activities detailed above is provided below:

¹⁴ This is the key quality management system accreditation that covers the manufacture of medical devices. It ensures the consistent design, development, production, installation and delivery through to disposal of medical devices that are safe for their intended purpose.



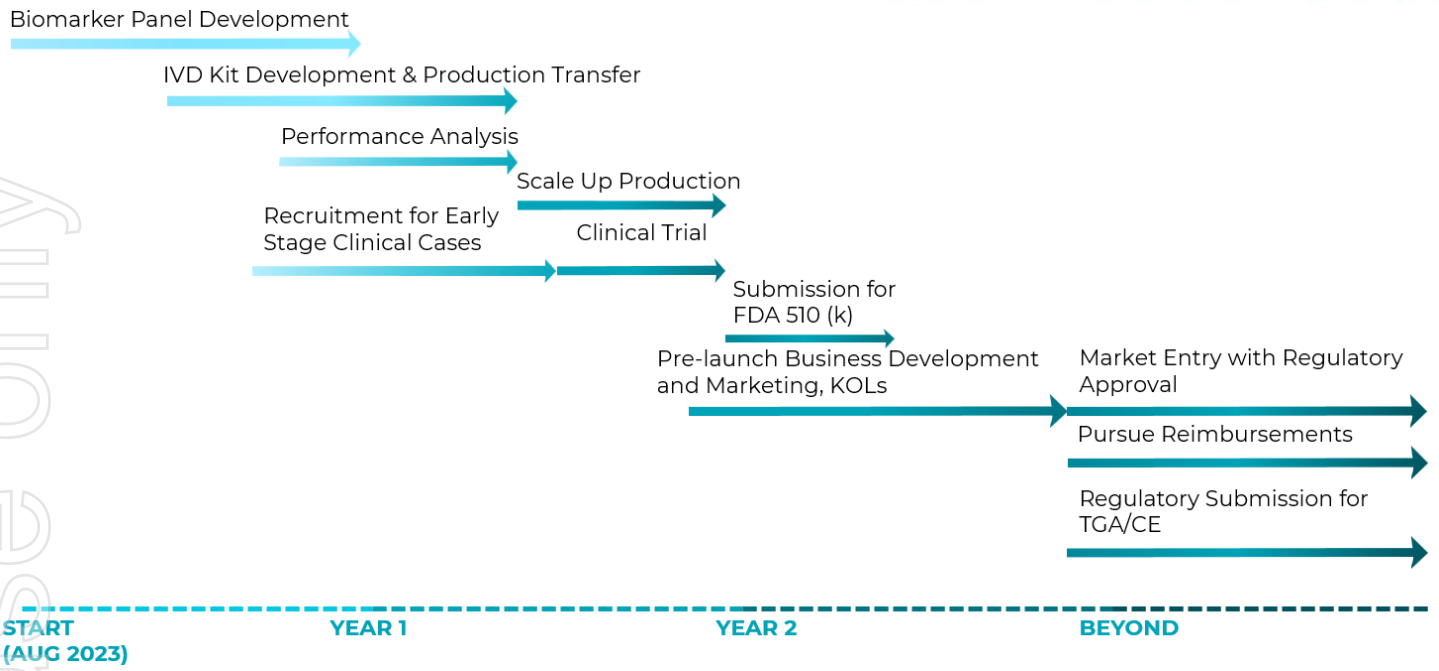


Figure 3: Indicative timeline for the commercial development of the Triage Test

The above timetable is indicative and is subject to change and to the Company obtaining further funding. There are no guarantees that the Company will be able to obtain further funding on terms satisfactory to the Company, or at all.

(iv) **Commercialisation strategy**

Transitioning the Triage Test from the research and development phase to commercialisation of the test, will involve various steps. Including, amongst other things:

- (A) test performance evaluation to ensure that the Triage Test is robust, scalable and capable of meeting the performance expectations of patients, clinicians, and testing laboratories; and
- (B) demonstrating safety and efficacy to the relevant regulatory bodies.

The key milestones to achieve commercialisation of the Triage Test are outlined below. These milestones, and the Company’s activities following Admission generally, should be read in conjunction with the risk factors detailed in Section 4.

Milestone	Details
Antibody development	<ul style="list-style-type: none"> Key to the successful commercialisation of the Triage Test will be the reliable and reproducible supply of high-quality antibodies. Research and development to date has been performed using a combination of proprietary antibodies and commercially sourced test kits for some of the target biomarker proteins. To mitigate the risks associated with the supply and quality of these key antibodies, the Company will develop and validate its own



	<p>antibodies and monoclonal antibodies for each of the target biomarker proteins.</p>
<p>IVD kit development</p>	<ul style="list-style-type: none"> • Enzyme-linked immunosorbent assays (ELISA) will be developed using antibodies developed by the Company. The performance of the In Vitro Diagnostic (IVD) kit, together with the algorithm that converts protein biomarker concentrations to an ovarian cancer risk score, will be qualified using patient samples and compared head-to-head with the equivalent commercially available kits. • Laboratory scale production and purification protocols will be translated into standard operating procedures that support the scalable production of these antibodies. • Implementation of a quality management systems that allow it to become ISO 13485 certified (the key quality management system accreditation that covers the manufacture of medical devices).
<p>Test performance evaluation</p>	<ul style="list-style-type: none"> • Further test evaluation to ensure that the product is robust, scalable, meets the performance expectations of patients, clinicians, and testing laboratories, as well as demonstrating safety and efficacy to the relevant regulatory bodies. • In support of the Company's FDA application, evidence that the Triage Test is 'Substantially Equivalent' to similar on-market tests. • These performance evaluation tests are expected to commence following the antibody development activities (and in parallel with the IVD kit development)
<p>Regulatory submissions (USA, Australia and Europe)</p>	<ul style="list-style-type: none"> • Regulatory approval provides access to target markets and a path to reimbursement approvals in the future. • FDA approval via a 510(k) application is intended to be the Company's first major regulatory submission. • The key steps in the FDA application process are as follows: (i) implement a quality management system that is ISO 13485 compliant; (ii) develop a technical file that addresses test performance characteristics and benchmarks against existing Predicate Device(s); and (iii) development of suitable product production, labelling, and instructions for use and test reporting requirements. Refer to Section 3.7 below for further information regarding the FDA application and approval process generally.



	<ul style="list-style-type: none"> • It is intended that Australian regulatory approval will be sought with the TGA under The Medical Device Single Audit Program (MDSAP) following a successful FDA approval. Refer to Section 3.7 below for further information regarding the TGA application and approval process generally. • It is intended that European regulatory approval will be sought via the 'medical device single audit program' (MDSAP) certification and 'conformity assessment' following a successful FDA approval. Refer to Section 3.7 below for further information regarding the European application and approval process generally.
--	--

(v) **Target market and demographic**

Early detection and characterisation of ovarian lesions is of utmost importance for adequate clinical management. For this reason, pre-surgical referral to a gynaecologic oncologist for those patients at high-risk of having malignancy is essential and has a proven impact on outcomes.

Current clinical guidelines, including those published by The American College of Obstetricians and Gynaecologists (**ACOG**) and The Royal College of Obstetricians and Gynaecologists (**RCOG, UK**) recommend that pre and post-menopausal women presenting with an adnexal mass be pre-operatively assessed to determine whether that mass is likely to be benign or malignant.¹⁵

The Company's target demographic for its Triage Test is intended to be:

- (A) patients who have been diagnosed with an ovarian lesion or adnexal mass; and
- (B) as a replacement to the existing current leading and comparable ovarian cancer triage tests.

(b) **Recurrence Test**

(i) **General**

Ovarian cancer has a low cure rate. Despite treatment, over 70% of patients with ovarian cancer will develop recurrence of the disease within three years.¹⁶

The current 'gold-standard' for monitoring disease recurrence is CA-125, which has FDA approval for this purpose. However, performance estimates for the use of CA-125 in this setting vary substantially, with estimates of Sensitivity¹⁷ ranging from 62-94%.¹⁸ Accordingly, an improved method for

¹⁵ [https://www.jogc.com/article/S1701-2163\(19\)30826-6/fulltext](https://www.jogc.com/article/S1701-2163(19)30826-6/fulltext). <https://www.nice.org.uk/guidance/cg122>. <https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/ovarian-masses-in-premenopausal-women-management-of-suspected-green-top-guideline-no-62/>. <https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/ovarian-cysts-in-postmenopausal-women-green-top-guideline-no-34/>. RCOG, UK and ACOG have not provided their consent to be named or for the statement to be included in this Prospectus.

¹⁶ <https://www1.racgp.org.au/ajgp/2020/october/advances-in-epithelial-ovarian-cancer>. The author has not provided their consent for the statement to be included in this Prospectus.

¹⁷ Sensitivity indicates the percentage of patients with cancer who correctly test positive.

¹⁸ [https://www.ajog.org/article/S0002-9378\(11\)00317-6/fulltext](https://www.ajog.org/article/S0002-9378(11)00317-6/fulltext). The author has not provided their consent for the statement to be included in this Prospectus.



detecting disease recurrence would allow for earlier intervention with second line surgery and therapies.

The Recurrence Test is a post-surgical test designed to identify whether a cancer is recurring following surgical removal and chemotherapy of a primary tumour.

The Recurrence Test requires further research and development in order to progress the test from 'proof of concept' stage through to α -prototype and, eventually, commercialisation.

(ii) **Existing level of operations**

Phase	Status
Proof of concept studies complete	Completed
Functional requirements and customer needs established	Current status

(iii) **Proposed activities following Admission**

The activities to be undertaken during the two year period following Admission, include:

- (A) conducting independent clinical studies on target patient populations who have had surgery to remove an ovarian cancer;
- (B) evaluation of additional biomarkers to de-risk panel selection; and
- (C) statistical modelling to confirm the preferred biomarker panel.

An indicative timeline for the activities detailed above is provided below:



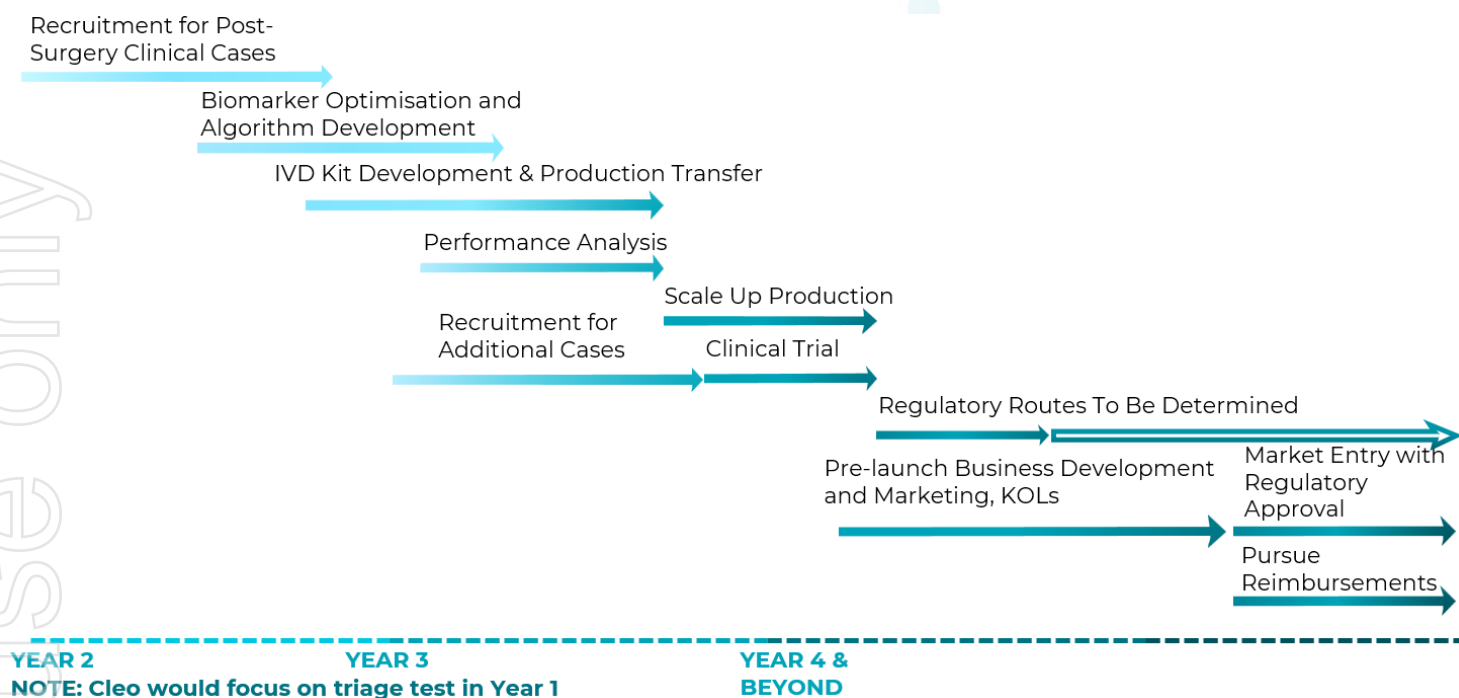


Figure 4: Indicative timeline for the commercial development of the Recurrence Test

The above timetable is indicative and is subject to change and to the Company obtaining further funding. There are no guarantees that the Company will be able to obtain further funding on terms satisfactory to the Company, or at all.

(iv) **Target market and demographic**

Over 70% of patients with ovarian cancer will develop recurrence of disease within three years.¹⁹ Early detection of tumour recurrence potentially allows improved patient management and the early intervention with second line treatment modalities.

The Company’s target demographic for its Recurrence Test will be every female who has had a surgery to remove malignant ovarian tumours.

(c) **Screening Test**

(i) **General**

The impetus for cancer screening tests is that solid tumours are more easily treated and potentially curable if they are identified early, prior to metastatic spread. When patients are diagnosed with ovarian cancer earlier, they have an increased survival rate – over 90% of Stage 1 patients are alive five years after diagnosis compared to less than 40% of Stage 4 patients.²⁰ However, only 24% of ovarian cancers are currently diagnosed at Stage 1 and Stage 2.²¹

There is currently no recommended screening test for ovarian cancer. Whilst both transvaginal ultrasound and measurement of the tumour marker CA-125

¹⁹ <https://www1.racgp.org.au/ajgp/2020/october/advances-in-epithelial-ovarian-cancer>. The author has not provided their consent for the statement to be included in this Prospectus.

²⁰ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.

²¹ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.



have been investigated for this purpose, it has been proven that neither is sufficiently sensitive or specific enough to enable the early detection of ovarian cancer in asymptomatic patients. Accordingly, there is an urgent requirement for better technologies to address this unmet clinical need.

The Screening Test is designed to identify early-stage ovarian cancer in women who do not present symptoms consistent with or indicative of ovarian cancer.

Proof of concept data suggests that the core biomarkers used in the Screening Test outperform CA-125 for the detection of Stage 1 ovarian cancer.

The Screening Test requires further research and development in order to progress the test from the 'proof of concept' stage through to α -prototype and, eventually, commercialisation.

(ii) **Existing level of operations**

Phase	Status
Proof of concept studies complete	Completed
Functional requirements and customer needs established	Completed
α -prototype identified and evaluated	Current status

(iii) **Proposed activities following Admission**

The activities to be undertaken during the two year period following Admission, include:

- (A) conducting independent clinical studies, with a focus on 'high-risk' patients to confirm test performance;
- (B) cross-validation of the science in independent prospective study cohorts;
- (C) including additional biomarkers to de-risk panel selection; and
- (D) statistical modelling to confirm preferred biomarker panel.

An indicative timeline for the activities detailed above is provided below:



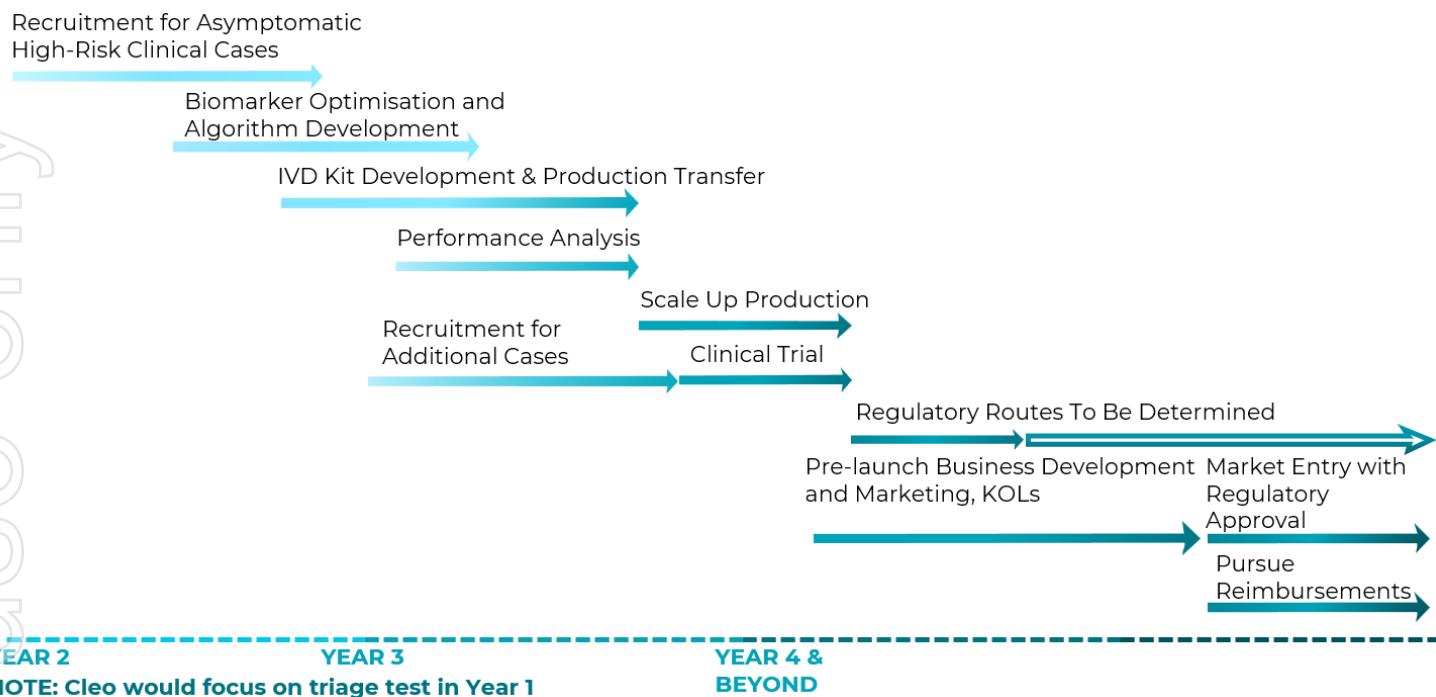


Figure 5: Indicative timeline for the commercial development of the Screening Test

The above timetable is indicative and is subject to change and to the Company obtaining further funding. There are no guarantees that the Company will be able to obtain further funding on terms satisfactory to the Company, or at all.

(iv) **Target market and demographic**

The low detection rate for early-stage ovarian cancer using existing technologies is as a result of (amongst other things):

- (1) disease progression is typically asymptomatic, with the majority of symptoms not appearing until an advanced stage of progression; and
- (2) the currently existing screening tools (CA-125 and transvaginal ultrasound) have poor sensitivities and specificities for detecting early ovarian cancer.

Given the requirement for prospective clinical data to support the screening application of the test, the Screening Test will be initially offered for use in patients with a known hereditary mutation in the BRCA1 or BRCA2 genes or to patients with an elevated family history of ovarian cancer. Both of these patient groups are at substantially increased risk of developing ovarian cancer to the general population. Notwithstanding that observation, the Company will be making applications to existing prospective studies to access validation data within a general screening population, with a view to making the test more generally available.



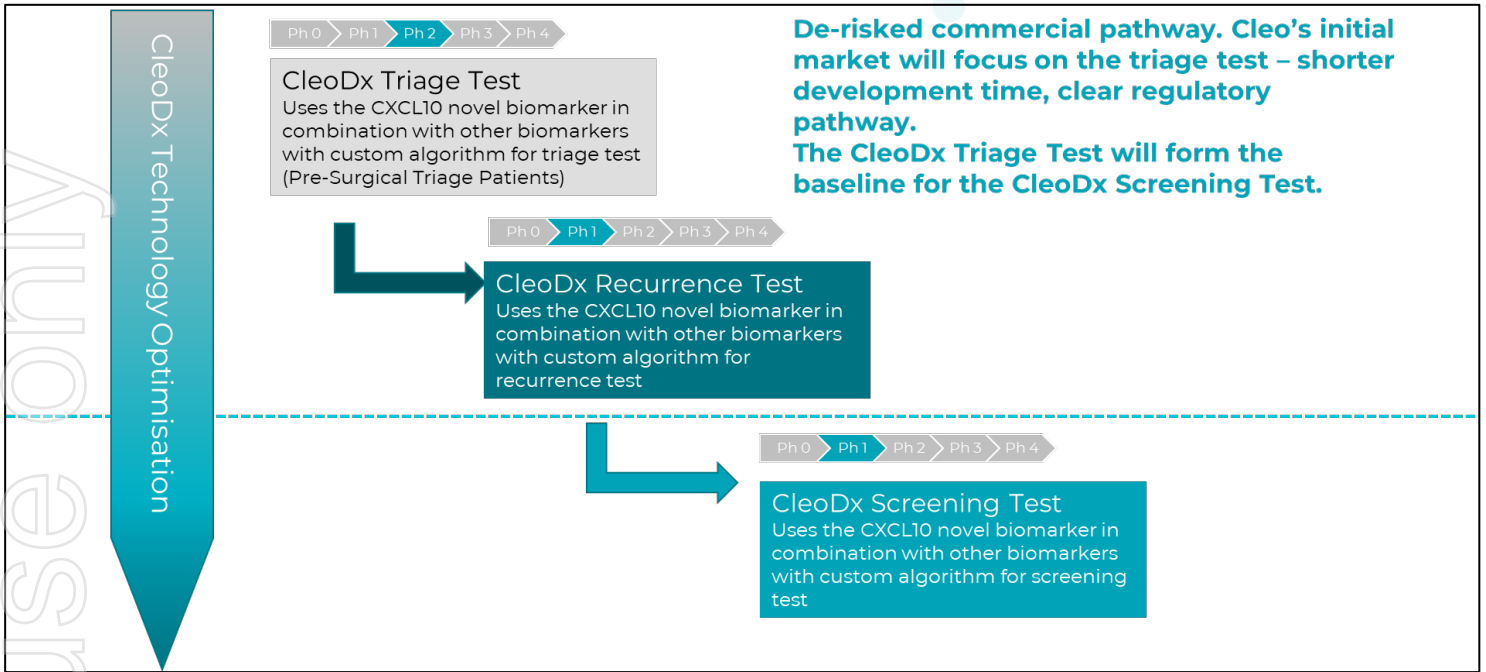


Figure 6: Phased commercial development of the three Test

2.4 Business model

The Company has implemented a commercialisation strategy, which focuses on bringing the Triage Test to market as the Company's first product. The proposed strategy enables the Company to deliver a commercial product whilst ongoing development and regulatory activities for the Screening Test and the Recurrence Test remain under development.

The Triage Test is intended to take the form of an immunoassay, with primary end users to be patients aged between 18 and 75 within the following target demographics:

- patients who have been diagnosed with an ovarian lesion or adnexal mass; and
- as a replacement to the existing current leading and comparable ovarian cancer test (CA125).

The antibodies, control proteins and the algorithm linking blood concentrations of the target biomarker proteins to an ovarian cancer risk score, are intended to form the key components of the three Tests.

The following test formats are proposed:

- ELISA kit**

A simple and widely used immunoassay system is an ELISA.

The 'sandwich' ELISA (a two-layered system incorporating "capture" and "detection" antibodies) is considered the most powerful ELISA format and this is anticipated to be the lead format for the proposed Triage Test. Centralised diagnostic laboratories can generally run such assays using existing infrastructure and with minimal training. These assays are widely sold by major multinational diagnostics companies.

The Company intends to package manufactured antibodies and control proteins into ELISA kits that can be sold to testing laboratories.

The ELISA kits can be used either by a laboratory scientist manually or adapted for use in common diagnostic laboratory high-throughput ELISA instruments and plate readers. Such kits may be provided for each of the target proteins in the test panel. It is envisaged that the laboratory would also license a software program developed and provided by the Company, which are compatible with the relevant Tests that automatically calculates the concentration for each target protein, entering these data into an algorithm that delivers the test outcome report (positive or negative or probability of malignancy). The Company will engage a third party software developer to ensure that its software programs will be compatible with the technology platforms already in place at various diagnostic laboratories. The Company has not yet engaged such a developer, but expects to be able to readily engage such a developer on a contractual basis during the IVD kit development stage of the commercial development of the Triage Test.

(b) **Vendor-specific immunoassay**

Development of ELISA assays on established vendor-specific diagnostic platforms may also provide potential for accelerated market penetration of the Triage Test. In this situation, the Company would create custom optimised antibodies and reagents and sell them directly to a vendor, who would then package them for application on their proprietary systems.

This format would enable the Company to choose strategically whether to partner on a regional basis or exclusively with a leading multinational vendor.

2.5 Sources of financing

From Admission, the Company's key sources of financing will consist of the \$12,000,000 (before costs) to be raised under the Public Offer (assuming the Minimum Subscription is raised) in addition to its existing cash balance just before the Prospectus Date. The Company may be required to raise additional capital in the future to fund its operations (see Section 4.1(a) for further details).

The Company does not have any debt facilities or lines of credit.

2.6 Sources of expenses

The Company expects its expenses will primarily consist of:

- (a) the costs of the Offer (see Section 8.8);
- (b) cost of employees' salaries and wages and associated staff on-costs;
- (c) research and development expenses, some of which are capitalised as intangible assets;
- (d) intellectual property and patent maintenance and protection costs;
- (e) capital expenditure associated with manufacturing;
- (f) business development, sales and marketing;
- (g) consumables and machine maintenance costs; and
- (h) general administration/overhead and corporate expenses.



2.7 Key business model dependencies

The key dependencies for the Company to meet its objectives are:

- (a) sufficient market awareness and industry adoption;
- (b) build a sufficient customer base of ongoing commercial arrangements;
- (c) being able to continue to maintain the Hudson Licence Agreement and to maintain, protect and develop the Licenced Technology;
- (d) further product development to increase the functionality and performance of the Licenced Technology;
- (e) sufficient funding to ensure the Company is able to complete development;
- (f) future access to additional capital, should it be required to fund potential future growth;
- (g) a stable in-bound supply chain to ensure the ongoing ability to design, manufacture and deliver its products;
- (h) the ability to design and deliver an effective operating model that can scale to deliver global;
- (i) the ability to continually protect and advance the Company's existing knowledge and intellectual property rights and trade secrets;
- (j) attracting and retaining key staff and personnel; and
- (k) retaining competent operational management and prudent financial administration, including the availability and reliability of appropriately skilled and experienced employees, contractors and consultants.

2.8 Intellectual property

On 23 March 2023, the patent in Australia was granted (as patent number 2020404453). The patent in the United States is expected to be granted in the next three months. The PCT Application is currently pending in China, Europe, Israel, India, Japan, Korea, New Zealand and Singapore.

A summary of the Company's patent applications is detailed below:

Country	Official No.	Status	Predicted expiry
Australia	2020404453	Granted	18 December 2040
Australia	2023201412	Pending	18 December 2040
China	202080096729.7	Pending	18 December 2040
Europe	20901736.7	Pending	18 December 2040
Israel	294045	Pending	18 December 2040



Country	Official No.	Status	Predicted expiry
India	202217041027	Pending	18 December 2040
Japan	2022-538319	Pending	18 December 2040
Korea	10-2022-7025148	Pending	18 December 2040
New Zealand	789356	Pending	18 December 2040
Singapore	11202250168F	Pending	18 December 2040
United States	17/783,528	Allowed	18 December 2040
United States	To be confirmed	Not yet filed	18 December 2040

As more data is accrued on the Company's individual test formats, subsequent to the original patent filing, the Company may 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.

The Hudson Licence Agreement also includes know-how and expertise relating to blood-based protein biomarkers for ovarian cancer which indicates potential for:

- (a) the improved detection of early stage cancers;
- (b) the detection of post-surgical disease recurrence; and
- (c) prognostic markers to help inform disease management.

In addition to the above, the Company also protects its trade secrets and know how through contractual provisions entered into with its customers, employees, contractors and other parties as required.

The Company will implement patent life extension and new intellectual property strategies. Intellectual property developed by third party contractors will be captured using appropriate contracts.

For further information please see the Intellectual Property Report contained in Annexure A.

2.9 Dividend policy

The Company does not expect to pay dividends in the near future as its focus will primarily be on growing the existing business.

Any future determination as to the payment of dividends by the Company will be at the discretion of the Directors and will depend on the availability of distributable earnings, operating results, the financial condition of the Company, future capital requirements and other factors considered relevant by the Directors. The Company cannot give any assurances in relation to the payment of dividends or franking credits.



3. Industry overview

3.1 Introduction

The Company is focused on the development of non-invasive blood based IVD tests to detect the presence, and recurrence, of ovarian cancer. The Company's first product to market is intended to be the Triage Test which has to date produced strong results to accurately differentiate patients with malignant ovarian cancer from those with benign gynaecological conditions. As noted in Section 2, the Tests rely on the same underlying core technology. Using sequential clinical trials, the Company intends to expand the potential uses for this technology in its Screening Test and Recurrence Test.

The Company aims to improve the diagnostic process and procedures for detecting ovarian cancer and, in this regard, improve quality-of-life outcomes for patients who have been diagnosed with ovarian cancer. The Licenced Technology development strategy is centred around three key pillars:

- (a) *Detect effectively* - enhance the accuracy of ovarian cancer detection, particularly at early stages of development and thereby reduce the rate of false positives and false negatives;
- (b) *Detect earlier* – providing improved ability to identify and triage patients more effectively, and pave the way towards earlier diagnosis of malignancy with the aim of allowing earlier intervention in the treatment of patients with ovarian cancer; and
- (c) *Treat efficiently* - improve the referral process and better inform clinical decision-making workflows.

There are various factors that increase a female's risk of developing ovarian cancer. Age, family history, hormonal and reproductive factors, lifestyle, geographical location all impact a female's chance of developing ovarian cancer. However, there is currently no screening procedure for ovarian cancer recommended for routine use in the general population. Moreover, the current existing screening tools (CA-125 and transvaginal ultrasound) have poor sensitivities and specificities for detecting early ovarian cancer. In this regard, the Company is seeking to address certain market needs with its proposed portfolio of ovarian cancer tests.

3.2 Ovarian cancer – a global issue

Ovarian cancer is the seventh most common form of cancer, and the eighth most common cause of death from cancer in females worldwide.²² There were more than 313,000 new cases of ovarian cancer in 2020, with approximately 200,000 deaths.²³ The majority of ovarian cancer patients are diagnosed at very late stages of the disease, typically Stages 3 or 4, where treatment is more difficult and largely ineffective.

Ovarian cancer is considered a rare disease; however, it is one of the most lethal of cancers for females, with a five-year survival for less than 40% of patients at advanced stages of the disease.²⁴

²² <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21492>. The author has not provided their consent for the statement to be included in this Prospectus.

²³ <https://qco.iarc.fr/today/data/factsheets/cancers/25-Ovary-fact-sheet.pdf>. The author has not provided their consent for the statement to be included in this Prospectus.

²⁴ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.



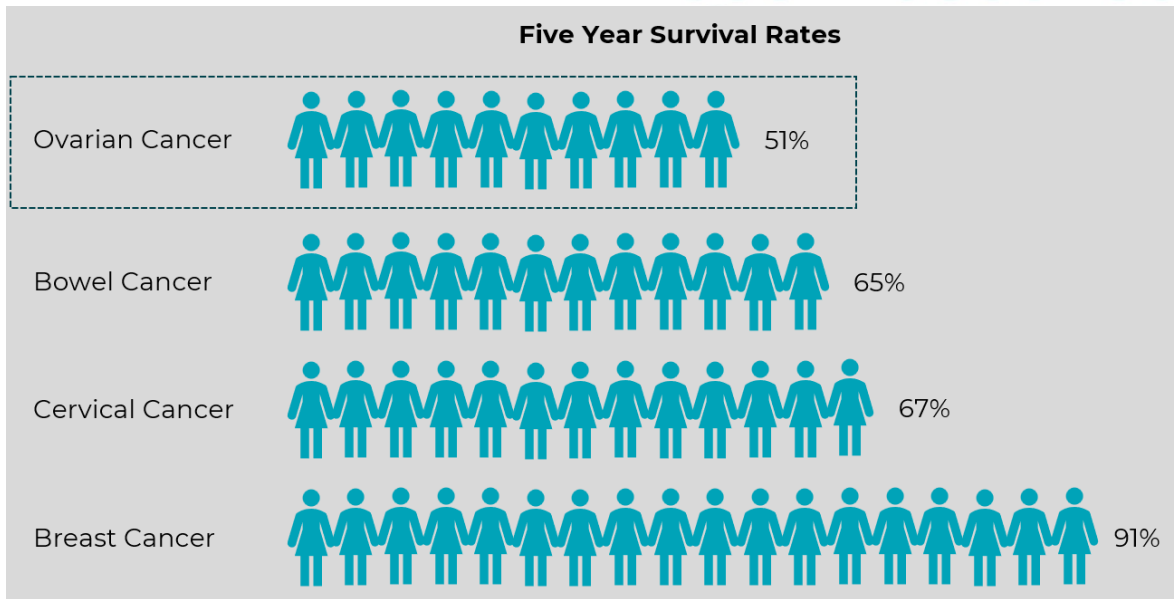


Figure 7: 5-year relative survival rates for women’s cancers across all stages. Derived from the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) Program²⁵

Age standardised incidence rates of ovarian cancer vary around the world. The WHO’s Global Cancer Observatory (**GLOBOCAN**) 2020 data shows ovarian cancer is highest in first world regions (including Europe, the United States and Oceania).²⁶

GLOBOCAN predicts that by 2040, the incidence rates of ovarian cancer will increase by 37%, with a predicated total of approximately 429,000 new cases per year.²⁷ Morality rates are also expected to rise, with the number of deaths per year to reach up to approximately 48%, representing a predicated total of approximately 305,000 deaths per year.²⁸



²⁵ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.

²⁶ <https://gco.iarc.fr/today/data/factsheets/cancers/25-Ovary-fact-sheet.pdf>. The author has not provided their consent for the statement to be included in this Prospectus.

²⁷ <https://gco.iarc.fr/>. The author has not provided their consent for the statement to be included in this Prospectus.

²⁸ <https://gco.iarc.fr/>. The author has not provided their consent for the statement to be included in this Prospectus.



Figure 8: Summary of the recorded incidence and mortality rates of ovarian cancer for 2020 and estimates for 2040²⁹

	Ovarian cancer incidence 2020	Ovarian cancer mortality 2020
USA	8.8	4.1
Europe	8.1	4.9
Australia	6.4	3.9
	Predicted ovarian cancer incidence for 2040	Predicted ovarian cancer mortality for 2040
USA	12.1	6.1
Europe	11.1	7.3
Australia	8.8	5.8

Note: Rate per 100,000 women.

3.3 Impact of diagnosis timing

Ovarian cancers comprise at least five different histological subtypes with different identifiable risk factors, cells of origin, molecular compositions, clinical features, and treatments. The most diagnosed form of ovarian cancers is the epithelial histological subtype (accounting for ~90% of all diagnoses),³⁰ including serous, endometrioid, clear-cell and mucinous carcinomas. High-grade serous carcinoma is the most commonly diagnosed epithelial ovarian cancer, and typically presents as an advanced stage, aggressive disease with a high mortality rate.

Pathological evaluation and tumour staging of ovarian cancer is based on surgical assessment of the cancer at initial diagnosis, including removal of lymph nodes, tissue biopsy and abdominal fluid, and uses the International Federation of Gynaecology and Obstetrics staging system.

Most females with ovarian cancer are diagnosed in later life, the median age of diagnosis is 63 years old.³¹ Ovarian cancers are typically asymptomatic during early progression, and even in patients with advanced disease, symptoms can be nonspecific and easily missed, or attributed to other disease processes. As such, diagnosis frequently only occurs when the cancer has reached a late stage (either Stage 3 or 4) and symptoms have become apparent and require intervention.

²⁹ <https://gco.iarc.fr/>. The author has not provided their consent for the statement to be included in this Prospectus.

³⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7290868/>. The author has not provided their consent for the statement to be included in this Prospectus.

³¹ <https://www.cancer.org/cancer/types/ovarian-cancer/about/key-statistics.html>. The author has not provided their consent for the statement to be included in this Prospectus.



For personal use only

Early and accurate diagnosis is critical to increased survival rates. Over 90% of patients are alive five years after diagnosis if their disease is detected whilst confined to the ovary (Stage 1), compared to less than 40% when detected at Stage 4.³² Currently, only 18% of ovarian cancers are diagnosed at Stage 1.³³ Accordingly, improved detection methods for early-stage ovarian cancer may have the potential to increase overall survival rates.

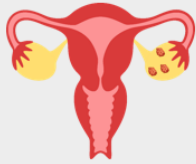
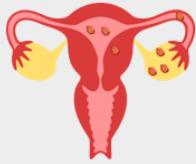
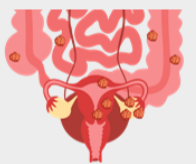

Stage	I	II	III	IV
Description				
	Cancer is found in one or both of the ovaries	Cancer has spread to other parts of the pelvis (e.g. uterus)	Cancer has spread to the abdomen (e.g. intestines)	Cancer has spread beyond the abdomen (e.g. lungs)
5-Year Relative Survival Rate	89%	71%	41%	20%
Percent of cases at diagnosis	23%	8%	34%	26%

Figure 9: The clinical stages and associated 5-year survival rates of ovarian cancer³⁴

3.4 Economics

Cancer represents a significant source of disease burden, both clinically and economically.

In 2015, US healthcare costs associated with cancer were \$183 billion and projections based on population growth suggested an increase to \$246 billion by 2030.³⁵ According to the National Cancer Institute, the expenditure on ovarian cancer was approximately \$6.4 billion in 2020.³⁶

Costs for ovarian cancer treatment are approximately 3.4-fold higher on a per-patient basis when the disease is detected at Stage 4, compared to Stage 1.³⁷ Accordingly, a successful diagnostic for early-stage ovarian cancer has the potential to not only save lives, but also provide a significant economic benefit to healthcare systems globally.

3.5 Current testing landscape

The current existing diagnostic tools (CA-125 and transvaginal ultrasound) have poor sensitivities and specificities for detecting early ovarian cancer. Sensitivity for early stage (Stage 1 and 2) ovarian cancer must improve to have a greater impact on mortality.

Moreover, although the existing diagnostic tools are helpful for detecting ovarian cancer (particularly late stage), results from the Company’s clinical studies have shown that the Triage Test significantly outperforms these current clinical standard tests.

³² <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.

³³ <https://seer.cancer.gov/statfacts/html/ovary.html>. The author has not provided their consent for the statement to be included in this Prospectus.

³⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6621554/>. The author has not provided their consent for the statement to be included in this Prospectus.

³⁵ <https://bmchealthservres.biomedcentral.com/counter/pdf/10.1186/s12913-022-08457-6.pdf>. The author has not provided their consent for the statement to be included in this Prospectus.

³⁶ https://progressreport.cancer.gov/after/economic_burden#field_additional_information. The author has not provided their consent for the statement to be included in this Prospectus.

³⁷ <https://bmchealthservres.biomedcentral.com/counter/pdf/10.1186/s12913-022-08457-6.pdf>. The author has not provided their consent for the statement to be included in this Prospectus.





Region	USA	EUR	AUS
New cases	26.5k	66.7k	1.8k
Living with cancer	235k	590k	16k
Number of women >50 who could benefit from annual screening	61.6M	83.6M	4.2M

Figure 10: Estimated addressable markets for the Screening Test (Those Living with Cancer would be eligible for a recurrence test every 3 months for 5-years of follow-up)³⁸

Addressable markets are limited by items such as patent protection, regulatory approvals and access to distribution, amongst other factors. The Company’s patent protection is set out in Section 2.8 and its regulatory pathway is set out in Section 3.7. Subject to the grant of a patent in the USA, the Company’s primary target market will be the USA, followed by Australia and Europe.

In patients with indicative symptoms for ovarian cancer, diagnostic work-up includes physical (pelvic) examination of the patient; radiographic imaging (usually transvaginal ultrasonography); and a CA-125 blood test. These three tests are generally used to determine the need for referral to a specialist for exploratory surgery - laparoscopic surgery with removal of the mass is routinely recommended. Biopsies are not generally performed on potential ovarian tumours due to the risk of ‘seeding’ the abdominal cavity during the procedure (seeding occurs when tumour cells are dislodged during the procedure and subsequently grow to form new tumours inside the abdomen). A definitive diagnosis can only be made following surgery.

The Directors believe the Company’s three ovarian cancer tests will hopefully address certain unmet needs of the diagnostic landscape for ovarian cancer, as outlined below.

³⁸ <https://seer.cancer.gov/statfacts/html/ovary.html>. <https://qco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf>. <https://www.canceraustralia.gov.au/cancer-types/ovarian-cancer/statistics#:~:text=In%202018%2C%20there%20were%201%2C710,will%20be%20diagnosed%20in%20Australia.> <https://www.census.gov/data/datasets/time-series/demo/popest/2020s-national-detail.html>. <https://www.abs.gov.au/statistics/people/population/population-census/latest-release#:~:text=The%202021%20Census%20counted%2025%2C422%2C788%20people%20in%20Australia,with%20the%20median%20age%20of%2039%20years%20old>. The authors have not provided their consent for the statements to be included in this Prospectus.



Unmet need	Cleo test to address unmet need	Potential benefits
Accurate identification and differentiation of masses prior to surgical intervention	Triage Test	<ul style="list-style-type: none"> Allows for appropriate design of treatment options before surgical intervention. Improved resource allocation and patient outcomes.
Identification of early-stage ovarian cancer	Screening Test	<ul style="list-style-type: none"> Allows medical intervention before cancer spreads when treatment is most effective. Potential decrease in overall mortality rates.
Early identification of cancer recurrence	Recurrence Test	<ul style="list-style-type: none"> Allows for earlier intervention to control / manage disease progression. Provides time to explore alternative treatment options (if available).

3.6 Competitive landscape

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

There are various commercial players based in Australia and internationally, which are seeking to develop IVD cancer diagnostics for ovarian cancer. These companies and their products are at varying stages of development. Based on publicly available information, the Company considers the following entities to be its main competitors in the ovarian cancer diagnostics space:

Company	Diagnostic focus	Stage of development	Website
Fujirebio Diagnostics Inc	Multiple cancers and diseases	ROMA triage test, currently available on market	https://www.fujirebio.com
Aspira Women's Health	Gynecologic health	OVA1 triage test, currently available on market	https://aspirawh.com
GRAIL	Multi-cancer diagnostics	Galleri multitask, currently in implementation trials	https://grail.com/
Exact Sciences	Multi-cancer diagnostics	Development stage (not yet commercially available)	https://www.exactsciences.com



INOVIQ Ltd (ASX: IIQ)	Multiple cancers	Development stage (not yet commercially available)	https://www.inoviq.com
InterVenn Biosciences	Multiple cancers and diseases	LDT, currently available on market	https://intervenn.com

The above competitors have not provided their consent for the above statements to be included in this Prospectus.

3.7 Regulatory approval pathways

The Triage Test is intended to be the Company's first product to market.

It is envisaged that the Company will seek FDA approval first for the Triage Test, followed by TGA and CE approvals, in Australia and Europe (respectively). FDA approval is intended to be sought via a 510(k) application which is based upon a 'Predicate Device' already on market. The Company expects that a successful FDA application will establish a clear path forward for TGA and CE approvals to follow shortly thereafter.

Following manufacture of the final Triage Test prototype, expected to be in the form of an ELISA kit, the Company will conduct further test performance evaluation to confirm, at a minimum, substantial equivalence with the existing diagnostic tests, together with standard validation and verification of kit components.

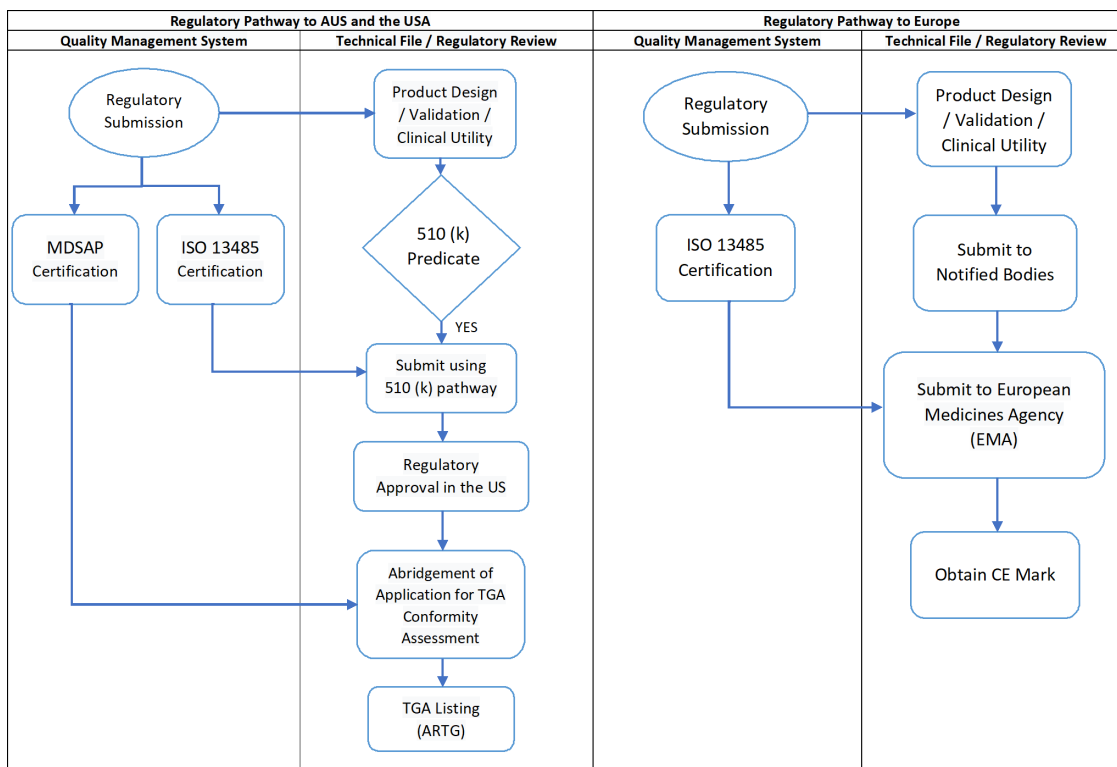


Figure 11: Regulatory approval pathways for the Triage Test in the USA, Europe and Australia



4. Risk factors

The Securities offered under this Prospectus are considered speculative. Before applying for Securities, any prospective investor should be satisfied that they have a sufficient understanding of the risks involved in making an investment in the Company and whether it is a suitable investment, having regard to their own investment objectives, financial circumstances and taxation position.

There can be no guarantee that the Company will deliver on its business strategy, or that any forward-looking statement contained in this Prospectus will be achieved or realised. Investors should note that past performance is not a reliable indicator of future performance.

The Directors strongly recommend investors examine the contents of this Prospectus and consult their professional advisers before deciding whether to apply for Securities pursuant to this Prospectus.

In addition, investors should be aware there are risks associated with an investment in the Company. There are certain specific risks which relate directly to the Company's business and are largely beyond the control of the Company and the Directors because of the nature of the business of the Company. Those risks, along with other specific and general risks involved in investing in the Company, are set out in more detail in this Section 4.

The risks described below are not to be taken as exhaustive. Where relevant, the risks below assume completion of the Offers have occurred. The specific risks considered below, and other risks and uncertainties not currently known to the Company, or that are currently considered immaterial, may materially and adversely affect the Company's business operations, the financial performance of the Company and the value and market price of the Company's Securities.

4.1 Risks specific to the Company and the industry generally

(a) Additional capital requirements

The Company has no operating revenue and is unlikely to generate any operating revenue unless and until the Triage Test is successfully developed and commercialised. The future capital requirements of the Company will depend on many factors including its business development activities. The Company believes its available cash and the net proceeds of the Public Offer should be adequate to fund its activities and objectives for the two year period following Admission as detailed in Sections 1.5 and 2.5 above.

The Company's proposed activities following Admission involve significant financial risk and capital investment. The Company may never generate revenue or achieve profitability.

The Company will require further financing in the future, in addition to amounts raised pursuant to the Public Offer. The Company also has an obligation to pay \$1,500,000 (excluding GST) to Hudson upon the satisfaction of the first regulatory approval of the Technology in the USA, Australia, Europe or Japan. The Company has not set aside funds for the payment of the \$1,500,000 in its current use of funds (see Section 1.5) and may be required to raise capital through the issue of further Shares prior to paying the \$1,500,000, which will have a dilutionary impact on Shareholders. It is also possible further capital may be required at an earlier stage if any risks, including those described in this Section 4 materialise. Any additional equity financing may be dilutive to Shareholders, may be undertaken at lower prices than the then market price (or Offer Price) or may involve restrictive covenants which limit the Company's



operations and business strategy. Debt financing, if available, may involve restrictions on financing and operating activities or the registering of security interests over the Company's assets. Although the Directors believe that additional capital can be obtained, no assurances can be made that appropriate capital or funding, if and when needed, will be available on terms favourable to the Company or at all.

The Company may undertake additional offerings of Securities in the future. The increase in the number of Shares issued and outstanding and the possibility of sales of such Shares may have a depressive effect on the price of Shares. In addition, as a result of the offering of such additional Shares, the voting power of the Company's existing Shareholders will be diluted.

(b) **Intellectual property risks**

The Company's success, in part, depends on its ability to obtain patents, maintain trade secret protection, and operate without infringing the intellectual proprietary rights of third parties. If patents are not granted, or granted only for limited claims, the Company's licenced intellectual property may not be adequately protected and may be able to be copied, reproduced or otherwise circumvented by third parties.

There is no guarantee that the Company's licenced intellectual property comprises all the rights that the Company may require to commercialise its products. There can also be no assurance that any patents which the Company may own, access or control will afford the Company commercially significant protection of its technology or its products.

The Company's existing intellectual property includes the Company's licencing rights under the Hudson Licence Agreement (see Section 7.1 for further information). The Company has, under the Hudson Licence Agreement, acquired (amongst other things) the rights to various patent applications pending in a number of countries based on international (PCT) application no PCT/AU2020/051403. On 23 March 2023, the patent in Australia was granted (as patent number 2020404453). The patent in the United States is expected to be granted in the next three months. Patent applications are currently pending in China, Europe, Israel, India, Japan, Korea, New Zealand and Singapore. Refer to section 1.4.2 of the Intellectual Report at Annexure A for further details.

Although the Patent in Australia has been granted, investors should be aware that the granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid the Company's patented technology. Moreover, 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 also possible that 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.

There is a risk that the Company's licenced intellectual property rights, including its patents (granted and applications), may be challenged (or threatened to be) by a third party at any time. If any of the Company's licenced intellectual property rights are challenged, the Company would need to defend such claims, which is costly and may result in the Company incurring significant costs, management time and reputational damage, any of which would be adverse to the Company's financial performance.

The Company is aware that in the US diagnostic methods generally are becoming increasingly difficult to patent. If the Company's US patent application is ultimately not granted by the United States Patent and Trademark Office (**USPTO**), although the Company's patent application would constitute prior art, competitors may seek to



utilise the information contained in the Company's US patent application to develop competing products which could adversely impact the Company's ability to commercialise its products in the US or otherwise substantially dilute its market share.

(c) **Licencing risk**

Pursuant to the Hudson Licence Agreement, the Company has a worldwide exclusive licence to use, sub-licence, develop, modify and commercialise the Licenced Technology which underpins its operations, rather than having ownership of that intellectual property. Termination of the Hudson Licence Agreement would have an adverse effect on the operations and financial position of the Company.

Hudson has a right to terminate the Hudson Licence Agreement if the Company commits a material breach, and that breach is not remedied within 30 days after notice to do so (see Section 7.1 for further details). If the Hudson Licence Agreement is terminated this will have a material adverse effect on the Company's operations, its ability to continue to commercialise the Tests and, in this regard, maintain a listing on ASX. As previously noted, the Company may pursue and assess other new business opportunities in the biotechnology and medtech sectors over time which complement its business. These new business opportunities may take the form of direct or passive investments. At present, the Company is not pursuing any such acquisitions.

As at the Prospectus Date, the Directors confirm that the Company is not in breach of the Hudson Licence Agreement, and they are not aware of any facts or circumstances that may give Hudson a right to terminate the Hudson Licence Agreement.

(d) **Intellectual property infringement**

The Company has engaged FB Rice to develop and implement an intellectual property strategy to seek to establish patent protection in its proposed key markets as a means of enabling the Company to guard its exclusivity, maintain an advantage over competitors and provide it with a basis for enforcement in the event of infringement (or potential infringement) of the Company's licenced intellectual property rights by third parties. Notwithstanding this strategy, there is always a risk of third parties claiming an involvement in medical discoveries and, if disputes arise, such claims or disputes can adversely affect the Company, its reputation and financial performance. Further, competition in retaining and sustaining protection of intellectual property, and the complex nature of intellectual property and its protection, can lead to expensive and lengthy disputes for which there can be no guaranteed outcome.

In the event of a dispute, the Company's potential competitors may potentially be able to sustain costs of litigation or proceedings more effectively than the Company because of comparatively greater financial resources. In addition, parties making claims against the Company may obtain injunctive or other relief to prevent the Company from further developing or commercialising its products. In the event a successful claim of infringement is made 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 such licences at a reasonable cost, or at all, it may encounter delays and lose substantial resources while seeking to develop alternative products.

The Company is unable to state with certainty that another party will not claim (or threaten) its rights are infringed or, if litigation claiming that the Company is infringing the intellectual property rights of a third party is launched, what the result of any such litigation will be.



The enforcement of intellectual property rights is dependent on a strong and impartial rule of law. In the event that intellectual property infringement occurs in a jurisdiction without a strong and impartial judicial system that recognises the Company's licenced intellectual property rights, infringement of the Company's licenced intellectual property may occur and the Company may be unable to successfully enforce its rights.

(e) **Trade secrets and confidentiality**

The Company relies on trade secrets, which include information relating to the method, construction and use of its products. The protective measures employed by the Company may not provide adequate protection of its trade secrets which may erode any 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 Company's trade secrets.

There can be no assurance employees, consultants or third parties will not breach confidentiality, infringe and/or misappropriate the Company's licenced intellectual property. The Company seeks to mitigate the risk of unauthorised use of its intellectual property by limiting disclosure of sensitive material to particular employees, consultants and others on a need to know basis. Where appropriate, parties having access to such sensitive information will be required to provide written commitments to confidentiality and ownership of intellectual property.

(f) **Development and uncertainty of research**

The development and commercialisation of medical diagnostic products is subject to an inherent and high risk of failure. The key steps in the Company's development strategy for the Triage Test are set out in Section 2.3(a)(iv) above and, in summary, include:

- (i) **(antibody development)**: the successful in-house development of protein reagents and monoclonal antibodies for each of the target biomarker proteins which is anticipated to reduce reliance on commercial assays;
- (ii) **(test performance evaluation)**: test evaluation to ensure that the product is robust, scalable, meets the performance expectations of patients, clinicians, and testing laboratories, as well as demonstrating safety and efficacy to the relevant regulatory bodies; and
- (iii) **(regulatory submissions)**: subject to the foregoing, the initial FDA 510(k) application and subsequent Australian and European regulatory approvals.

The Company's efforts to develop in-house reagents for its Triage Test may be unsuccessful resulting in a reliance on commercially available reagents, which may increase supply and quality control risks. On the other hand, in-house reagents may have different performance characteristics from those commercially available reagents used in earlier clinical trials for the Triage Test, giving rise to additional research and development and the potential for greater than anticipated complexity, cost and delays in commercialisation of the Triage Test.

Success in commercialisation of the Triage Test is dependent upon the satisfaction of the milestones set out in Section 2.3(a)(iv) above. Failure to achieve any one or more of these milestones could have an adverse effect on the Company's development activities and financial position.

Related to the above, the Company is and will continue to be reliant on the results received from the research and development it undertakes on its Screening Test and



Recurrence Test, including, for example, the results of clinical studies. While the Company is encouraged by trial results to date and will conduct or participate in future clinical trials on the advice of management and consultants with considerable industry experience, as it seeks to move to commercialisation of its Screening Test and Recurrence Test in the long term, those trials can be expensive, time consuming and involve potential delay. There is no certainty the results of those trials will demonstrate any material benefit or advancement in efficacy over existing alternatives or potential new products, and there is the potential for the product to be found to be ineffective or unsafe for public use. Further, the success of clinical trials may be impacted by the ability to recruit patients to participate, lack of product effectiveness in trials, compliance with ethics protocols, modifications or adaptations to trial protocols, failure to meet trial end points, and changes to regulations governing the conduct of trials.

Separately, there is the potential that the results of clinical trials for the Screening Test and the Recurrence Test may deliver results which requires a change in strategy (see also Section 4.1(m) below) which, in particular may result in a decision to remove existing, and/or add additional, target biomarker proteins to the current prototype biomarker panel resulting in additional research and development and greater than anticipated complexity and cost in commercialisation.

(g) **Regulatory approvals**

Product commercialisation and development involves lengthy processes that are dependent on the evaluation by external groups such as the FDA (in the US), 'CE marking' (in the European Union) and approval from the TGA (in Australia). There is no guarantee the Company will meet the relevant regulator's benchmarks for its Triage Test, which may require the Company to conduct further clinical studies, resulting in significant cost and delay, and which may ultimately result in a failure to receive the necessary regulatory approvals in one, or multiple, key markets for the Company's Triage Test.

(h) **Market acceptance and competitor risks**

Ultimately any products developed by the Company need to find acceptance in a competitive market. Market acceptance depends on numerous factors, including convincing potential consumers and partners of the attractiveness of the Company's product and the ability to manufacture products to a sufficient quality and quantity to meet commercial demand at an acceptable cost. These and other factors may cause the Company's product to not gain market acceptance and will negatively affect the profitability of the Company.

The Company is subject to risk from competitors including the introduction of new and emerging technologies or inventions, and/or improvements or price reductions in existing diagnostic or treatment options for ovarian cancer. An overview of the competitive landscape is set out in Section 3.6 above.

The medical diagnostic industry is highly competitive and includes large, well-established and well-funded corporations who have access to substantially greater resources and more markets than the Company and which may be able to adopt aggressive research and development and marketing strategies to rapidly capture market share. There may also be other aggressive, fast-moving, early stage, start-up companies that are developing comparable or competing technologies. The Company intends to maintain a close watching brief on existing and emerging diagnostic tests for ovarian cancer as well new patent applications relevant to the field as they are published.



(i) **Reimbursement**

In both domestic and foreign markets, sales of Cleo'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.

(j) **Sufficiency of funding**

The Company has provided an indication of how it intends to apply its existing funds, including funds raised under the Public Offer, over the 24 months period following the Company's Admission (see Section 1.5 above for further information).

The Company will need to engage various consultants in connection with the manufacture of protein reagents for its products, regulatory affairs and the conduct of future clinical trials for its Screening Test and Recurrence Test. The Company has allocated funds to such engagements in its use of funds in Section 1.5 above. However, no assurances can be made that the Company's preferred candidates, if and when needed, will be available, and that the terms of any such engagements will be on terms favourable to the Company or within the proposed budget.

(k) **Dependence on key personnel and contractors**

The Company is dependent on the expertise of its key management and its ability to contract with third-party research and development providers including for the conduct of future clinical trials for its Screening Test and Recurrence Test. The loss of key management or the inability to reach agreements with research and development providers could materially adversely affect the Company. Given the nature of the Company's activities, its ability to achieve its development and commercialisation program is dependent on its ability to attract and maintain appropriately qualified personnel either within the Company or through contractual arrangements.

(l) **Product risks and liability**

As with all new public health products, even if the Company was successful in development of its products and obtains regulatory approvals, there is no assurance unforeseen adverse events or manufacturing defects will not arise. Adverse events could expose the Company to product liability claims in litigation, potentially resulting in any regulatory approval (when/if obtained) being removed and damages being awarded against the Company. In such event, the Company's liability may exceed the Company's insurance coverage (if any). The efficacy and results of trials relating to future products will rely on the proper implementation of use/testing protocols which may include requirements for clinicians and diagnostic labs to adhere to standard operating procedures for collection and processing of blood samples. While none of the anticipated requirements of the proposed Cleo products are expected to be onerous or unusual, a failure to adhere to these requirements may adversely affect the efficacy and reliability of test results.



(m) **Change in strategy**

The Company's plans and strategies may evolve over time due to review and assessment of, amongst other things, trial results and data, market trends, the outcome of its intellectual property registrations/applications, changes in policy or regulations, the level of market acceptance in particular jurisdictions or markets and the emergence of new technologies or improvements in existing technology. As a result, the current strategies, approaches, plans and products of the Company may not reflect the strategies, approaches, plans and products pursued at a later date. Any such changes have the potential to expose the Company to additional risks.

As noted in Section 2.4 above, bringing the Triage Test to market is the Company's key focus. However, the Company also understands the importance of opportunities for diversification. While investigation and development of new product opportunities will be important to the Company's future, active pursuit of such opportunities is intended to remain secondary to the Triage Test commercialisation program.

4.2 General risks

(a) **Securities investments**

There are risks associated with any securities investment. The prices at which the securities of the Company trade may fluctuate in response to a number of factors. Furthermore, the stock market, and in particular the market for technology companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. There can be no guarantee that trading prices will be sustained. These factors may materially affect the market price of the securities of the Company regardless of its operational performance.

(b) **Share market conditions**

Share market conditions may affect the value of the Company's quoted Securities regardless of the Company's operating performance. Share market conditions are affected by many factors such as:

- (i) general economic outlook;
- (ii) introduction of tax reform or other new legislation;
- (iii) pandemics;
- (iv) interest rates and inflation rates;
- (v) changes in investor sentiment toward particular market sectors;
- (vi) the demand for, and supply of, capital; and
- (vii) terrorism or other hostilities.

The market price of securities can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.

(c) **Government and legal risk**

Changes in government, monetary policies, taxation, and other laws can have a significant impact on the Company's assets, operations and ultimately the financial

performance of the Company and its Shares. Such changes are likely to be beyond the control of the Company and may affect industry profitability as well as the Company's capacity to undertake its activities.

The Company is not aware of any reviews or changes that would affect its interests. However, changes in community attitudes on matters such as taxation, competition policy and environmental issues may bring about reviews and possibly changes in government policies. There is a risk that such changes may affect the Company's development plans. Any such government action may also require increased capital or operating expenditures and could prevent or delay certain operations by the Company.

(d) **Litigation risks**

The Company is exposed to possible litigation risks including, without limitation, intellectual property claims, contractual disputes, occupational health and safety claims and employee claims. Further, the Company may be involved in disputes with other parties in the future which may result in litigation. Any such claim or dispute if proven, may impact adversely on the Company's operations, financial performance, and financial position. The Company is not currently engaged in any litigation.

(e) **General economic and political risks**

Changes in the general economic and political climate in Australia and on a global basis may impact on economic growth, interest rates, taxation and tariff laws, the rate of inflation and domestic security which may affect the value and viability of any activities that may be conducted by the Company.

(f) **Insurance**

Insurance against all risks associated with the Company's business is not always available or affordable. The Company maintains insurance where it is considered appropriate for its needs however it will not be insured against all risks either because appropriate cover is not available or because the Directors consider the required premiums to be excessive having regard to the benefits that would accrue.

(g) **Unforeseen expenditure risks**

Expenditure may need to be incurred which has not been taken into account in the preparation of this Prospectus. Although the Company is not aware of any such additional expenditure requirements, if such expenditure is subsequently required or incurred, this may adversely impact budgeted expenditure proposals by the Company.

4.3 Speculative investment

The above list of risk factors ought not to be taken as exhaustive of the risks faced by the Company or 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 Securities offered under this Prospectus. Therefore, the Securities to be issued pursuant to this Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Securities.

Potential investors should consider that the investment in the Company is speculative and should consult their professional advisers before deciding whether to apply for Securities pursuant to this Prospectus.

5. Financial information

5.1 Introduction

The financial information of the Company contained in this Section includes the:

- (a) the audited historical statement of profit or loss and other comprehensive income for the period from incorporation (30 November 2021) to 30 June 2022 (**FY22**) and for the half-year period ended 31 December 2022 (**1HFY23**) (the **Historical Statement of Profit or Loss**);
- (b) the audited historical statement of cash flows for the period ended FY22 and 1HFY23 (**Historical Statement of Cash Flows**);
- (c) the audited historical statement of financial position as at 31 December 2022 (**Historical Statement of Financial Position**);

(together, the **Historical Financial Information**); and
- (d) pro forma historical statement of financial position as at 31 December 2022 and the associated details of the pro forma adjustments (the **Pro Forma Statement of Financial Position** or **Pro Forma Financial Information**),

(collectively referred to as **Financial Information**).

The Company has a 30 June financial year end.

All amounts disclosed in Section 5 are presented in Australian dollars, which is Cleo's functional and presentation currency, unless otherwise noted and are rounded to the nearest dollar. Rounding in the Financial Information may result in some discrepancies between the sum of components, the totals outlined within the tables and percentage calculations.

The Directors are responsible for the preparation and presentation of the Financial Information in this Prospectus which has been reviewed by BDO Corporate Finance (East Coast) Pty Ltd (**Investigating Accountant** or **BDO**) in accordance with the Australian Standard on Assurance ASAE 3450 *Assurance Engagements involving Corporate Fundraising and/or Prospective Financial Information*.

BDO has prepared an Independent Limited Assurance Report in respect of the Financial Information in this Prospectus, (**Investigating Accountant's Report**). A copy of this report, which includes an explanation of the scope and limitations of the Investigating Accountant's work, is attached to this Prospectus at Annexure B.

The Financial Information should be read together with the other information contained in the prospectus, including:

- (a) the risk factors described in Section 4;
- (b) the use of funds described in Section 1.5;
- (c) the indicative capital structure described in Section 1.6;
- (d) the Investigating Accountant's Report, set out in Annexure B; and
- (e) the other information contained in this Prospectus.



The Financial Information in this Prospectus is intended to present potential investors and users with information to assist them in understanding financial performance, cash flows and financial position of the Company.

Nevertheless, please note that past performance is not an indication of future performance.

5.2 Basis of preparation and presentation of the Financial Information

The Historical Financial Information included has been extracted from the Company's financial statements for FY22 and 1HFY23, which were audited by BDO Audit Pty Ltd (the **Auditor**) in accordance with the Australian Auditing Standards (**Audited Financial Statements**).

The Historical Financial Information 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 ground that the Company will be able to continue as a going concern as a result of the proceeds from the Offer.

BDO Audit Pty Ltd issued unmodified audit opinions on the Company's financial statements for FY22 and 1HFY23.

The Pro Forma Statement of Financial Position has been derived from the Historical Statement of Financial Position and includes pro forma adjustments to reflect the impact of the Offer and material transactions to Allotment Date, as if those events and transactions had occurred as at 31 December 2022. The pro forma adjustments have estimated the Allotment Date to be 30 June 2023.

The Pro Forma Financial Information does not reflect the actual financial results of the Company. The Directors believe that it provides useful information as it illustrates to investors the financial position of the Company immediately after completion of the Offers.

The Financial Information has been prepared in accordance with the recognition and measurement principles of the Australian Accounting Standards and Interpretations (**AAS**) issued by the Australian Accounting Standards Board (**AASB**), the Corporations Act 2001, and the significant accounting policies set out in Section 5.7. The Financial Information also comply with the International Financial Reporting Standards (**IFRS**) as issued by the International Accounting Standards Board (**IASB**).

The Financial Information is presented in abbreviated form, insofar as it does not include the disclosures and notes required in an annual financial report prepared in accordance with AAS and other mandatory reporting requirements applicable to the general purpose financial reports prepared in accordance with the Corporations Act 2001. Significant accounting policies applied to the Historical Financial Information are set out in Section 5.7.



5.3 Historical Statement of Profit or Loss

The table below sets out the Company's audited historical statement of profit or loss and other comprehensive income for the period FY22 and 1HFY23.

	1HFY23	FY22
	\$	\$
Other income	5,386	-
Expenses		
Employee benefits expense	(234,096)	-
Professional fees	(44,399)	(19,791)
Research and development expenditure	(82,165)	(23,306)
Depreciation and amortisation	(16,667)	-
Finance expense	(6,082)	(834)
Other expenses	(43,389)	-
Loss before income tax expense	(421,412)	(43,931)
Income tax expense	-	-
Loss after income tax expense for the period attributable to the company	(421,412)	(43,931)

5.4 Historical Statement of Cash Flows

The table below sets out the Company's historical statement of cashflows for FY22 and 1HFY23.

	1HFY23	FY22
	\$	\$
<i>Cash flows from operating activities</i>		
Payments to suppliers and employees (inclusive of GST)	(249,041)	-
Net cash used in operating activities	(249,041)	-
<i>Cash flows from investing activities</i>		
Payments for intangible asset	(300,000)	(200,000)
Payments for property plant and equipment	(4,679)	-
Net cash used in investing activities	(304,679)	(200,000)
<i>Cash flows from financing activities</i>		
Proceeds from issue of shares	-	1
Proceeds from borrowings	-	200,000
Repayment of borrowings	(200,000)	-
Issue of convertible notes	1,513,500	41,500
Sundry loans	-	1,250
Net cash from financing activities	1,313,500	242,751
Net increase in cash and cash equivalents	759,780	42,751
Cash and cash equivalents at the beginning of the financial period	42,751	-
Cash and cash equivalents at the end of the financial period	802,531	42,751



For personal use only

5.5 Historical and Pro Forma Statement of Financial Position

The table below sets out the Company's historical statement of financial position as at 31 December 2022, extracted without adjustment from the Audited Financial Statements, and the Pro Forma Statement of Financial Position.

The Pro Forma Statement of Financial Position has been provided for illustrative purposes only and is not represented as being necessarily indicative of the Company's view of its actual or prospective financial position.

\$	Notes	Historical Statement of Financial Position 1HFY23	Pro Forma adjustments	Impact of the offer	Pro Forma Statement of Financial Position 30-June 2023
Assets					
Cash and cash equivalents	5.8 (i)	802,531	(371,635)	10,917,967	11,348,863
Trade and other receivables	5.8 (ii)	6,249	(39)	54,000	60,210
Total current assets		808,780	(371,674)	10,971,967	11,409,073
Property plant and equipment	5.8 (iii)	4,679	59,464	-	64,143
Intangible assets	5.8 (iv)	483,333	(25,000)	-	458,333
Total non-current assets		488,012	34,464	-	522,476
Total assets		1,296,792	(337,210)	10,971,967	11,931,549
Liabilities					
Trade and other payables	5.8 (v)	117,235	44,188	-	161,423
Convertible loan note	5.8 (vi)	1,510,000	(1,510,000)	-	-
Employee benefits	5.8 (vii)	643	2,148	-	2,791
Total current liabilities		1,627,878	(1,463,664)	-	164,214
Total liabilities		1,627,878	(1,463,664)	-	164,214
Net assets / (liabilities)		(331,086)	1,126,454	10,971,967	11,767,335
Equity					
Issued capital	5.8 (viii)	46,531	3,100,000	10,736,037	13,882,568
Reserves	5.8 (ix)	87,726	527,429	434,626	1,049,781
Accumulated losses	5.8 (x)	(465,343)	(2,500,975)	(198,696)	(3,165,014)
Total equity		(331,086)	1,126,454	10,971,967	11,767,335



For personal use only

(a) Reconciliation of Historical and Pro Forma Statement of Financial Position

\$'			1HFY23
Statutory net liabilities			(331,086)
Hudson consideration shares			-
Conversion of convertible notes			1,600,000
Share-based payments			-
Expenditures to Allotment Date			(473,546)
Capital raise			12,000,000
Transaction costs			(1,028,033)
Pro-forma net assets			11,767,335

5.6 Description of pro forma adjustments

The Pro Forma Statement of Financial Position has been derived from the Historical Statement of Financial Position, after reflecting the Director's pro forma adjustments for the following transactions which are proposed to occur immediately before or following completion of the Offers, as if they had occurred at 31 December 2022:

(a) Pro forma adjustments:

- (i) As part of the consideration for the Hudson Licence Agreement with Hudson, the Company is to issue fully paid ordinary Shares to the value of \$1,500,000, prior to the issue of the Prospectus at the offer price, which represents 7,500,000 shares. Please refer to Section 7.1 for further details of this agreement.
- (ii) The Company have issued a total of 1,600,000 seed raising convertible notes prior to the IPO. The convertible notes convert to fully paid ordinary Shares prior to admission to the ASX at a conversion price of \$0.10 (50% of issue price), which results in the issue of 16,000,000 shares to the note holders. Please refer to Section 7.4 for further details.
- (iii) Non-executive Directors, Lucina Nolan and Tom Jobling have accepted to receive 1,500,000 options each in the Company on April 2023, please refer to Section 8.2 of the Prospectus for details of these options. The Company have valued these shares using a Black-Scholes valuation model. Given no vesting conditions, the fair value of the options are expensed on grant date.
- (iv) The Board have approved the issue of 1,500,000 options to iRX advisors, in recognition of their 24 month service agreement to the Company for investor relations and marketing services beginning on listing date. Please refer to Section 8.3 for further details of these options. Given no vesting date, the fair value of the options are expensed on grant date.
- (v) Roll forward of the statement of financial position to the Allotment Date, in connection with the Offer, reflecting estimated cash outflows associated with operational expenditures, anticipated asset purchases, and further share-based payment expenses.

(b) Impact of the offer:

- (i) The Company seeks to raise \$12,000,000 through the issue of 60,000,000 shares at an offer price of \$0.20, net of transaction costs.



- (ii) Transaction costs in connection with the Offer is estimated to be cash outlays of \$1,082,033, in addition to the 5,000,000 options issued as consideration for the lead managers, please refer to Section 8.3 for details of the options granted to the Lead Manager.

5.7 Summary of significant Accounting Policies

(a) Overview

The principal accounting policies adopted in the preparation of the financial statements are set out below. These policies have been consistently adopted to all the years presented, unless otherwise stated.

The Company have adopted all the new and amended AAS issued by AASB that are mandatory for FY22 and 1HFY23 periods. Any new or amended AAS that are not yet mandatory have not been early adopted.

The preparation of the Financial Information requires the Directors to make judgements, estimates and assumptions that effect the reported amounts in the Financial Information. The Directors continually evaluate its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenues and expenses. The Directors base its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events that the Directors believe to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal actual results.

(b) Current and non-current classification

Assets and liabilities are presented in the Historical and Pro Forma Statement of Financial Position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the company's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in the company's normal operating cycle; it is held primarily for the purposes of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

(c) Goods and Services Tax ('GST') and other similar taxes

Revenue, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the tax authority is included in other receivables or other payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flows.



Commitment and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the tax authority.

(d) **Income tax**

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- (i) When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- (ii) When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

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

The carrying amount of recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

(e) **Cash and cash equivalents**

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

(f) **Intangible assets**

Intangible assets acquired as part of a business combination, other than goodwill, are initially measured at their fair value at the date of the acquisition. Intangible assets acquired separately are initially recognised at cost. Indefinite life intangible assets are not amortised and are subsequently measured at cost less any impairment. Finite life intangible assets are subsequently measured at cost less amortisation and any impairment. The gains or losses recognised in profit or loss arising from the derecognition of intangible assets are measured as the difference between net disposal proceeds and the carrying amount of the intangible asset. The method and



useful lives of finite life intangible assets are reviewed annually. Changes in the expected pattern of consumption or useful life are accounted for prospectively by changing the amortisation method or period.

In regards to the future contingent considerations as part of the Hudson Licence Agreement, the Company have made the following accounting policy elections; The Company will expense the \$1,500,000 payment via issued capital upon lodgement of a prospectus by the Company. The \$1,500,000 payment in cash or issued capital upon achievement of the first product and all royalty and sub-licence levies will be expensed as incurred.

Research and development

Research costs are expensed in the period in which they are incurred. Development costs are capitalised when it is probable that the project will be a success considering its commercial and technical feasibility; the Company is able to use or sell the asset; the Company has sufficient resources and intent to complete the development; and its costs can be measured reliably. Capitalised development costs are amortised on a straight-line basis over the period of their useful life.

Patents and trademarks

Costs associated with patents are expensed as they are incurred.

Estimated useful life of intangible assets

The company determines the estimated useful life of its intangible assets, and the related amortisation charge. The useful life could change significantly as a result of technical innovations or other events. Amortisation charges will increase where the useful life are less than the previous estimate of useful life, or where there is technical obsolescence.

The company's acquired licence will be amortised over its useful life from the commencement of the licence agreement with Hudson, in accordance with the terms of the licence agreement. The useful life is estimated based on the sales life cycle and patent period of the licenced technology. No sales have yet been made, or patents secured. The current estimated useful life of the licenced technology is 10 years and will be reassessed as the licenced technology is developed.

Impairment of non-financial assets

Intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of an asset's fair value less costs of disposal and value-in-use. The value-in-use is the present value of the estimated future cash flows relating to the asset using a pre-tax discount rate specific to the asset or cash-generating unit to which the asset belongs. Assets that do not have independent cash flows are consolidated together to form a cash-generating unit.

(g) **Trade and other payables**

These amounts represent liabilities for goods and services provided to the company prior to the end of the financial period and which are unpaid. Due to their short-term

nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

(h) **Borrowings**

Loans and borrowings are initially recognised at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortised cost using the effective interest method.

(i) **Convertible notes**

The convertible notes issued by the Company is a non-derivative financial instrument accounted for at amortised cost.

The interest expensed for the period is calculated by applying an effective interest rate of 15 percent to the liability component since the loan notes were issued. The liability component is measured at amortised cost. The difference between carrying amount of the liability component at the date of issue and the amount reported in the reporting at period end represents effective interest rate less interest paid to that date.

Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with the substance of the contractual agreements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the company are recognised at the proceeds received, net of direct issue costs.

Repurchase of the company's own equity instruments is recognised and deducted directly in equity. No gain or loss is recognised in profit or loss on the purchase, sale, issue or cancellation of the company's own equity instruments.

Compound instruments

The component parts of convertible loan notes issued by the company are classified separately as financial liabilities and equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument. A conversion option that will be settled by the exchange of a fixed amount of cash or another financial asset for a fixed number of the company's own equity instruments is an equity instrument.

At the date of issue, the fair value of the liability component is estimated using the prevailing market interest rate for a similar non-convertible instrument. This amount is recorded as a liability on an amortised cost basis using the effective interest method until extinguished upon conversion or at the instrument's maturity date.

The conversion option classified as equity is determined by deducting the amount of the liability component from the fair value of the compound instrument as a whole. This is recognised and included in equity, net of income tax effects, and is not subsequently remeasured. In addition, the conversion option classified as equity will remain in equity until the conversion option is exercised, in which case the balance recognised in equity will be transferred to issued capital. Where the conversion option remains unexercised at the maturity date of the convertible loan note, the balance recognised in equity will be transferred to retained earnings/accumulated losses. No



gain or loss is recognised in profit or loss upon conversion or expiration of the conversion option.

Transaction costs that relate to the issue of the convertible loan notes are allocated to the liability and equity components in proportion to the allocation of the gross proceeds. Transaction costs relating to the equity component are recognised directly in equity. Transaction costs relating to the liability component are included in the carrying amount of the liability component and are amortised over the lives of the convertible loan notes using the effective interest method.

(j) **Issued capital**

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

(k) **Share based payment**

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date. The fair value is determined by using either the Binomial or Black-Scholes model taking into account the terms and conditions upon which the options were granted.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled employee benefits reserve.

Equity-settled share-based payment transactions with parties other than employees are measured at the fair value of the goods or services received, except where that fair value cannot be estimated reliably, in which case they are measured at the fair value of the equity instruments granted, measured at the date the entity obtains the goods or the counterparty renders the service.

For cash-settled share-based payments, a liability is recognized for the goods or services acquired, measured initially at the fair value of the liability. At the end of each reporting period until the liability is settled, and at the date of settlement, the fair value of the liability is remeasured, with any changes in fair value recognized in profit or loss for the year.

5.8 Additional notes to the Financial Information

i) Cash and cash equivalents	\$
Balance – 31 December 2022	802,531
<i>Pro forma adjustments</i>	
Receipts from issue of Convertible notes	90,000
Estimated expenditures incurred to Allotment Date	(461,635)
	(371,635)
<i>Impact of the offer</i>	
Gross proceeds from the Offer	12,000,000
Estimated Transaction costs of the Offer settled in cash	(1,082,033)
	10,917,967
Pro forma balance	11,348,863
ii) Trade and other receivables	\$
Balance – 31 December 2022	6,249
<i>Pro forma adjustments</i>	
Estimated expenditures incurred to Allotment Date	(39)
	(39)
<i>Impact of offer</i>	
GST recoverable from Transaction costs of the Offer	54,000
	54,000
Pro forma balance	60,210
iii) Property plant and equipment	\$
Balance – 31 December 2022	4,679
<i>Pro forma adjustments</i>	
Acquisition of equipment and software made to Allotment Date	62,997
Depreciation expense to Allotment Date	(3,533)
	59,464
Pro forma balance	64,143
iv) Intangible assets	\$
Balance – 31 December 2022	483,333
<i>Pro forma adjustments</i>	
Amortisation expense to Allotment Date	(25,000)
	(25,000)
Pro forma balance	458,333
v) Trade and other payables	\$
Balance – 31 December 2022	117,235
<i>Pro forma adjustments</i>	
Estimate liabilities incurred to Allotment Date	44,188
	44,188
Pro forma balance	161,423
vi) Convertible loan note	\$
Balance – 31 December 2022	1,510,000
<i>Pro forma adjustments</i>	
Convertible notes issued on April 2023	90,000

Convertible notes conversion at \$0.10 prior to the IPO	(1,600,000)
	<u>(1,510,000)</u>
Pro forma balance	-
	\$
vii) Employee benefits	
Balance – 31 December 2022	643
<i>Pro forma adjustments</i>	
Additional employee provisions to Allotment Date	2,148
	<u>2,148</u>
Pro forma balance	<u>2,791</u>

viii) Share capital	Number of shares	\$
Balance – 31 December 2022	45,000,001	46,531
<i>Pro forma adjustments</i>		
Issue of shares in accordance with the Hudson Licence Agreement	7,500,000	1,500,000
Conversion of convertible notes	16,000,000	1,600,000
	<u>23,500,000</u>	<u>3,100,000</u>
<i>Impact of the offer</i>		
Issue of shares under the prospectus	60,000,000	12,000,000
Lead Manager's fees (options)	-	(434,626)
Lead Manager fees settled via cash	-	(738,000)
Other capitalised IPO costs	-	(91,337)
	<u>60,000,000</u>	<u>10,736,037</u>
Proforma balance	<u>128,500,001</u>	<u>13,882,568</u>

ix) Reserves	Number of options	\$
Balance – 31 December 2022	4,500,000	87,726
<i>Proforma adjustments</i>		
Share base payment expense for the period	-	136,265
Options granted to Directors	3,000,000	260,776
Options granted to iRX advisors	1,500,000	130,388
	<u>4,500,000</u>	<u>527,429</u>
<i>Impact of the offer</i>		
Lead Manager's fees (options)	5,000,000	434,626
	<u>5,000,000</u>	<u>434,626</u>
Proforma balance	<u>14,000,000</u>	<u>1,049,781</u>

x) Accumulated losses	\$
Balance – 31 December 2022	(465,343)
<i>Pro forma adjustments</i>	
Issue of shares in accordance with Hudson licence Agreement	(1,500,000)
Share base payment expense for the period	(136,265)
Options granted to Directors	(260,776)
Options granted to iRX advisors	(130,388)
Estimated expenditures incurred to Allotment Date	(473,546)
	<u>(2,500,975)</u>
<i>Impact of the offer</i>	
IPO costs expensed	(198,696)
	<u>(198,696)</u>
Pro forma balance	<u>(3,165,014)</u>



For personal use only

6. Board, management and corporate governance

6.1 Board of Directors

The Board is comprised of:

- (a) Dr Richard Allman – Chief Executive Officer and Executive Director;
- (b) Dr Andrew Stephens – Chief Scientific Officer and Executive Director;
- (c) Professor Tom Jobling – Non-Executive Director and Lead Medical Advisor;
- (d) Lucinda Nolan – Non-Executive Director; and
- (e) Mr Adrien Wing – Non-Executive Chair.

6.2 Directors' profiles

The names and details of the Directors are:

(a) **Dr Richard Allman – Chief Executive Officer and Executive Director**

PhD (Microbiology) from The University of Wales

Dr Richard Allman has over 30 years of scientific research leadership and innovation with a clear focus on commercialisation. He has wide experience in research leadership, innovation management, and intellectual property strategy, covering oncology, diagnostics, and product development.

Previously Chief Scientific Officer at Genetic Technologies Limited (ASX: GTG). Recent successes include the strategic design and management of a second generation breast cancer risk assessment test from concept to commercial launch and a similar test for colorectal cancer. These tests have now been NATA accredited and comprise the first commercially available polygenic risk tests in Australia. More recently he has supervised the underlying R&D, translation, regulatory approval, patent filing and commercial launch of a Covid-19 disease severity test within a 12-month period. This strategy has been utilised to expedite a product development pipeline covering 6 major cancers, cardiovascular disease and type-2 diabetes which were commercially launched in March 2022.

Dr Allman is not considered to be an independent director by virtue of his proposed executive position within the Company.

(b) **Dr Andrew Stephens – Chief Scientific Officer and Executive Director**

PhD (Molecular Biology) from Monash University Australia

Dr Stephens is a career research scientist with 20 years' experience in molecular and cellular biology research. He has broad experience in academic and pre-clinical research, and a strong focus on translation and the commercialisation of research findings. He established and leads an independent academic research group at the Hudson Institute of Medical Research, investigating mechanisms that contribute to the formation, progression and dissemination of high grade, serous epithelial ovarian cancers. Since 2010, his research has focused on biomarker identification and development in ovarian cancer, and the development of therapeutic strategies to

improve patient outcomes. He is also actively involved across the biotech sector, with appointments to the scientific advisory for Invion Ltd and AMTBio Pty Ltd.

Dr Stephens has over 60 academic publications and numerous patents (pending and provisional) in the cancer therapeutic and diagnostic space.

Dr Stephens is not considered to be an independent director by virtue of his proposed executive position within the Company.

(c) **Professor Tom Jobling - Lead Medical Advisor and Non-Executive Director**

Bachelor of Medicine, Bachelor of Surgery, Fellow of the Royal College of Obstetricians and Gynaecologists, Fellow of Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Certificate of Gynaecological Oncology, Doctor of Medicine, Head of Gynaecological Oncology at Monash Health

Professor Thomas Jobling is Director of Gynaecologic Oncology at Monash Medical Centre. He graduated from Monash University in 1980 and did his post graduate sub specialist training in Gynaecologic Oncology in London at the Royal Marsden and St Bartholomews hospitals. Professor Jobling has subsequently been elected as a Member of the Society of Pelvic Surgeons and is also Founder of the Ovarian Cancer Research Foundation (1999). He previously held the Chairmen position of Ovarian Cancer Research Foundation Board. His major interests are in radical surgery for ovarian cancer and the application of robotic surgery for gynaecological malignancy.

Professor Jobling is an active member of a Research Team in bio marker detection and proteomics in ovarian cancer. He is involved as a collaborative investigator on a number of international clinical trials and is a Member of the Australia and New Zealand Gynaecologic Oncology Group, the Australian Society of Gynaecologic Oncology, the Victorian Co-operative Oncology Group and the International Society of Gynaecological Cancer.

Professor Jobling is considered to be an independent Director and is free from any business or other relationship that could materially interfere with, or reasonably be perceived to interfere with, the independent exercise of his judgement.

(d) **Ms Lucinda Nolan – Non-Executive Director**

Master of Arts from Melbourne University, Bachelor of Arts with Honours from Melbourne University, Alumni of the Advanced Management Programme at Harvard University

Lucinda Nolan is a non-executive director and was most recently the CEO of the Ovarian Cancer Research Foundation. She has a wealth of knowledge and experience across the public sector and not-for-profit environments. Prior to joining the Ovarian Cancer Research Foundation, she was selected as the first female CEO of the Country Fire Authority, one of the world's largest volunteer-based emergency services organisations. She also spent 32 years with Victoria Police, reaching the rank of Deputy Commissioner. Much of her role there was dedicated to reductions in crime rates and the continual improvement of service delivery in the face of complex and competing crime, disorder, and service demands. She was awarded the Australian Police Medal in 2009.

Ms Nolan is also the Chair of BankVic and a director on the Boards at Alkira Box Hill Inc. and the Melbourne Archdiocese of Catholic Schools (MACS). She has a Master of Arts and a Bachelor of Arts (Honours) from Melbourne University and is an alum of the Advanced Management Programme at Harvard University.

Ms Nolan is considered to be an independent Director and is free from any business or other relationship that could materially interfere with, or reasonably be perceived to interfere with, the independent exercise of her judgement.

(e) **Mr Adrien Wing - Non-Executive Chair**

Bachelor of Business (Accountancy) from Royal Melbourne Institute of Technology (RMIT) and Certified Practising Accountant (CPA)

Adrien Wing began his professional career practising in the audit and corporate advisory divisions of a chartered accounting firm. Mr Wing has over 25 years' experience in the corporate sector with the large portion of this experience in ASX small caps, lead in IPO transactions and post listing reverse takeovers and acquisitions across a range of industry sectors and jurisdictions. Mr Wing has a strong pedigree in the life sciences industry being the founder of Rhythm Biosciences Ltd and bringing that entity to the ASX in 2017.

Mr Wing currently serves as an officer/director on the following company boards: (i) New Age Exploration Ltd (ASX: NAE) - Director and Joint Company Secretary; (ii) Red Sky Energy Ltd (ASX: ROG) - Director and Joint Company Secretary; (iii) Sparc Technologies Ltd (ASX: SPN) - Company Secretary; and (iv) Osmond Resources Ltd (ASX: OSM) - Company Secretary.

Mr Wing is not considered to be an independent Director because of his expected substantial shareholding in the Company at Admission.

Each Director has confirmed to the Company that they anticipate being available to perform their respective duties as a Director without constraint having regard to their other commitments.

6.3 Interests of Directors

No Director of the Company (or entity in which they are a partner or director) has, or has had in the two years before the Prospectus Date, any interests in:

- (a) the formation or promotion of the Company;
- (b) property acquired or proposed to be acquired by the Company in connection with its formation or promotion of the Offers; and
- (c) the Offers.

No amounts have been paid or agreed to be paid and no value or other benefit has been given or agreed to be given to:

- (a) any Director to induce to become, or to qualify as, a Director; and
- (b) any Director of the Company for services which he (or an entity in which his is a partner or director) has provided in connection with the formation or promotion of the Company or the Offers,

except as disclosed in this Prospectus.

6.4 Security holdings of Directors and key management personnel

Based on the intentions of the Directors and key management personnel as at the Prospectus Date in relation to the Offers, the Directors and key management personnel and their related entities will have the following interests in Securities on Admission:

Directors and key management personnel	Shares ⁽¹⁾	Voting power (%) ⁽²⁾	Options ⁽³⁾
Dr Richard Allman ⁽⁴⁾	1,500,000	1.17	2,500,000
Dr Andrew Stephens ⁽⁵⁾	500,000	0.39	1,500,000
Professor Tom Jobling ⁽⁶⁾	1,250,000	0.97	1,500,000
Lucinda Nolan ⁽⁷⁾	Nil	Nil	1,500,000
Mr Adrien Wing ⁽⁸⁾	14,250,000	11.09	Nil

Notes:

1. As at the Prospectus Date, the Directors have indicated that they intend to apply for Shares under the Offers in the amounts specified above. This number is indicative only and is otherwise subject to the allocation policy set out in Section 1.2.
2. Assumes the Minimum Subscription is raised and that no further Shares are issued or Options exercised and converted into Shares.
3. See Section 8.2 for the terms and conditions of the Options.
4. Securities are held directly by Dr Richard Allman.
5. Securities are held indirectly by Fotovet Pty Ltd ATF for the Stephens Family Trust, an entity of which Dr Andrew Stephens is the sole director and shareholder. Dr Andrew Stephens participated in the convertible note seed raising and holds \$50,000 worth of Seed Raising Convertible Notes (representing 500,000 Shares).
6. Securities are held directly by Professor Tom Jobling. Tom Jobling has indicated to the Company that he may apply for up to 250,000 Shares under the Public Offer
7. Securities are held directly by Lucinda Nolan.
8. Securities are held as follows:
 - (a) 6,500,000 Shares are held indirectly by Wing Investment Holdings Pty Ltd ATF The Wing Family Trust, an entity of which Adrien Wing is a director and his spouse, Michelle Wing, is the controller and beneficiary of the trust. Adrien Wing has indicated to the Company that he intends to apply for up to 1,250,000 Shares under the Public Offer which is expected to be held by Wing Investment Holdings Pty Ltd ATF The Wing Family Trust; and
 - (b) 6,500,000 Shares are held directly by Adrien Wing's spouse, Michelle Wing.

6.5 Disclosure of Directors and key management personnel

No Director or key management personnel has been the subject of any disciplinary action, criminal conviction, personal bankruptcy or disqualification in Australia or elsewhere in the last 10 years which is relevant or material to the performance of their duties as a Director or which is relevant to an investor's decision as to whether to subscribe for Shares. No Director or key management personnel has been an officer of a company that has entered into any form of external administration as a result of insolvency during the time that they were an officer, or within a 12 month period after they ceased to be an officer.

6.6 Remuneration of Directors and key management personnel

The Constitution provides that the Company may remunerate the Directors. The remuneration shall, subject to any resolution of a general meeting, be fixed by the Directors. The maximum aggregate amount of fees that can be paid to Non-Executive Directors is currently set at \$500,000 per annum. The remuneration of the Executive Directors will be determined by the Board.



Since incorporation of the Company, the Directors have received remuneration (including superannuation) / directors' fees, as set out below:

Person	Remuneration / directors' fees
Adrien Wing	\$80,080
Dr Richard Allman	\$145,228
Dr Andrew Stephens	\$94,025
Professor Tom Jobling	Nil
Lucinda Nolan	Nil

6.7 Related party transactions

The Company has entered into the following related party transactions on arms' length terms:

- (a) Seed Raising Convertible Note Agreements with Dr Andrew Stephens and various other unrelated parties (see Section 7.4);
- (b) executive services agreement with Dr Richard Allman and Dr Andrew Stephens (see Section 7.5);
- (c) letters of appointment with each of its Directors on standard terms (see Section 7.5); and
- (d) deeds of indemnity, insurance and access with each of its Directors on standard terms (see Section 7.6).

At the Prospectus Date, no other material transactions with related parties and Directors' interests exist that the Directors are aware of, other than those disclosed in the Prospectus.

6.8 ASX Corporate Governance Council Principles and Recommendations

The Company has adopted comprehensive systems of control and accountability as the basis for the administration of corporate governance. The Board is committed to administering the Company's policies and procedures with openness and integrity, pursuing the true spirit of corporate governance commensurate with the Company's needs.

To the extent applicable, the Company has adopted the 4th edition of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations (**Recommendations**).

In light of the Company's size and nature, the Board considers that the current Board (and the proposed Board upon Admission) is a cost effective and practical method of directing and managing the Company. As the Company's activities develop in size, nature and scope, the size of the Board and the implementation of additional corporate governance policies and structures will be reviewed.

The Company's main corporate governance policies and practices as at the Prospectus Date are detailed below. The Company's full Corporate Governance Plan is available in a dedicated corporate governance information section of the Company's website at <http://www.cleodx.com>.

(a) **Board of Directors**

The Board is responsible for the corporate governance of the Company. The Board develops strategies for the Company, reviews strategic objectives and monitors performance against those objectives. Clearly articulating the division of responsibilities between the Board and management will help manage expectations and avoid misunderstandings about their respective roles and accountabilities.

In general, the Board assumes (amongst others) the following responsibilities:

- (i) providing leadership and setting the strategic objectives of the Company;
- (ii) appointing and when necessary replacing the Chair;
- (iii) approving the appointment and when necessary replacement, of other senior executives;
- (iv) undertaking appropriate checks before appointing a person, or putting forward to security holders a candidate for election, as a Director;
- (v) overseeing management's implementation of the Company's strategic objectives and its performance generally;
- (vi) approving operating budgets and major capital expenditure;
- (vii) overseeing the integrity of the Company's accounting and corporate reporting systems including the external audit;
- (viii) overseeing the Company's process for making timely and balanced disclosure of all material information concerning the Company that a reasonable person would expect to have a material effect on the price or value of the Company's securities;
- (ix) ensuring that the Company has in place an appropriate risk management framework and setting the risk appetite within which the Board expects management to operate; and
- (x) monitoring the effectiveness of the Company's governance practices.

The Company is committed to ensuring that appropriate checks are undertaken before the appointment of a Director and has in place written agreements with each Director which detail the terms of their appointment.

(e) **Composition of the Board**

Election of Board members is substantially the province of the Shareholders in a general meeting. The Board currently consists of two Executive Directors and three Non-Executive Directors. The Company considers that both Professor Tom Jobling and Lucinda Nolan being the Non-Executive Directors are independent. As the Company's activities develop in size, nature and scope, the composition of the Board and the implementation of additional corporate governance policies and structures will be reviewed.

(f) **Identification and management of risk**

The Board's collective experience will assist in the identification of the principal risks that may affect the Company's business. Key operational risks and their management will be recurring items for deliberation at Board meetings.



(g) **Ethical standards**

The Board is committed to the establishment and maintenance of appropriate ethical standards.

(h) **Independent professional advice**

The Directors, at the Company's expense, may obtain independent professional advice on issues arising in the course of their duties.

(i) **Remuneration arrangements**

The remuneration of any Executive Director will be decided by the Board, without the affected Executive Director participating in that decision-making process.

In addition, subject to any necessary Shareholder approval, a Director may be paid fees or other amounts as the Directors determine where a Director performs special duties or otherwise performs services outside the scope of the ordinary duties of a Director (e.g. non-cash performance incentives such as options).

Directors are also entitled to be paid reasonable travel and other expenses incurred by them in the course of the performance of their duties as Directors.

The Board reviews and approves the Company's remuneration policy in order to ensure that the Company is able to attract and retain executives and Directors who will create value for Shareholders, having regard to the amount considered to be commensurate for an entity of the Company's size and level of activity as well as the relevant Directors' time, commitment and responsibility.

The Board is also responsible for reviewing any employee incentive and equity-based plans including the appropriateness of performance hurdles and total payments proposed.

(j) **Securities trading policy**

The Board has adopted a policy that sets out the guidelines on the sale and purchase of securities in the Company by its key management personnel (i.e. Directors and, if applicable, any employees reporting directly to the Executive Directors). The policy generally provides that the written acknowledgement of the Chair (or the Board in the case of the Chair) must be obtained prior to trading.

(k) **Diversity policy**

The Board values diversity and recognises the benefits it can bring to the organisation's ability to achieve its goals. Accordingly, the Company has set in place a diversity policy. This policy outlines the Company's diversity objectives in relation to gender, age, cultural background and ethnicity. It includes requirements for the Board to establish measurable objectives for achieving diversity, and for the Board to assess annually both the objectives, and the Company's progress in achieving them.

(l) **Audit and risk**

The Company will not have a separate audit or risk committee until such time as the Board is of a sufficient size and structure, and the Company's operations are of a sufficient magnitude for a separate committee to be of benefit to the Company. In the meantime, the full Board will carry out the duties that would ordinarily be assigned to that committee under the written terms of reference for that committee, including but not limited to, monitoring and reviewing any matters of significance affecting financial reporting and compliance, the integrity of the financial reporting of the Company, the

Company's internal financial control system and risk management systems and the external audit function.

(m) **External audit**

The Company in general meetings is responsible for the appointment of the external auditors of the Company, and the Board from time to time will review the scope, performance and fees of those external auditors.

(n) **Social media policy**

The Board has adopted a social media policy to regulate the use of social media by people associated with the Company or its subsidiaries to preserve the Company's reputation and integrity. The policy outlines requirements for compliance with confidentiality, governance, legal, privacy and regulatory parameters when using social media to conduct Company business.

(o) **Whistleblower policy**

The Board has adopted a whistleblower protection policy to ensure concerns regarding unacceptable conduct including breaches of the Company's code of conduct can be raised on a confidential basis, without fear of reprisal, dismissal or discriminatory treatment. The purpose of this policy is to promote responsible whistleblowing about issues where the interests of others, including the public, or of the organisation itself are at risk.

(p) **Anti-bribery and anti-corruption policy**

The Board has a zero-tolerance approach to bribery and corruption and is committed to acting professionally, fairly and with integrity in all business dealings. The Board has adopted an anti-bribery and anti-corruption policy for the purpose of setting out the responsibilities in observing and upholding the Company's position on bribery and corruption provide information and guidance to those working for the Company on how to recognise and deal with bribery and corruption issues.

6.9 Departures from Recommendations

Following Admission, the Company will be required to report any departures from the Recommendations in its annual financial report.

The Company's compliance and departures from the Recommendations as at the Prospectus Date are detailed in the table below.

Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
PRINCIPLE 1 - LAY SOLID FOUNDATIONS FOR MANAGEMENT AND OVERSIGHT		
Recommendation 1.5 A listed entity should: <ul style="list-style-type: none"> (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 	Partially	The Company has implemented a diversity policy which will be made available at the Company's website. The Company's diversity strategies include: <ul style="list-style-type: none"> (a) recruiting from a diverse pool of candidates for all



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
<p>the composition of its board, senior executives and workforce generally; and</p> <p>(c) disclose in relation to each reporting period:</p> <p>(i) the measurable objectives set for that period to achieve gender diversity;</p> <p>(ii) the entity's progress towards achieving those objectives; and</p> <p>(iii) either:</p> <p>(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</p> <p>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 the Act.</p>		<p>positions, including senior management and the Board;</p> <p>(b) considering the implementation of measurable objectives;</p> <p>(c) reviewing succession plans to ensure an appropriate focus on diversity;</p> <p>(d) identifying specific factors to take account of in recruitment and selection processes to encourage diversity;</p> <p>(e) developing programs to develop a broader pool of skilled and experienced senior management and Board candidates, including, workplace development programs, mentoring programs and targeted training and development;</p> <p>(f) providing opportunities for employees on extended parental leave to maintain their connection to the entity;</p> <p>(g) promoting workplace structures that assist employees balance their work, family and other responsibilities effectively and assist in the development of a more diverse pool of skilled and experienced employees whilst improving performance;</p> <p>(h) developing a culture which takes account of domestic responsibilities of employees; and</p> <p>(i) any other strategies the Board develops from time to time.</p> <p>Due to the size of the Board and small number of employees, the Company has not set measurable</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
		objectives for the current reporting period.
<p>Recommendation 1.6 A listed entity should:</p> <p>(a) have and disclose a process for periodically evaluating the performance of the board, its committees and individual directors; and</p> <p>(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.</p>	Partially	<p>The Charters of the Company's Board and Remuneration and Nomination Committee, which is currently a function of the Board, outlines the processes to be used for evaluating the performance of, and the development and improvement of, the Board, its committees, and its individual Directors.</p> <p>These reviews will be carried out in accordance with the Company's Performance Evaluation Policy, which is available on the Company's website.</p> <p>The Board has assessed the current and future needs of the Company, and has set expectations for itself, its committees and its Directors.</p> <p>The Remuneration and Nomination Committee (which is currently a function of the Board) will conduct the Board and Committee performance reviews against these expectations. Based upon the reviews, individuals and groups will be provided with feedback on their performance and the results will provide a key input into the future expectations set by the Board.</p> <p>The Performance Evaluation Policy has been newly adopted and therefore no performance evaluation has been undertaken in accordance with those processes contained within the policy during the current reporting period.</p>
<p>Recommendation 1.7 A listed entity should:</p> <p>(a) have and disclose a process for evaluating the performance of its senior executives at least once every reporting period; and</p> <p>(b) disclose for each reporting period whether a performance evaluation has been</p>	Partially	<p>The Board reviews the performance of its senior executives on an annual basis. A senior executive, for these purposes, means key management personnel (as defined in the Corporations Act), other than non-executive Directors.</p> <p>The applicable processes for these evaluations can be found in the</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
<p>undertaken in accordance with that process during or in respect of that period.</p>		<p>Charters of the Company's Board and Remuneration and Nomination Committee and the Company's Performance Evaluation Policy, which are available on the Company's website.</p> <p>The performance evaluation policy has been newly adopted and therefore no performance evaluation has been undertaken in accordance with those processes contained within the policy during the current reporting period.</p>
PRINCIPLE 2 – STRUCTURE THE BOARD TO BE EFFECTIVE AND ADD VALUE		
<p>Recommendation 2.1 The Board of a listed entity should:</p> <p>(a) have a nomination committee which:</p> <p>(i) has at least three members, a majority of whom are independent directors; and</p> <p>(ii) is chaired by an independent director, and disclose:</p> <p>(iii) the charter of the committee;</p> <p>(iv) the members of the committee; and</p> <p>(v) 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</p> <p>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.</p>	No	<p>Due to the size of the Board, the Company does not have a separate nomination committee. The roles and responsibilities of a nomination committee are currently undertaken by the Board.</p> <p>The duties of the full Board in its capacity as a nomination committee are set out in the Company's Remuneration and Nomination Committee Charter.</p> <p>When the Board meets as a remuneration and nomination committee it carries out those functions which are delegated to it in the Company's Remuneration and Nomination Committee Charter. Items that are usually required to be discussed by a Remuneration and Nomination Committee are marked as separate agenda items at Board meetings when required.</p> <p>The Board has adopted a Remuneration and Nomination Committee Charter which describes the role, composition, functions and responsibilities of a Nomination Committee.</p> <p>The Board as a whole reviews the size, structure and composition of the Board including competencies and diversity, in addition to reviewing Board succession plans and continuing development. At present, the Board considers that no efficiencies or other benefits</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
		would be gained by establishing a separate nomination committee.
<p>Recommendation 2.2</p> <p>A listed entity should have and disclose a board skills matrix setting out the mix of skills and diversity that the board currently has or is looking to achieve in its membership.</p>	Partially	<p>The Board is structured to facilitate the effective discharge of its duties and to add value through its deliberations. It seeks to achieve a Board composition with a balance of diverse attributes relevant to the Company's operations and markets, including skills sets, background, gender, geography and industry experience. In addition to those general skills expected for Board membership, the following skills have also been identified as being necessary such as research and development, commercialisation, innovation management, operational management, corporate governance, equity capital markets, legal, and commercial negotiations.</p> <p>A profile of each Director setting out their skills, experience and period of office will be set out in the Directors' Report section of the latest Annual Report.</p> <p>The Company has not disclosed a Board skill matrix.</p>
<p>Recommendation 2.4</p> <p>A majority of the board of a listed entity should be independent directors.</p>	No	<p>On listing, the Board will not be comprised of a majority of independent directors, with two out of five considered to be independent directors.</p> <p>The Board considers its present composition to be appropriate, given the small size of the Board reflects the size of the Company's operations. However, the Board will monitor this composition and, if deemed appropriate, recruit additional independent Non-Executive Directors.</p>
<p>Recommendation 2.5</p> <p>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.</p>	No	<p>Adrien Wing is not considered to be independent director by virtue of his expected substantial shareholding in the Company on listing.</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
		<p>The Board Charter provides that, to the extent possible, the chair of the Board should be an independent director.</p> <p>The Board has formed the view that, given the size and composition of the Board, it is not considered necessary to have an independent chair.</p>
PRINCIPLE 4 – SAFEGUARD THE INTEGRITY OF CORPORATE REPORTS		
<p>Recommendation 4.1</p> <p>The board of a listed entity should:</p> <p>(a) have an audit committee which:</p> <p style="margin-left: 20px;">(i) has at least three members, all of whom are non-executive directors and a majority of whom are independent directors; and</p> <p style="margin-left: 20px;">(ii) is chaired by an independent director, who is not the chair of the board,</p> <p>and disclose:</p> <p style="margin-left: 20px;">(iii) the charter of the committee;</p> <p style="margin-left: 20px;">(iv) the relevant qualifications and experience of the members of the committee; and</p> <p style="margin-left: 20px;">(v) 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</p> <p>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</p>	<p>Partially</p>	<p>As a consequence of the size and composition of the Board (comprising the Executive Directors and Non-Executive Directors) the Board does not have a stand-alone audit committee.</p> <p>The Board as a whole has responsibilities typically assumed by an audit committee, including but not limited to:</p> <p>(a) verifying and safeguarding the integrity of the Company's stakeholder reporting;</p> <p>(b) reviewing and approving the audited annual and reviewed half-yearly financial reports;</p> <p>(c) reviewing the appointment of the external auditor, their independence and performance, the audit fee, any questions of their resignation or dismissal and assessing the scope and adequacy of the external audit; and</p> <p>(d) a risk management function.</p> <p>That is, matters typically dealt with by an audit committee are dealt with by the full Board.</p> <p>Information on the Company's procedures for the selection and appointment of the external auditor and the rotation of external audit partners is set out in the Policy on Selection, Appointment and Rotation of External Auditors,</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
external auditor and the rotation of the audit engagement partner.		which is available on the Company's website.
PRINCIPLE 7 – RECOGNISE AND MANAGE RISK		
<p>Recommendation 7.1</p> <p>The board of a listed entity should:</p> <p>(a) have a committee or committees to oversee risk, each of which:</p> <p>(i) has at least three members, a majority of whom are independent directors; and</p> <p>(ii) is chaired by an independent director,</p> <p>and disclose:</p> <p>(iii) the charter of the committee;</p> <p>(iv) the members of the committee; and</p> <p>(v) 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</p> <p>if it does not have a risk committee or committees that satisfy paragraph (a) above, disclose that fact and the processes it employs for overseeing the entity's risk management framework.</p>	No	<p>As a consequence of the size and composition of the Company's Board (comprising the Executive Directors and Non-Executive Directors) the Board does not have a stand-alone risk committee.</p> <p>The Board as a whole has responsibilities typically assumed by a risk committee, including but not limited to:</p> <p>(a) ensuring that an appropriate risk-management framework is in place and is operating properly; and</p> <p>(b) reviewing and monitoring legal and policy compliance systems and issues.</p> <p>That is, matters typically dealt with by a risk committee are dealt with by the full Board. At present, the Board considers that no efficiencies or other benefits would be gained by establishing a separate risk committee.</p>
PRINCIPLE 8 – REMUNERATE FAIRLY AND RESPONSIBLY		
<p>Recommendation 8.1</p> <p>The board of a listed entity should:</p> <p>(a) have a remuneration committee which:</p> <p>(i) has at least three members, a majority of whom are independent directors; and</p>	No	<p>As a consequence of the size and composition of the Board (comprising the Executive Directors and Non-Executive Directors) the Board does not have a standalone remuneration committee.</p> <p>The Board as a whole has responsibilities typically assumed</p>



Principles and Recommendations	Compliance (Yes / No / Partially)	Explanation for Departures
<p>(ii) is chaired by an independent director, and disclose:</p> <p>(iii) the charter of the committee;</p> <p>(iv) the members of the committee; and</p> <p>(v) 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</p> <p>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.</p>		<p>by a remuneration committee, including but not limited to:</p> <p>(a) reviewing the remuneration (including short-term and long-term incentive schemes and equity-based remuneration, where applicable) and performance of Directors;</p> <p>(b) setting policies for senior executive remuneration, setting the terms and conditions of employment for senior executives, undertaking reviews of senior executive performance, including setting goals and reviewing progress in achieving those goals; and</p> <p>(c) reviewing the Company's senior executive and employee incentive schemes (including equity-based remuneration) (where applicable) and making recommendations to the Non-Executive Chair on any proposed changes.</p> <p>That is, matters typically dealt with by a remuneration committee are dealt with by the full Board. The Company has adopted a Remuneration and Nomination Committee Charter available on the Company's website. At present, the Board considers that no efficiencies or other benefits would be gained by establishing a separate remuneration committee.</p>



7. Material contracts

The Directors consider that certain contracts entered into by the Company are material to the Company or are of such a nature that an investor may wish to have particulars of them when assessing whether to apply for Securities under the Offers. The provisions of such material contracts are summarised in this Section 7.

7.1 Hudson Licence Agreement

On 29 August 2022, the Company entered into the Hudson Licence Agreement with Hudson pursuant to which Hudson agreed to licence certain technology to the Company including patents, certain anti-bodies and cell-lines and exclusive know-how relating to Tests (**Licensed Technology**).

A summary of the material terms of the Hudson Licence Agreement is detailed below:

- (a) (**Exclusive licence**): The licence is a worldwide exclusive licence to use, sub-licence, develop, modify and commercialise the Licensed Technology within the screening and diagnostic field.
- (b) (**Conditions precedent**): As at the Prospectus Date, all of the conditions precedent under the Hudson Licence Agreement have been satisfied.
- (c) (**Term**): Other than in accordance with Section 7.1(f), the Hudson Licence Agreement will remain in force on a region-by-region basis, for the period commencing on the date of the first commercial sale or supply of a product after receipt of applicable marketing approval in respect of the sale and supply of the product in that region, and ending on the latter of:
 - (i) ten years from such date; or
 - (ii) the expiry of the last valid issued patent or patent application in any region, (referred to in this Section as the '**Royalty Term**').
- (d) (**Consideration**): As consideration for the grant of the licence, the Company agreed to:
 - (i) pay a deposit of \$200,000 (which has been paid);
 - (ii) pay a signing fee of \$300,000 (exclusive of GST) (which has been paid);
 - (iii) issue to Hudson \$1,500,000 worth of fully paid ordinary Shares in the Company at the Offer Price (representing 7,500,000 Shares), which are expected to be escrowed for a period of 24 months from Admission (**Hudson Consideration Shares**); and
 - (iv) upon the Company achieving regulatory approval for its first product in any of the US, Australia, Europe or Japan, pay Hudson \$1,500,000 (excluding GST).
- (e) (**Royalty**): As consideration for the grant of the licence, the Company agreed to grant to Hudson a royalty calculated as the sum of:
 - (i) the gross amount of monies collected or actually received by the Company, its affiliates and sub-licensees (where applicable) per quarter during the Royalty Term, with respect to sales or supplies of any product multiplied by the royalty rate (being 3%), less any applicable deductions; and



- (ii) the gross amount of monies collected or actually received by the Company from sub-licensees (other than affiliates) under sub-licensing arrangements for the right to use the Licenced Technology multiplied by the receipts percentage (subject to certain conditions, being a rate of either 20%, 15% or 10%).

It is a term of the Hudson License Agreement that where the achievement of first regulatory approval would create an obligation to pay Hudson a royalty pursuant to Section 7(d)(iv) above, the Company will be required to pay the higher of (but not both), the amount payable under Section 7(d)(iv) or the amount that would be payable under Section 7(e).

The Company has a right at any time after the satisfaction of the condition in Section 7(d)(iv) to extinguish the royalty by making a payment to Hudson (in cash or in Shares, as agreed by Hudson). The amount payable will be determined by agreement or by an independent expert as to the fair market value of the royalty entitlement.

- (f) **(Termination):**
- (i) The Company may terminate the Hudson Licence Agreement if it does not achieve a listing on the ASX within 18 months of the commencement date of the Agreement (being 29 February 2024).
- (ii) Either party may terminate the Hudson Licence Agreement where a party commits a material breach, and that breach is not remedied within 30 days after notice to do so.
- (iii) Upon termination of the Hudson Licence Agreement for any reason, all outstanding amounts payable by the Company to Hudson will become immediately due and payable and all licences granted by Hudson to the Company will terminate.

The Hudson Licence Agreement otherwise contains terms and conditions (including standard representations, warranties and indemnities) considered standard for an agreement of this nature.

7.2 Research Services Agreement

On 29 August 2022, the Company entered into a research services agreement with Hudson, pursuant to which Hudson has provided services to the Company in connection with the Licenced Technology as agreed between the Company and Hudson from time to time (**Research Services Agreement**).

The existing statement of works under the Research Services Agreement is due to expire on 29 August 2023. The Company considers the Research Services Agreement to be a legacy agreement which is no longer material to the Company and does not intend to renew the Research Services Agreement. The Company anticipated requiring the services of Hudson personnel to assist with the:

- (a) generation of a statistical model;
- (b) expression, purification and testing of monoclonal antibodies suitable for use in the mART; and
- (c) validation of the Licensed Technology.

The Company has undertaken the above activities, is not reliant on the provision of services of any personnel provided under the Research Services Agreement and does not consider



the Research Services Agreement to be material to the Company's current or future operations. The Company does not anticipate any disruptions to its business as a result of not renewing the Research Services Agreement.

7.3 Lead Manager Mandate

The Company entered into a mandate agreement dated 16 May 2023 appointing Taylor Collison Limited to act as exclusive Lead Manager and broker in respect of the Public Offer (**Lead Manager Mandate**).

Under the Lead Manager Mandate, the Lead Manager will provide services and assistance customarily provided in connection with marketing and execution of an initial public offer.

The Company will pay the following fees to the Lead Manager (or its nominees) pursuant to the Lead Manager Mandate, subject to the successful completion of the Public Offer:

- (a) a management fee of 2% of the proceeds from the Public Offer;
- (b) a capital raising fee of 4% of the proceeds from the Public Offer; and
- (c) the Lead Manager Options.

See Section 1.8 for further information regarding the Lead Manager's interests in the Offers.

The Lead Manager Mandate otherwise contains terms and conditions (including standard representations, warranties and indemnities) considered standard for an agreement of this nature.

7.4 Seed Raising Convertible Note Agreements

Prior to Admission, the Company undertook a seed raising via the issue of convertible notes, raising approximately \$1,600,000. The convertible notes were negotiated on arm's length with subscriptions from new and existing Shareholders of the Company, including Dr Andrew Stephens.

A summary of the Seed Raising Convertible Note Agreements is detailed below:

- (a) **(Face Value)**: The convertible notes were issued with a face value of \$1.00 each.
- (b) **(Interest)**: No interest is payable by the Company.
- (c) **(Maturity Date)**: The earlier to occur of, amongst other things, the business day prior to Admission of the Company to the official list of ASX or any other prescribed exchange.
- (d) **(Conversion Price)**: The conversion price is 50% of the Offer Price, being \$0.10.
- (e) **(Security)**: The convertibles notes are unsecured.
- (f) **(Issue of Shares)**: Within 5 business days of the Maturity Date, the Company must issue and allot that number of shares at the Conversion Price to each note holder.

The Seed Raising Convertible Note Agreements otherwise contains terms and conditions (including standard representations, warranties and indemnities) considered standard for an agreement of this nature. The Seed Raising Convertible Note Agreements were executed between August 2022 and April 2023.

As at the date of this Prospectus, Dr Andrew Stephens (via Fotovet Pty Ltd ATF for the Stephens Family Trust, an entity of which Dr Andrew Stephens is the sole director and



shareholder) holds Seed Raising Convertible Note Agreements with a face value of \$50,000 which, under the Conversion Offer, will convert into 500,000 Shares. The terms of the Seed Raising Convertible Note Agreements on issue to Fotovet Pty Ltd ATF for the Stephens Family Trust are identical with the terms of the other Seed Raising Convertible Note Agreements entered into between the Company and other unrelated parties.

7.5 Employment Agreements and Letters of Appointment

(a) **Employment Agreement – Dr Richard Allman**

The Company has entered into an employment agreement with Dr Richard Allman on 30 August 2022, pursuant to which Dr Allman will be appointed as the Company's Chief Executive Officer.

Pursuant to the agreement, Dr Allman is entitled to receive \$180,000 per annum (excluding statutory superannuation). In addition, the Company has agreed to issue to Dr Allman (or his nominees) 2,500,000 Options on the terms and conditions set out in Section 8.2.

The Board may, in its absolute discretion invite Dr Allman to participate in bonus and/or other incentive schemes in the Company that it may implement from time to time, subject to compliance with the Corporations Act and Listing Rules.

The agreement is for an indefinite term, continuing until terminated by either the Company or Dr Allman giving not less than three months written notice of termination to the other party (or shorter period in limited circumstances). Subject to the Corporations Act and the Listing Rules, the Company may terminate the agreement for convenience at any time by making a payment to Dr Allman equal to 3 months of the salary component of his remuneration package.

Dr Allman is also subject to restrictions in relation to the use of confidential information during and after his employment with the Company ceases and being directly or indirectly involved in a competing business during the continuance of his employment with the Company and for a period of up to 12 months after his employment with the Company ceases, on terms which are otherwise considered standard for agreements of this nature.

In addition, the agreement contains additional provisions considered standard for agreements of this nature.

(b) **Employment Agreement – Dr Andrew Stephens**

The Company has entered into an employment agreement with Dr Andrew Stephens on 13 September 2022, pursuant to which Dr Stephens will be appointed as an Executive Director. Dr Stephens has also been appointed by the Company as its Chief Scientific Officer.

Pursuant to the agreement, Dr Stephens is entitled to receive up to \$180,000 per annum (excluding statutory superannuation) pro-rated for three business days a week (being \$108,000). In addition, the Company has agreed to issue to Dr Stephens (or his nominees) 1,500,000 Options on the terms and conditions set out in Section 8.2.

The Board may, in its absolute discretion invite Dr Stephens to participate in bonus and/or other incentive schemes in the Company that it may implement from time to time, subject to compliance with the Corporations Act and Listing Rules.

The agreement is for an indefinite term, continuing until terminated by either the Company or Dr Stephens giving not less than three months written notice of



termination to the other party (or shorter period in limited circumstances). Subject to the Corporations Act and the Listing Rules, the Company may terminate the agreement for convenience at any time by making a payment to Dr Stephens equal to 3 months of the salary component of his remuneration package.

Dr Stephens is also subject to restrictions in relation to the use of confidential information during and after his employment with the Company ceases and being directly or indirectly involved in a competing business during the continuance of his employment with the Company and for a period of up to 12 months after his employment with the Company ceases, on terms which are otherwise considered standard for agreements of this nature.

In addition, the agreement contains additional provisions considered standard for agreements of this nature.

(c) **Non-Executive Director Letter of Appointment – Professor Tom Jobling**

The Company has entered into a non-executive director letter of appointment with Professor Tom Jobling pursuant to which the Company has agreed to pay Professor Jobling \$4,000 per month (plus GST), on and from the date of the Company's admission to the official list of ASX.

In addition, the Company has agreed to issue to Professor Jobling (or his nominees) 1,500,000 Options on the terms and conditions set out in Section 8.2.

The agreement contains additional provisions considered standard for agreements of this nature.

(d) **Non-Executive Director Letter of Appointment – Adrien Wing**

The Company has entered into a non-executive director letter of appointment with Mr Adrien Wing pursuant to which the Company has agreed to pay Mr Wing \$7,500 per month (plus GST), which is accrued and payable on and from the date of receipt of ASX in-principle approval as the Company's suitability for admission to the official list of the ASX.

The agreement contains additional provisions considered standard for agreements of this nature.

(e) **Non-Executive Director Letter of Appointment – Lucina Nolan**

The Company has entered into a non-executive director letter of appointment with Lucina Nolan pursuant to which the Company has agreed to pay Ms Nolan \$4,000 per month (plus GST), on and from the date of the Company's admission to the official list of ASX.

In addition, the Company has agreed to issue to Ms Nolan (or her nominees) 1,500,000 Options on the terms and conditions set out in Section 8.2.

The agreement contains additional provisions considered standard for agreements of this nature.

7.6 Deeds of indemnity, insurance and access

The Company is party to a deed of indemnity, insurance and access with each of the Directors. Under these deeds, the Company indemnifies each Director to the extent permitted by law against any liability arising as a result of the Director acting as a director of the Company. The Company is also required to maintain insurance policies for the benefit of the

relevant Director and must allow the Directors to inspect board papers in certain circumstances. The deeds are considered standard for documents of this nature.

For personal use only



8. Additional information

8.1 Rights attaching to Shares

A summary of the rights attaching to the Shares is detailed below. This summary is qualified by the full terms of the Constitution (a full copy of the Constitution is available from the Company on request free of charge) and does not purport to be exhaustive or to constitute a definitive statement of the rights and liabilities of Shareholders. These rights and liabilities can involve complex questions of law arising from an interaction of the Constitution with statutory and common law requirements. For a Shareholder to obtain a definitive assessment of the rights and liabilities which attach to the Shares in any specific circumstances, the Shareholder should seek legal advice.

- (a) **(Ranking of Shares):** At the Prospectus Date, all Shares are of the same class and rank equally in all respects. Specifically, the Shares issued pursuant to this Prospectus will rank equally with existing Shares.
- (b) **(Voting rights):** Subject to any rights or restrictions, at general meetings:
 - (i) every Shareholder present and entitled to vote may vote in person or by attorney, proxy or representative;
 - (ii) has one vote on a show of hands; and
 - (iii) has one vote for every Share held, upon a poll.
- (c) **(Dividend rights):** Shareholders will be entitled to dividends, distributed among members in proportion to the capital paid up, from the date of payment. No dividend carries interest against the Company and the declaration of Directors as to the amount to be distributed is conclusive.

The Company must not pay a dividend unless the Company's assets exceed its liabilities immediately before the dividend is declared and the excess is sufficient for the payment of the dividend.

- (d) **(Variation of rights):** The rights attaching to the Shares may only be varied by the consent in writing of the holders of three-quarters of the Shares, or with the sanction of a special resolution passed at a general meeting.
- (e) **(Transfer of Shares):** Shares can be transferred upon delivery of a proper instrument of transfer to the Company or by a transfer in accordance with the ASX Settlement Operating Rules. The instrument of transfer must be in writing, in the approved form, and signed by the transferor and the transferee. Until the transferee has been registered, the transferor is deemed to remain the holder, even after signing the instrument of transfer.

In some circumstances, the Directors may refuse to register a transfer if upon registration the transferee will hold less than a marketable parcel. The Board may refuse to register a transfer of Shares upon which the Company has a lien.

- (f) **(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.

The Directors may convene a general meeting at their discretion. General meetings shall also be convened on requisition as provided for by the Corporations Act.



- (g) **(Unmarketable parcels):** The Company's Constitution provides for the sale of unmarketable parcels (being a parcel of Shares less than \$500.00) subject to any applicable laws and provided a notice is given to the minority Shareholders stating that the Company intends to sell their relevant Shares unless an exemption notice is received by a specified date.
- (h) **(Rights on winding up):** If the Company is wound up, the liquidator may with the sanction of special resolution, divide the assets of the Company amongst members as the liquidator sees fit.
- (i) **(Restricted Securities):** A holder of Restricted Securities (as defined in the Listing Rules) must comply with the requirements imposed by the Listing Rules in respect of Restricted Securities.

8.2 Terms and conditions of Director and employee Options

- (a) **(Entitlement):** Subject to the terms and conditions set out below, each Option entitles the holder to the issue of one fully paid ordinary share in the capital of the Company (Share).
- (b) **(Quotation of the Options):** The Company will not apply for quotation of the Options on any securities exchange.
- (c) **(Exercise Price):** The Options have an exercise price of \$0.30 each.
- (d) **(Expiry Date):** The Options expire at 5:00pm (AEST) three years from the date of quotation of the Company's Shares on the official list of the Australian Securities Exchange (Official List of ASX).

An Option not exercised before the Expiry Date will automatically lapse on the Expiry Date.

- (e) **(Notice of Exercise):** The holder may exercise their Options by lodging with the Company, on or prior to the Expiry Date:
 - (i) in whole or in part, and if exercised in part, a minimum of \$1,000 worth of Options must be exercised on each occasion;
 - (ii) a written notice of exercise of Options specifying the number of Options being exercised (**Exercise Notice**); and
 - (iii) a cheque or electronic funds transfer for the Exercise Price for the number of Options being exercised. Cheques shall be in Australian currency made payable to the Company and crossed "Not Negotiable". An Exercise Notice is only effective when the Company has received the full amount of the Exercise Price in cleared funds.

The holder may not exercise the Options (and the Company is not required to issue Shares upon such exercise) if it would be unlawful to do so.

- (f) **(Timing of issue of Shares and quotation of Shares on exercise):** As soon as practicable after the valid exercise of an Option by the holder, the Company will:
 - (i) issue, allocate or cause to be transferred to the holder the number of Shares to which the holder is entitled;
 - (ii) issue a substitute Certificate for any remaining unexercised Options held by the holder;



- (iii) if required and subject to paragraph (g), give ASX a notice that complies with section 708A(5)(e) of the Corporations Act; and
- (iv) in the event that the Company has been admitted to the Official List of ASX, do all such acts, matters and things to obtain the grant of quotation of the Shares by ASX in accordance with the Listing Rules.

All Shares issued upon the exercise of Options will upon issue rank equally in all respects with the then issued Shares.

- (g) **(Cashless exercise of Options):** The holder may elect not to be required to provide payment of the Exercise Price for the number of Options specified in a Notice of Exercise but that on exercise of those Options the Company will transfer or allot to the holder that number of Shares equal in value to the positive difference between the then Market Value of the Shares at the time of exercise and the Exercise Price that would otherwise be payable to exercise those Options (with the number of Shares rounded down to the nearest whole Share).

Market Value means, at any given date, the volume weighted average price per Share traded on the ASX over the five (5) trading days immediately preceding that given date.

- (h) **(Escrow):** In the event the Company is admitted to the Official List of ASX, the holder may be required to enter into an escrow agreement in accordance with the requirements of Chapter 9 of the ASX Listing Rules for the Options (Escrow). By applying for Options, the holder will be taken to have acknowledged and agreed that the holder will execute all documents required by the Company to give effect to the Escrow in the form required by the ASX.
- (i) **(Restrictions on transfer of Shares):** If the Company is required but unable to give ASX a notice that complies with section 708A(5)(e) of the Corporations Act, Shares issued on exercise of the Options may not be traded until 12 months after their issue unless the Company, at its sole discretion, elects to issue a prospectus pursuant to section 708A(11) of the Corporations Act.
- (j) **(Quotation of Shares on exercise):** In the event that the Company has been admitted to the Official List of ASX, the Company will apply for official quotation on ASX of all Shares issued upon exercise of the Options within 5 Business Days after the date of issue of those Shares.
- (k) **(Options not transferrable):** The Options will not be transferable without the prior written approval of the Board.
- (l) **(Participation in new issues):** There are no participation rights or entitlements inherent in the Options and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Options without exercising the Options. However, the Company will give the holder notice of the proposed issue prior to the date for determining entitlements to participate in any such issue.
- (m) **(Adjustment for bonus issues of Shares):** If the Company makes a bonus issue of Shares or other Securities to existing Shareholders (other than an issue in lieu or in satisfaction of dividends or by way of dividend reinvestment):
 - (i) the number of Shares which must be issued on the exercise of an Option will be increased by the number of Shares which the Option holder would have received if the Option holder had exercised the Option before the record date for the bonus issue; and
 - (ii) no change will be made to the Exercise Price.



- (n) **(Adjustment for entitlement issue):** If the Company makes an issue of Shares pro rata to existing Shareholders (other than an issue in lieu or in satisfaction of dividends or by way of dividend reinvestment) the Exercise Price of an Option will not be adjusted following an entitlement offer.
- (o) **(Adjustments for reorganisation):** If there is any reorganisation of the issued share capital of the Company, the rights of the Option holder will be varied in accordance with the Listing Rules.
- (p) **(Return of capital rights):** The Options do not confer any right to a return of capital, whether in a winding up, upon a reduction of capital or otherwise.
- (q) **(Rights on winding up):** The Options have no right to participate in the surplus profits or assets of the Company upon a winding up of the Company.
- (r) **(Dividend and voting rights):** The Options do not confer on the holder an entitlement to vote at general meetings of the Company or to receive dividends.
- (s) **(Takeovers prohibition):**
- (i) the issue of Shares on exercise of the Director Options is subject to and conditional upon the issue of the relevant Shares not resulting in any person being in breach of section 606(1) of the Corporations Act; and
 - (ii) the Company will not be required to seek the approval of its members for the purposes of item 7 of section 611 of the Corporations Act to permit the issue of any Shares on exercise of the Director Options.
- (t) **(Amendments required by ASX):** The terms of the Options may be amended as considered necessary by the Board in order to comply with the ASX Listing Rules, or any directions of ASX regarding the terms provided that, subject to compliance with the Listing Rules, following such amendment, the economic and other rights of the holder are not diminished or terminated.
- (u) **(Constitution)** Upon the issue of the Shares on exercise of the Options, the holder will be bound by the Company's Constitution.

8.3 Terms and condition of Lead Manager Options and Advisor Options

- (a) **(Entitlement):** Subject to the terms and conditions set out below, each Option entitles the holder to the issue of one fully paid ordinary share in the capital of the Company (Share).
- (b) **(Issue Price):** The Options are issued for nil cash consideration.
- (c) **(Exercise Price):** The Options are exercisable at \$0.30 each.
- (d) **(Expiry Date):** Each Option will expire at 5:00pm (AWST) three years from the date of quotation of the Company's Shares on the official list of the Australian Securities Exchange (**Expiry Date**). An Option not exercised before the Expiry Date will automatically lapse on the Expiry Date.
- (e) **(Exercise Period):** The Options are exercisable at any time and from time to time on or prior to the Expiry Date.
- (f) **(Notice of Exercise):** The Options may be exercised by notice in writing to the Company in the manner specified on the Option certificate (Notice of Exercise) and



payment of the Exercise Price for each Option being exercised in Australian currency by electronic funds transfer or other means of payment acceptable to the Company.

Any Notice of Exercise of an Option received by the Company will be deemed to be a notice of the exercise of that Option as at the date of receipt of the Notice of Exercise and the date of receipt of the payment of the Exercise Price for each Option being exercised in cleared funds (**Exercise Date**).

- (g) (**Issue of Shares**): As soon as practicable after the valid exercise of an Option, the Company will:
- (i) issue, allocate or cause to be transferred to the holder the number of Shares to which the holder is entitled;
 - (ii) issue a substitute Certificate for any remaining unexercised Options held by the holder;
 - (iii) if required, and subject to clause (h), give ASX a notice that complies with section 708A(5)(e) of the Corporations Act; and
 - (iv) do all such acts, matters and things to obtain the grant of quotation of the Shares by ASX in accordance with the Listing Rules.
- (h) (**Restrictions on transfer of Shares**): If the Company is required but unable to give ASX a notice that complies with section 708A(5)(e) of the Corporations Act, or such a notice for any reason is not effective to ensure that an offer for sale of the Shares does not require disclosure to investors, Shares issued on exercise of the Options may not be traded until 12 months after their issue unless the Company, at its sole discretion, elects to issue a prospectus pursuant to section 708A(11) of the Corporations Act. The Company is authorised by the holder to apply a holding lock on the relevant Shares during the period of such restriction from trading.
- (i) (**Ranking**): All Shares issued upon the exercise of Options will upon issue rank equally in all respects with other Shares.
- (j) (**Transferability of the Options**): The Options are not transferable, except with the prior written approval of the Company at its sole discretion and subject to compliance with the Corporations Act and Listing Rules.
- (k) (**Dividend rights**): An Option does not entitle the holder to any dividends.
- (l) (**Voting rights**): An Option does not entitle the holder to vote on any resolutions proposed at a general meeting of the Company, subject to any voting rights provided under the Corporations Act or the ASX Listing Rules where such rights cannot be excluded by these terms.
- (m) (**Quotation of the Options**): The Company will not apply for quotation of the Options on any securities exchange.
- (n) (**Adjustments for reorganisation**): If there is any reorganisation of the issued share capital of the Company, the rights of the Option holder will be varied in accordance with the Listing Rules.
- (o) (**Entitlements and bonus issues**): Subject to the rights under clause (p), holders will not be entitled to participate in new issues of capital offered to shareholders such as bonus issues and entitlement issues.



- (p) **(Adjustment for bonus issues of Shares):** If the Company makes a bonus issue of Shares or other securities to existing Shareholders (other than an issue in lieu or in satisfaction of dividends or by way of dividend reinvestment):
- (i) the number of Shares which must be issued on the exercise of an Option will be increased by the number of Shares which the Option holder would have received if the Option holder had exercised the Option before the record date for the bonus issue; and
 - (ii) no change will be made to the Exercise Price.
- (q) **(Return of capital rights):** The Options do not confer any right to a return of capital, whether in a winding up, upon a reduction of capital or otherwise.
- (r) **(Rights on winding up):** The Options have no right to participate in the surplus profits or assets of the Company upon a winding up of the Company.
- (s) **(Takeovers prohibition):**
- (i) the issue of Shares on exercise of the Options is subject to and conditional upon the issue of the relevant Shares not resulting in any person being in breach of section 606(1) of the Corporations Act; and
 - (ii) the Company will not be required to seek the approval of its members for the purposes of item 7 of section 611 of the Corporations Act to permit the issue of any Shares on exercise of the Options.
- (t) **(No other rights)** An Option does not give a holder any rights other than those expressly provided by these terms and those provided at law where such rights at law cannot be excluded by these terms.
- (u) **(Amendments required by ASX)** The terms of the Options may be amended as considered necessary by the Board in order to comply with the ASX Listing Rules, or any directions of ASX regarding the terms provided that, subject to compliance with the Listing Rules, following such amendment, the economic and other rights of the holder are not diminished or terminated.
- (v) **(Constitution)** Upon the issue of the Shares on exercise of the Options, the holder will be bound by the Company's Constitution.

8.4 Summary of the Company's Employee Securities Incentive Plan

The full terms of the Plan may be inspected at the registered office of the Company during normal business hours. A summary of the terms of the Plan is set out below. It is intended that both the Executive and Non-Executive Directors will participate in the Plan. As at the date of this Prospectus no Director currently participates in the Plan.

- (a) **(Eligible Participant):** Eligible Participant means a person that has been determined by the Board to be eligible to participate in the Plan from time to time and is an "ESS participant" (as that term is defined in Division 1A) in relation to the Company or an associated entity of the Company. This relevantly includes, amongst others:
- (i) an employee or director of the Company or an individual who provides services to the Company;
 - (ii) an employee or director of an associated entity of the Company or an individual who provides services to such an associated entity;
 - (iii) a prospective person to whom paragraphs (i) or (ii) apply;



- (iv) a person prescribed by the relevant regulations for such purposes; or
- (v) certain related persons on behalf of the participants described in paragraphs (i) to (iv) (inclusive).

(b) **(Maximum allocation)**

- (i) The Company must not make an offer of Securities under the Plan in respect of which monetary consideration is payable (either upfront, or on exercise of convertible securities) where the total number of Plan Shares (as defined in paragraph (m) below) that may be issued, or acquired upon exercise of Plan Convertible Securities offered, when aggregated with the number of Shares issued or that may be issued as a result of offers made under the Plan at any time during the previous 3 year period would exceed 5% of the total number of Shares on issue at the date of the offer or such other limit as may be specified by the relevant regulations or the Company's Constitution from time to time.
- (ii) The maximum number of equity securities proposed to be issued under the Plan for the purposes of Listing Rule 7.2, Exception 13 is 12,900,000 (**ASX Limit**). This means that, subject to the following paragraph, the Company may issue up to the ASX Limit under the Plan, without seeking Shareholder approval and without reducing its placement capacity under Listing Rule 7.1.

The Company will require prior Shareholder approval for the issue of Securities under the Plan to Directors, their associates, and any other person whose relationship with the Company or a Director or a Director's associate is such that, in ASX's opinion, the acquisition should be approved by Shareholders. The issue of Securities with Shareholder approval will not count towards the ASX Limit.

(c) **(Purpose):** The purpose of the Plan is to:

- (i) assist in the reward, retention and motivation of Eligible Participants;
- (ii) link the reward of Eligible Participants to Shareholder value creation; and
- (iii) align the interests of Eligible Participants with shareholders of the Group (being the Company and each of its Associated Bodies Corporate), by providing an opportunity to Eligible Participants to receive an equity interest in the Company in the form of Securities.

(d) **(Plan administration):** The Plan will be administered by the Board. The Board may exercise any power or discretion conferred on it by the Plan rules in its sole and absolute discretion, subject to compliance with applicable laws and the Listing Rules. The Board may delegate its powers and discretion.

(e) **(Eligibility, invitation and application):** The Board may from time to time determine that an Eligible Participant may participate in the Plan and make an invitation to that Eligible Participant to apply for Securities on such terms and conditions as the Board decides. An invitation issued under the Plan will comply with the disclosure obligations pursuant to Division 1A.

On receipt of an invitation, an Eligible Participant may apply for the Securities the subject of the invitation by sending a completed application form to the Company. The Board may accept an application from an Eligible Participant in whole or in part. If an Eligible Participant is permitted in the invitation, the Eligible Participant may, by notice in writing to the Board, nominate a party in whose favour the Eligible Participant wishes to renounce the invitation.



A waiting period of at least 14 days will apply to acquisitions of Securities for monetary consideration as required by the provisions of Division 1A.

- (f) **(Grant of Securities)**: The Company will, to the extent that it has accepted a duly completed application, grant the successful applicant (**Participant**) the relevant number of Securities, subject to the terms and conditions set out in the invitation, the Plan rules and any ancillary documentation required.
- (g) **(Terms of Convertible Securities)**: Each 'Convertible Security' represents a right to acquire one or more Shares (for example, under an option or performance right), subject to the terms and conditions of the Plan.

Prior to a Convertible Security being exercised a Participant does not have any interest (legal, equitable or otherwise) in any Share the subject of the Convertible Security by virtue of holding the Convertible Security. A Participant may not sell, assign, transfer, grant a security interest over or otherwise deal with a Convertible Security that has been granted to them. A Participant must not enter into any arrangement for the purpose of hedging their economic exposure to a Convertible Security that has been granted to them.

- (h) **(Vesting of Convertible Securities)**: Any vesting conditions applicable to the grant of Convertible Securities will be described in the invitation. If all the vesting conditions are satisfied and/or otherwise waived by the Board, a vesting notice will be sent to the Participant by the Company informing them that the relevant Convertible Securities have vested. Unless and until the vesting notice is issued by the Company, the Convertible Securities will not be considered to have vested. For the avoidance of doubt, if the vesting conditions relevant to a Convertible Security are not satisfied and/or otherwise waived by the Board, that Convertible Security will lapse.
- (i) **(Exercise of Convertible Securities and cashless exercise)**: To exercise a Convertible Security, the Participant must deliver a signed notice of exercise and, subject to a cashless exercise of Convertible Securities (see below), pay the exercise price (if any) to or as directed by the Company, at any time prior to the earlier of any date specified in the vesting notice and the expiry date as set out in the invitation.

At the time of exercise of the Convertible Securities, and subject to Board approval, the Participant may elect not to be required to provide payment of the exercise price for the number of Convertible Securities specified in a notice of exercise, but that on exercise of those Convertible Securities the Company will transfer or issue to the Participant that number of Shares equal in value to the positive difference between the Market Value of the Shares at the time of exercise and the exercise price that would otherwise be payable to exercise those Convertible Securities.

Market Value means, at any given date, the volume weighted average price per Share traded on the ASX over the 5 trading days immediately preceding that given date, unless otherwise specified in an invitation.

A Convertible Security may not be exercised unless and until that Convertible Security has vested in accordance with the Plan rules, or such earlier date as set out in the Plan rules.

- (j) **(Delivery of Shares on exercise of Convertible Securities)**: As soon as practicable after the valid exercise of a Convertible Security by a Participant, the Company will issue or cause to be transferred to that Participant the number of Shares to which the Participant is entitled under the Plan rules and issue a substitute certificate for any remaining unexercised Convertible Securities held by that Participant.



- (k) **(Forfeiture of Convertible Securities):** Where a Participant who holds Convertible Securities ceases to be an Eligible Participant or becomes insolvent, all unvested Convertible Securities will automatically be forfeited by the Participant, unless the Board otherwise determines in its discretion to permit some or all of the Convertible Securities to vest.

Where the Board determines that a Participant has acted fraudulently or dishonestly, or wilfully breached his or her duties to the Group, the Board may in its discretion deem all unvested Convertible Securities held by that Participant to have been forfeited.

Unless the Board otherwise determines, or as otherwise set out in the Plan rules:

- (i) any Convertible Securities which have not yet vested will be forfeited immediately on the date that the Board determines (acting reasonably and in good faith) that any applicable vesting conditions have not been met or cannot be met by the relevant date; and
 - (ii) any Convertible Securities which have not yet vested will be automatically forfeited on the expiry date specified in the invitation.
- (l) **(Change of control):** If a change of control event occurs in relation to the Company, or the Board determines that such an event is likely to occur, the Board may in its discretion determine the manner in which any or all of the Participant's Convertible Securities will be dealt with, including, without limitation, in a manner that allows the Participant to participate in and/or benefit from any transaction arising from or in connection with the change of control event.
- (m) **(Rights attaching to Plan Shares):** All Shares issued under the Plan, or issued or transferred to a Participant upon the valid exercise of a Convertible Security, (**Plan Shares**) will rank pari passu in all respects with the Shares of the same class. A Participant will be entitled to any dividends declared and distributed by the Company on the Plan Shares and may participate in any dividend reinvestment plan operated by the Company in respect of Plan Shares. A Participant may exercise any voting rights attaching to Plan Shares.
- (n) **(Disposal restrictions on Securities):** If the invitation provides that any Plan Shares or Convertible Securities are subject to any restrictions as to the disposal or other dealing by a Participant for a period, the Board may implement any procedure it deems appropriate to ensure the compliance by the Participant with this restriction.
- (o) **(Adjustment of Convertible Securities):** If there is a reorganisation of the issued share capital of the Company (including any subdivision, consolidation, reduction, return or cancellation of such issued capital of the Company), the rights of each Participant holding Convertible Securities will be changed to the extent necessary to comply with the Listing Rules applicable to a reorganisation of capital at the time of the reorganisation.

If Shares are issued by the Company by way of bonus issue (other than an issue in lieu of dividends or by way of dividend reinvestment), the holder of Convertible Securities is entitled, upon exercise of the Convertible Securities, to receive an allotment of as many additional Shares as would have been issued to the holder if the holder held Shares equal in number to the Shares in respect of which the Convertible Securities are exercised.

Unless otherwise determined by the Board, a holder of Convertible Securities does not have the right to participate in a pro rata issue of Shares made by the Company or sell renounceable rights.



- (p) **(Participation in new issues):** There are no participation rights or entitlements inherent in the Convertible Securities and holders are not entitled to participate in any new issue of Shares of the Company during the currency of the Convertible Securities without exercising the Convertible Securities.
- (q) **(Amendment of Plan):** Subject to the following paragraph, the Board may at any time amend any provisions of the Plan rules, including (without limitation) the terms and conditions upon which any Securities have been granted under the Plan and determine that any amendments to the Plan rules be given retrospective effect, immediate effect or future effect.
- No amendment to any provision of the Plan rules may be made if the amendment materially reduces the rights of any Participant as they existed before the date of the amendment, other than an amendment introduced primarily for the purpose of complying with legislation or to correct manifest error or mistake, amongst other things, or is agreed to in writing by all Participants.
- (r) **(Plan duration):** The Plan continues in operation until the Board decides to end it. The Board may from time to time suspend the operation of the Plan for a fixed period or indefinitely, and may end any suspension. If the Plan is terminated or suspended for any reason, that termination or suspension must not prejudice the accrued rights of the Participants.
- (s) **(Employee Share Trust):** The Board may in its sole and absolute discretion use an employee share trust or other mechanism for the purposes of holding securities for holders under the Plan and delivering Shares on behalf of holders upon exercise of Options or Performance Rights.

If a Participant and the Company (acting by the Board) agree in writing that some or all of the Securities granted to that Participant are to be cancelled on a specified date or on the occurrence of a particular event, then those Securities may be cancelled in the manner agreed between the Company and the Participant.

8.5 Effect of the Offers on control and substantial Shareholders

Based on the information known as at the Prospectus Date, on Admission the following persons will have an interest in 5% or more of the Shares on issue:

Name	Number of Shares	Voting power (%)
Adrien Wing ¹	14,250,000	11.09%
Richard Vom ²	8,850,000	6.89%
Hudson Institute of Medical Research ³	7,500,000	5.84%

Notes:

1. *Securities are held as follows:*
 - (a) *6,500,000 Shares are held indirectly by Wing Investment Holdings Pty Ltd ATF The Wing Family Trust, an entity of which Adrien Wing is a director and his spouse, Michelle Wing, is the controller and beneficiary of the trust. Adrien Wing has indicated to the Company that he intends to apply for up to 1,250,000 Shares under the Public Offer which is expected to be held by Wing Investment Holdings Pty Ltd ATF The Wing Family Trust; and*
 - (b) *6,500,000 Shares are held directly by Adrien Wing's spouse, Michelle Wing.*
2. *Securities are held as follows:*
 - (a) *1,850,000 Shares are held directly by Richard Vom; and*
 - (b) *7,000,000 Shares are held indirectly via Loumea Investment Pty Ltd, an entity of which Richard Vom is the sole director and shareholder.*



3. *Securities are held by Hudson Institute Investment Holdings Pty Ltd. As at the Prospectus Date, Hudson Institute of Medical Research has indicated to the Company that it does not intend to acquire any Shares under the Public Offer.*

8.6 Interests of Promoters, Experts and Advisers

(a) **No interest except as disclosed**

Other than as set out below or elsewhere in this Prospectus, no:

(i) persons or entity named in this Prospectus as performing a function in a professional, advisory or other capacity in connection with the preparation or distribution of this Prospectus; or

(ii) promoter of the Company;

holds at the Prospectus Date, or has held at any time during the last 2 years, any interest in:

(iii) the formation or promotion of the Company;

(iv) property acquired or proposed to be acquired by the Company in connection with its formation or promotion, or the Offers; or

(v) the Offers,

and the Company has not paid any amount or provided any benefit, or agreed to do so, to any of those persons for services rendered by them in connection with the formation or promotion of the Company or the Offers.

(b) **Share Registry**

XCEND Pty Ltd has been appointed to conduct the Company's share registry functions and to provide administrative services in respect to the processing of Applications received pursuant to this Prospectus and will be paid for these services on standard industry terms and conditions.

(c) **Auditor**

BDO Audit Pty Ltd has been appointed to act as Auditor to the Company. The Company estimates it will pay BDO Audit Pty Ltd a total of \$35,000 (excluding GST) for these services.

During the 24 months preceding lodgement of this Prospectus with ASIC, BDO Audit Pty Ltd has not provided services to the Company.

(d) **Corporate Lawyers**

Hamilton Locke Lawyers (**HL**) has acted as the Corporate Lawyers to the Company in relation to the Offers. The Company estimates it will pay HL \$85,000 (excluding GST) for these services. Subsequently, fees will be charged in accordance with normal charge out rates.

During the 24 months preceding lodgement of this Prospectus with ASIC, Hamilton Locke has not provided services to the Company.

(e) **Investigating Accountant**

BDO Corporate Finance (East Coast) Pty Ltd has acted as Investigating Accountant and has prepared the Independent Limited Assurance Report which is included in



Annexure B of this Prospectus. The Company estimates it will pay BDO Corporate Finance (East Coast) Pty Ltd a total of \$40,000 (excluding GST) for these services.

During the 24 months preceding lodgement of this Prospectus with ASIC, BDO Corporate Finance (East Coast) Pty Ltd has not provided services to the Company.

(f) **Intellectual Property Expert**

FB Rice as the Intellectual Property Expert and has prepared the Intellectual Property Expert's Report which is included in Annexure A of this Prospectus. The Company estimates it will pay FB Rice a total of \$11,000 (excluding GST) for these services.

During the 24 months preceding lodgement of this Prospectus with ASIC, FB Rice has not provided services to the Company.

(g) **Lead Manager**

Taylor Collison Limited has acted as the Lead Manager to the Public Offer. Details of the payments to be made to the Lead Manager is set out in Section 7.3. During the 24 months preceding lodgement of this Prospectus with ASIC, the Lead Manager have not provided services to the Company.

8.7 Consents

(a) Each of the parties referred to below:

- (i) do not make the Offers and has not authorised or caused the issue of this Prospectus or the making of the Offers;
- (ii) does not make, or purport to make, any statement that is included in this Prospectus, or a statement on which a statement made in this Prospectus is based, other than as specified below or elsewhere in this Prospectus;
- (iii) to the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this Prospectus other than a reference to its name and a statement contained in this Prospectus with the consent of that party as specified below; and
- (iv) has given and has not, prior to the lodgement of this Prospectus with ASIC, withdrawn its consent to the inclusion of the statements in this Prospectus that are specified below in the form and context in which the statements appear.

(b) **Share Registry**

XCEND Pty Ltd has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in this Prospectus as Share Registry of the Company in the form and context in which it is named.

(c) **Auditor**

BDO Audit Pty Ltd has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in this Prospectus as Auditor of the Company in the form and context in which it is named.

(d) **Investigating Accountant**

BDO Corporate Finance (East Coast) Pty Ltd has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in

this Prospectus as the Investigating Accountant to the Company in the form and context in which it is named and has given and not withdrawn its consent to the inclusion of the Independent Limited Assurance Report in the form and context in which it is included.

(e) **Corporate Lawyers**

Hamilton Locke has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in this Prospectus as the corporate lawyers to the Company in the form and context in which it is named and has given and not withdrawn its consent to the inclusion of the Solicitor's Report in the form and context in which it is included.

(f) **Intellectual Property Expert**

FB Rice has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in this Prospectus as the Intellectual Property Expert to the Company in the form and context in which it is named and has given and not withdrawn its consent to the inclusion of the Intellectual Property Expert's Report in the form and context in which it is included.

(g) **Lead Manager**

Taylor Collison Limited has given, and not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to being named in this Prospectus as the Lead Manager to the Public Offer in the form and context in which it is named.

Taylor Collison Limited has not made or purported to make any statement included in or accompanying the Prospectus, nor is any statement in or accompanying the Prospectus based on any statement made by Taylor Collison Limited.

(h) **Tom Jobling**

Professor Tom Jobling has given, and not withdrawn prior to the lodgement of this Prospectus with ASIC, his written consent to being named in this Prospectus and the statements in this Prospectus which are attributed to him, in the form and context in which they are included.

8.8 Expenses of Offers

The total approximate expenses of the Offers payable by the Company are:

	\$
Legal fees	93,500
Investigating Accountant fees	44,000
Intellectual Property Expert Report fees	11,000
Branding/website/IT/publishing	16,500
ASX / ASIC fees	116,750
Lead Manager fees	792,000



	\$
Share registry fees and other administrative expenses	2,750
Contingency fees	5,500
Total	1,082,000

Notes:

1. See Section 7.3 for a summary of the Lead Manager Mandate.
2. Figures above are inclusive of GST.

8.9 Continuous Disclosure Obligations

Following Admission, the Company will be a 'disclosing entity' (as defined in section 111AC of the Corporations Act) and, as such, will be subject to regular reporting and disclosure obligations. Specifically, like all listed companies, the Company will be required to continuously disclose any information it has to the market which a reasonable person would expect to have a material effect on the price or the value of the Shares (unless a relevant exception to disclosure applies). Price sensitive information will be publicly released through ASX before it is otherwise disclosed to Shareholders and market participants. Distribution of other information to Shareholders and market participants will also be managed through disclosure to ASX. In addition, the Company will post this information on its website after ASX confirms that an announcement has been made, with the aim of making the information readily accessible to the widest audience.

8.10 Litigation

So far as the Directors are aware, there is no current or threatened civil litigation, arbitration proceedings or administrative appeals, or criminal or governmental prosecutions of a material nature in which the Company (or any other member of the Group) is directly or indirectly concerned which is likely to have a material adverse effect on the business or financial position of the Company or the Group.

8.11 Documents available for inspection

Copies of the following documents are available for inspection during normal business hours at the registered office of the Company:

- (a) this Prospectus;
- (b) the Constitution; and
- (c) the consents referred to in Section 8.7 of this Prospectus.

8.12 Statement of Directors

The Directors report that after due enquiries by them, in their opinion, since the date of the financial statements in the Independent Limited Assurance Report in Annexure B, there have not been any circumstances that have arisen or that have materially affected or will materially affect the assets and liabilities, financial position, profits or losses or prospects of the Company, other than as disclosed in this Prospectus.



9. Authorisation

The Prospectus is issued by the Company and its issue has been authorised by a resolution of the Directors.

In accordance with section 720 of the Corporations Act, each Director has consented to the lodgement of this Prospectus with ASIC and has not withdrawn that consent.

This Prospectus is signed for and on behalf of the Company by:



Adrien Wing
Non-Executive Chair

Dated: 6 July 2023

For personal use only

10. Glossary of terms

These definitions are provided to assist persons in understanding some of the expressions used in this Prospectus.

\$ means Australian dollars.

AASB means the Australian Accounting Standards Board.

ACOG means the American College of Obstetricians and Gynaecologists.

Admission means admission of the Company to the Official List, following completion of the Offers.

Advisor Options means the 1,500,000 Options to be issued to IRX Advisors (or its nominees).

Applicant means a person who submits an Application Form.

Application means a valid application for Shares pursuant to this Prospectus.

Application Form means an application form attached to or accompanying this Prospectus (including any electronic form application form provided by an online application facility) for the Offers.

Application Monies means the amount of money submitted or made available by an Applicant in connection with an Application.

ASIC means the Australian Securities and Investments Commission.

ASX means ASX Limited (ACN 008 624 691) or, where the context requires, the financial market operated by it.

ASX Settlement means ASX Settlement Pty Limited (ACN 008 504 532).

ASX Settlement Rules means ASX Settlement Operating Rules of ASX Settlement.

Auditor means BDO Audit Pty Ltd (ACN 134 022 870).

Board means the board of Directors of the Company from time to time.

CE means Conformité Européenne certification is a regulatory standard that verifies certain products are safe for sale and use in the European Economic Area.

CHESS means the Clearing House Electronic Subregister System operated by ASX Settlement.

Closing Date means the date specified as the closing date of the Offers, or such other time and date as the Board determines.

Company means Cleo Diagnostics Ltd (ACN 655 717 169).

Completion means the date on which the Securities are issued and transferred to Applicants in accordance with the terms of the Offers.

Constitution means the constitution of the Company.

Conversion Offer means the offer of up to 16,000,000 Shares to the Noteholders (or their respective nominees) pursuant to the Seed Raising Convertible Note Agreement.



Conversion Shares means the Shares to be issued on conversion of the Seed Raising Convertible Notes in accordance with the Seed Raising Convertible Note Agreement, a summary of which is in Section 7.4.

Corporations Act means the *Corporations Act 2001* (Cth), as amended from time to time.

Directors means the directors of the Company from time to time and includes the Existing Directors and the Proposed Directors, as the context requires.

Electronic Prospectus means the electronic copy of this Prospectus located at the Company's website www.cleodx.com.

ELISA means enzyme-linked immunosorbent assay.

Expiry Date means 13 months after the Original Prospectus Date.

Exposure Period means the period of seven days after the date of lodgement of this Prospectus, which period may be extended by the ASIC by not more than seven days pursuant to section 727(3) of the Corporations Act.

FDA means the Food and Drug Administration.

Financial Information has the meaning given in Section 5.

Group means the Company and each of its subsidiaries.

Hudson means the Hudson Institute of Medical Research in Melbourne, Australia.

Hudson Licence Agreement means the licence agreement between Hudson and the Company, a summary of which is in Section 7.1.

Indicative Timetable means the indicative timetable for the Offers on page 11 of this Prospectus.

Investigating Accountant or **BDO** means BDO Corporate Finance (East Coast) Pty Ltd (ACN 050 038 170).

Investigating Accountant's Report or **Independent Limited Assurance Report** means the report prepared by the Investigating Accountant as presented in Annexure B.

IRX Advisors means IRX Advisors Pty Ltd (ACN 630 508 566).

IVD means in vitro diagnostic.

KOL means the dissemination of information concerning the Technology by key opinion leaders.

Lead Manager means Taylor Collison Limited (ACN 008 172 450).

Lead Manager Mandate means the mandate entered between the Company and the Lead Manager dated 16 May 2023 for the provision of lead manager services and bookrunner services in respect of the Public Offer.

Lead Manager Offer means the offer of up to 5,000,000 Options to the Lead Manager (or its nominees) as part consideration for the provision of lead manager and bookrunner services provided to the Company in connection with the Public Offer.

Lead Manager Options means the 5,000,000 Options to be issued to the Lead Manager (or its nominees) under the Lead Manager Offer.

Licenced Technology has the meaning given in Section 2.1.

Listing Rules means the listing rules of ASX.

mART means the 'Multiplex Active Ratio Test'.

MDSAP means medical device single audit program.

Minimum Subscription means the issue of 60,000,000 Shares under the Offers, to raise \$12,000,000 (before costs).

NICE UK means the National Institute for Health and Care Excellence.

Noteholder means a holder of a Seed Raising Convertible Note.

Offer Price means \$0.20 per Share.

Offers or Offer means any or all of the Public Offer, the Conversion Offer and the Lead Manager Offer (as the context requires).

Official List means the official list of ASX.

Official Quotation means official quotation by ASX in accordance with the Listing Rules.

Opening Date means the date specified as the opening date in the Indicative Timetable.

Option means an option, giving the holder the right, but not an obligation, to acquire a Share at a predetermined price and at a specified time in the future.

Original Prospectus means the prospectus dated 23 June 2023.

Original Prospectus Date means 23 June 2023.

p53 has the meaning given in Section 2.2(a)(ii).

Plan means the Cleo Diagnostics Ltd Employee Securities Incentive Plan.

Prospectus or Replacement Prospectus means this prospectus dated 6 July 2023.

Predicate Device means a medical device that may be legally marketed and used as a point of comparison for new medical devices seeking regulatory approval.

Prospectus Date means the date on which a copy of this Prospectus was lodged with ASIC, being 6 July 2023.

Public Offer means the offer of up to 60,000,000 Shares to be issued at a price of \$0.20 per Share, to raise up to \$12,000,000 (before costs).

Recommendations means the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations (4th Edition).

Relevant Issue Date means the date that the 12 month escrow period commences in respect of the Shares issued under the Conversion Offer, which will be a date determined by ASX in accordance with the Listing Rules and may be:

- (a) the date the subscribers under the Conversion Offer provided funds under the Seed Raising Convertible Note Agreements; or
- (b) the date the Shares are issued under the Conversion Offer; or
- (c) such other date as ASX may determine.



Section means a section of this Prospectus.

Securities means any securities, including Shares, Options or Performance Options, issued or granted by the Company.

Seed Raising Convertible Note Agreements has the meaning given in Section 7.4.

Sensitivity refers to the ability of a test to correctly identify patients with the tested for disease (true positive rate).

Share or Shares means a fully paid ordinary share or shares in the capital of the Company.

Shareholder means a holder of one or more Shares in the Company.

Specificity refers to the ability of a test to correctly identify people without the tested for disease (true negative rate).

Substantially Equivalent means a device is as least as safe and effective as its Predicate Device. A device is considered to be substantially equivalent to a Predicate Device if it:

- (a) has the same intended use as the Predicate Device; and
- (b) has technological characteristics which do not raise new questions of safety and effectiveness when compared to the Predicate Device.

TGA means the Therapeutic Goods Administration.

Tests means collectively the Triage Test, the Screening Test and the Recurrence Test.

USPTO means the United States Patent and Trademark Office.

For personal use only



Annexure A – Intellectual Property Report

For personal use only



For personal use only

FB RICE

Intellectual Property Report

Cleo Diagnostics Ltd

22 June 2023



The IP
Navigators

1.1 Introduction

Set out below is our report (the "Report") providing details and statuses of the intellectual property currently handled by FB Rice Pty Ltd ("FB Rice") on behalf of Cleo Diagnostics Ltd ("Cleo Diagnostics").

Section 1.2 provides an outline of the Background and Scope of the Report.

A general explanation of intellectual property and processes for obtaining intellectual property is provided in **Section 1.3** of the Report.

A summary of the intellectual property handled by FB Rice on behalf of Cleo Diagnostics is provided in **Section 1.4** of the Report. The summary includes details and statuses of the patent applications licenced by Cleo Diagnostics (Section 1.4.2).

Section 1.5 explains that we are not aware of any issues that affect proprietorship of the relevant patent applications in the portfolio and provides comments on the licence agreement between Hudson Institute of Medical Research and Cleo Diagnostics.

Section 1.6 provides general comments on Validity of Patents.

Section 1.7 provides general comments on Cleo Diagnostics' Freedom to Operate.

Section 1.8 outlines Limitations and Qualifications of this Report.

Section 1.9 provides a Statement of Independence by FB Rice.

1.2 Background and Scope

FB Rice has been instructed by Cleo Diagnostics to prepare the Report for inclusion in a prospectus to be issued by Cleo Diagnostics ("Prospectus"). Cleo Diagnostics has an exclusive licence agreement with Hudson Institute of Medical Research providing them with a royalty-bearing, non-transferable licence to use, develop, modify, commercialise and exploit the technology referred to in Section 1.4.2 below within the relevant patent jurisdiction within the field of diagnostic and screening technology.

To the best of our knowledge the Report is accurate as at its date, subject to the limitations and qualifications set out in Section 1.7 (in particular, subject to the sources of information described in Section 1.7.1). FB Rice is not aware of any material changes expected to occur to the status of the matters outlined below, except where indicated.

1.3 Intellectual Property

1.3.1 Meaning of Intellectual Property

The term "intellectual property" refers to a group of registrable and non-registrable rights, including rights in patents, designs, trade marks, plant varieties, copyright, confidential information and trade secrets. Intellectual property has many of the characteristics possessed by real and personal property. In particular, intellectual property is an asset, which may be bought, sold, licenced, exchanged, or otherwise transferred

as other forms of property. Accordingly, an intellectual property owner has the right to prevent the unauthorised use or sale of its property.

This Report is only directed to intellectual property which is in the form of patent applications/patents.

1.3.2 Patents

Patents cover inventions and provide a temporary monopoly in exchange for an inventor's full disclosure of the invention to the public. A patent provides protection for novel (new), inventive (non-obvious) and useful inventions for a fixed period, which is typically up to 20 years. For certain inventions, this period may be extended. To maintain a pending application or patent, it is necessary to pay renewal fees, usually on an annual basis. Patents may be granted in relation to a wide range of subject matter, such as new or improved products, new uses for products and methods. Such subject matter must, however, be industrially applicable.

A patent cannot be granted on a worldwide basis. Rather, patents must be obtained in every country where protection is required. Although there is a certain amount of harmonisation between the patent granting procedures and standards throughout the world, there are differences regarding the test for patentability. Accordingly, patent scope may vary from country to country and indeed a patent may not be granted in a particular country for failure to comply with the relevant standards.

1.3.3 Patenting Process

In most countries, the process of protecting patent rights begins with the submission of an initial patent application comprising a patent specification describing the invention. Filing an Australian patent application (provisional or complete), or other initial patent application in a foreign country, satisfies this requirement.

A fundamental requirement of most patent systems is that the invention is novel and inventive (non-obvious) at the time of filing, relative to what was publicly known or used at the date of the application. Accordingly, it is imperative that the specification contains a full disclosure of the invention. A patent specification generally consists of a description of the invention and so-called claims that indicate the scope of the protection conferred, or protection sought, for the invention.

Once the initial application has been filed, further applications in foreign countries must be filed within twelve (12) months, pursuant to an international Treaty called the Paris Convention, otherwise rights to the invention may be lost in those countries. In this regard, the Paris Convention provides that the filing of an initial patent application establishes a priority date for the invention in all other countries which are party to this Convention, including countries such as the USA, Japan, China and Australia, as well as regions such as Europe and Eurasia.

The filing of further patent applications in foreign countries may be pursued individually or in some instances by filing an application with a regional patent office that does the work for a number of countries, such as the European Patent Office and the African Regional Industrial Property Organisation. The Patent Cooperation Treaty ("PCT") may also be utilised for the filing of a single international patent application (PCT application). The PCT application reserves the applicant's rights to file individual applications in over

150 countries. Filing individual applications following the filing of a PCT application is known as entering the national or regional phase. If protection is also desired in the relatively few countries not covered by a PCT application, the applicant can file complete applications directly in those countries in parallel with the PCT application.

Once a PCT application has been filed it is subjected to what is called an “international search”, carried out by one of the major patent offices. The search results are then communicated to the patent applicant in an “International Search Report”, which is a listing of published documents that might affect the patentability of the invention claimed in the international application. The International Search Report is accompanied by a “Written Opinion”, setting out why the list of published documents are considered relevant. On the basis of the International Search Report the applicant may decide to withdraw the application. However, if the PCT application is not withdrawn, it is, together with the International Search Report, published by the International Bureau.

If the applicant decides to continue with the PCT application, then, within thirty (30) months of the initial patent application filing date, the PCT application must enter the national or regional phase via filings at individual national or regional patent offices. In some countries such as Australia and regions such as Europe, the deadline is thirty-one (31) months. At national or regional phase entry, standard documentation and fee requirements need to be satisfied in each country or region, and in non-English speaking countries that will include translating the PCT specification into the relevant language. Failure to enter the national or regional phase in a country or region will typically result in abandonment of the ability to secure patent protection in the respective country or region.

The national or regional applications progress under the jurisprudence and legislation of each country or region. In most jurisdictions, such as Australia, Europe, United States, China and Japan, examination by the relevant patent office comprises an examination of the art from which the invention pertains as it existed at the priority date of the application. Examination establishes what is referred to as the “state of the art”. The patent application is measured against the state of the art and an assessment is made regarding whether the invention described in the application is novel, inventive (non-obvious), useful and relates to patentable subject matter in that jurisdiction. Therefore, the time required to complete the process of examination differs from country-to-country and the scope of protection may differ depending upon the law of each country. In general, it will take several years from the date of application until the patent is actually granted/registered.

With respect to regional applications, like the European application, this involves filing a single application designating any of the countries that are signatories to the Convention covering that region. The single application is subjected to examination, and assuming that the application is allowed, it will proceed to the grant phase. The applicant can then elect to have patents validated in all or some of the originally designated countries, and the individual patents then function as though they were patents granted under standard national procedures.

1.3.4 Granted patents: Renewal Fees, Validity, Exploitation and Enforcement

It is necessary to pay renewal fees on a granted/registered patent, otherwise the patent will cease.

A patent owner has the exclusive rights to use the patented technology throughout the lifetime of a patent. This means that the owner can decide to exclusively use it for their own benefit and prevent others from using it. Alternatively, they can allow others to use it under the terms of a licence agreement. The terms of the licence agreement generally define the limited scope of the use of the patent and the consideration to be paid for the use of it.

Enforcement of patent rights varies from country-to-country. The remedies for unauthorised use (patent infringement) available to the patent owner often include an injunction, which effectively stops further infringement of the patent, damages or account of profits, and costs.

1.4 Cleo Diagnostics Intellectual Property Portfolio

1.4.1 Overview

Cleo Diagnostics has an exclusive licence agreement with Hudson Institute of Medical Research who is the owner of patent applications pending in a number of countries based on international (PCT) application no. PCT/AU2020/051403.

1.4.2 Patent Properties Licenced by Cleo Diagnostics

1.4.2.1 Patent Family: CXCL10 BINDING PROTEINS AND USES THEREOF

Summary

This patent family is based on PCT application no. PCT/AU2020/051403, filed on 18 December 2020 and published on 24 June 2021 as WO 2021/119761. PCT/AU2020/051403 claims priority to provisional application AU 2019904859, filed on 20 December 2019. The inventors are Andrew N. Stephens, Adam Rainczuk and Sung-Woog Kang (noting that Adam's name appears to be spelt incorrectly as "Adan" in the licence). Although this patent family remains owned by Hudson Institute of Medical Research, Cleo Diagnostics has an exclusive licence agreement with Hudson Institute of Medical Research and provides Cleo Diagnostics with a royalty-bearing, non-transferable licence to use, develop, modify, commercialise and exploit the technology outlined in this Section 1.4.2 as at the commencement date of 29 August 2022.

A patent has been granted (registered) in Australia. The patent application pending in the United States has been allowed, and should proceed to grant in the next 2 months, provided the issue fee is paid by the deadline (i.e., by 29 June 2023). Applications are currently pending in Australia (divisional), China, Europe, Israel, India, Japan, Korea, New Zealand and Singapore. Details of these applications are listed below.

Status

The Table below summarises the status of the applications related to PCT/AU2020/051403.

Country	Official No.	Status	Predicted Expiry
Australia	2020404453	Granted	18 December 2040
Australia	2023201412	Pending	18 December 2040
China	202080096729.7	Pending	18 December 2040
Europe	20901736.7	Pending	18 December 2040
Israel	294045	Pending	18 December 2040
India	202217041027	Pending	18 December 2040
Japan	2022-538319	Pending	18 December 2040
Korea	10-2022-7025148	Pending	18 December 2040
New Zealand	789356	Pending	18 December 2040
Singapore	11202250168F	Pending	18 December 2040
United States	17/783,528	Allowed	18 December 2040
United States	To be confirmed	Not yet filed	18 December 2040

Subject Matter

General

This patent family is directed towards C-X-C motif chemokine ligand 10 (CXCL10) binding proteins and methods of diagnosing a condition, such as a malignancy, comprising determining a level of CXCL10 in a subject. Determination of the level of CXCL10 may also be utilised to monitor tumour burden, malignancy progression or likelihood of tumour recurrence in a subject. In an embodiment, diagnosis comprises determining a ratio of active to total CXCL10, wherein a lower CXCL10 ratio in the subject compared to a reference ratio is indicative of a malignant condition.

Australia

The claims of the granted Australian patent provide protection for:

- (i) antibodies or antigen binding fragments thereof comprising a variable heavy chain (V_H) and variable light chain (V_L) with specific complementarity determining region (CDR) sequences that bind to full length human CXCL10, N-terminally truncated CXCL10 and citrullinated CXCL10; and
- (ii) antibodies or antigen binding fragments thereof comprising a variable heavy chain (V_H) and variable light chain (V_L) with specific complementarity determining region (CDR) sequences that bind to full length human CXCL10 with a specific binding affinity but do not bind N-terminally truncated CXCL10.

The granted Australian claims also provide protection for compositions, expression vectors and cells comprising the above-defined antibodies, as well as methods of detecting and/or diagnosing a malignant condition in a subject. Protection is also provided for monitoring tumour burden and/or tumour progression and/or tumour regression in a subject, comprising determining a ratio of active CXCL10 to total CXCL10 in the subject by utilising the above-defined antibodies or antigen binding fragments. The granted Australian claims also define treating a malignant condition in a subject following the diagnosis and/or detection of the malignant condition using the above-defined antibodies or antigen binding fragments.

A divisional application has also been filed in Australia to pursue additional subject matter.

United States of America

A request was filed for the U.S. application to accelerate prosecution under the Patent Prosecution Highway (PPH) with a view to obtain a rapid grant. This request was based on the claims that had been allowed for the corresponding Australian application.

The claims of the allowed U.S. application provide protection for:

- (i) CXCL10 antibodies or antigen binding fragments that bind to full length human CXCL10 with a specific binding affinity but do not bind N-terminally truncated, limited by the N-terminal valine and/or proline of the epitope NH₂-VPLSRTVRCTCISISNQPVNPRSLE-COOH to bind to full-length human CXCL10 and limited to a variable heavy chain (V_H) and variable light chain (V_L) with specific complementarity determining region (CDR) sequences;
- (ii) compositions, polynucleotides, expression vectors and cells thereof comprising (or encoding) the above-defined antibodies or antigen binding fragments; and
- (iii) uses of the cells defined above for preparing a CXCL10 binding protein.

Instructions have also been received by FB Rice to file a continuation application in the U.S.

Europe

In Europe it is typical to file a reduced claim set to avoid large extra claim fees. The European agent has been instructed to file claim amendments directed to detecting active CXCL10 and include claims directed to the following subject matter:

- (i) any CXCL10 binding protein that binds to full length human CXCL10, N-terminally truncated CXCL10 and citrullinated CXCL10 (not limited by sequence at this stage);
- (ii) any CXCL10 binding protein that binds to full length human CXCL10 with a specific binding affinity but does not bind N-terminally truncated and citrullinated CXCL10 (limited by the N-terminal valine and/or proline of the epitope NH₂-VPLSRTVRCTCISISNQPVNPRSLE-COOH to bind to full-length human CXCL10);
- (iii) compositions and polynucleotides respectively comprising or encoding the above-defined binding proteins;

(iv) methods of detecting and/or diagnosing a malignant condition in a subject, or monitoring tumour burden or progression or regression, comprising determining a ratio of active CXCL10 to total CXCL10 by utilising the above-defined antibodies or antigen binding fragments *in vitro* or *ex vivo*; and

(v) methods of detecting and/or diagnosing a condition comprising determining a level of CXCL10 utilising the binding protein defined above in (ii).

Israel

A request for examination has been filed with an amended set of claims based on the claims that have been granted for the corresponding Australian patent.

The pending claims encompass the following subject matter:

(i) antibodies or antigen binding fragments thereof comprising a variable heavy chain (V_H) and variable light chain (V_L) with specific complementarity determining region (CDR) sequences that bind to full length human CXCL10, N-terminally truncated CXCL10 and citrullinated CXCL10;

(ii) antibodies or antigen binding fragments thereof comprising a variable heavy chain (V_H) and variable light chain (V_L) with specific complementarity determining region (CDR) sequences that bind to full length human CXCL10 with a specific binding affinity but do not bind N-terminally truncated CXCL10;

(iii) compositions and polynucleotides respectively comprising or encoding the above-defined binding proteins;

(iv) methods of detecting and/or diagnosing a malignant condition in a subject, or monitoring tumour burden or progression or regression, comprising determining a ratio of active CXCL10 to total CXCL10 by utilising the above-defined antibodies or antigen binding fragments *in vitro* or *ex vivo*; and

(v) methods of treating a malignant condition comprising detecting and/or diagnosing the condition utilizing the above methods and administering a treatment to the subject.

China, Singapore, India, Japan, Korea and New Zealand

Prosecution has not commenced in any of these countries. The claims of the patent applications pending in each of China, Singapore, India, Japan, Korea and New Zealand currently contain the claims as filed for the PCT application PCT/AU2020/051403 and are directed to subject matter including:

(i) any CXCL10 binding protein that binds to full length human CXCL10, N-terminally truncated CXCL10 and citrullinated CXCL10 (not limited by sequence at this stage);

(ii) any CXCL10 binding protein that binds to full length human CXCL10 with a specific binding affinity but does not bind N-terminally truncated and citrullinated CXCL10 (not limited by sequence at this stage);

- (iii) compositions, polynucleotides, expression vectors and cells thereof comprising (or encoding) the above-defined binding proteins;
- (iv) methods of detecting and/or diagnosing a malignant condition in a subject, or monitoring tumour burden or progression or regression, comprising determining a ratio of active CXCL10 to total CXCL10 by utilising the above-defined antibodies or antigen binding fragments;
- (v) treating a malignant condition in a subject following the diagnosis/detection of the malignant condition using the above-defined antibodies or antigen binding fragments; and
- (vi) methods of diagnosing a condition comprising determining a level of CXCL10 utilising at least one CXCL10 binding protein defined above.

1.5 Proprietorship and Licencing – Chain of Title

Typically, a patent for an invention may only be granted to the inventor(s) or to a person who has entitlement to the invention by way of assignment, employment contract or other means.

FB Rice understands that Hudson Institute of Medical Research is entitled to be recorded as the owner of the intellectual property rights listed in Section 1.4.2 above. We have not seen the relevant employment agreements. However, some countries, such as the United States and India, require an executed assignment document. In this regard, as part of filing US 17/783,528 and IN 202217041027 the inventors have executed assignment documents on 1 August 2022 recognising that Hudson Institute of Medical Research is entitled to their rights.

It is important to note that there are legal mechanisms by which third parties can bring evidence that they have sole or joint entitlement to an invention and any patent application or patent obtained for that invention. We are not aware of any issues regarding the ownership or entitlement with respect to the intellectual property rights listed in Section 1.4.2 above.

Cleo Diagnostics has an exclusive licence agreement with Hudson Institute of Medical Research providing them with a royalty-bearing, non-transferable licence to use, develop, modify, commercialise and exploit the intellectual property referred to in Section 1.4.2 within the relevant patent jurisdiction within the field of diagnostic and screening technology, as at the commencement date of 29 August 2022. It is noted in the licence that the intellectual property remains owned by Hudson Institute of Medical Research.

As at the date of this Report, we did not identify any issues that would affect the validity of the licence agreement between Cleo Diagnostics and Hudson Institute of Medical Research.

1.6 Validity

The ultimate validity of a patent cannot be guaranteed and various legal mechanisms exist to challenge their validity. For example, validity of patents (or patent applications) may be challenged in the following ways:

- (a) during examination, or re-examination;
- (b) in opposition proceedings after acceptance or grant;
- (c) in court during revocation proceedings brought by a third party; or
- (d) in court during infringement proceedings initiated against an alleged infringer.

As at the date of this Report, we are not aware of any litigation being commenced in respect to any patent rights referred to in this Report.

1.7 Freedom to Operate

When preparing this Report, Cleo Diagnostics provided FB Rice with a copy of search results that were obtained by a third party (Clarivate) and asked to consider whether any potential freedom to operate issues exist in so far as whether Cleo Diagnostics is entitled to freely use and commercialise its products and/or methods. Based on our review of these results, we have not identified any issues in relation to the ability of Cleo Diagnostics to freely use and commercialise the technology outlined in Section 1.4.2. As FB Rice did not conduct the search, it cannot be held liable for the accuracy of the search results and/or search strategy utilised.

1.8 Limitations and Qualifications

1.8.1 Information Sources

In preparing this Report, in addition to reviewing our internal databases, we relied upon information contained in relevant publicly available databases and registers with respect to the intellectual property rights listed in Section 1.4.2 above. FB Rice is not responsible for the accuracy of the information available in public databases or registers and accordingly cannot guarantee the accuracy of this information.

1.8.2 Jurisdictional Requirements

Each jurisdiction has its own laws and particular requirements that need to be met for the grant and maintenance of a patent. For example, the assessment of patentability varies from jurisdiction-to-jurisdiction, and inventions, which may be granted and registrable in one jurisdiction, may be excluded from grant and registration in another. Moreover, the different jurisdictional requirements may result in variation of the scope of protection obtained for the same patents in different jurisdictions. The outcome of examination of the patent application by the office of one jurisdiction is not binding on the office of any other jurisdiction. Similarly, international PCT searches and examination reports are not binding on national patent applications during examination in the national phase.

In some jurisdictions there is a duty to disclose certain information to the relevant patent office. This information can include relevant prior art information known to the applicant or its agents, or search results issued in respect of corresponding foreign applications. Failure to disclose such information may adversely affect the validity and/or enforceability of the patent.

There may be changes to patent, law and its interpretation by the courts in a particular jurisdiction from time-to-time, which may have an impact on patents in the relevant jurisdiction.

1.8.3 Patentability Search Limitations

A patentability search, such as those carried out by various patent offices, cannot be guaranteed to locate all prior art that may exist which is potentially relevant to the assessment of novelty and inventive step of a claimed invention. Such searches are generally computer-based searches and are dependent on the database search strategy and the coverage provided by the databases used. For example, the databases may not cover older published documents and/or certain jurisdictions. Further, patentability searching is subject to the accuracy of records, as well as the indexing and classification of the subject matter comprising the records. The scope of each search is also dependent on the search strategy utilised and, for example, the keyword(s) selected for the search.

Besides documentary prior art, commercialisation or secret use of an invention by, or with the authority of, a patent applicant (or their predecessor in title), public use of an invention and non-confidential oral disclosures before the priority date of a patent application may also be relevant to the assessment of patentability. As patentability searches are conducted on published documents, they would not locate such other forms of prior art disclosures.

Accordingly, although patentability searches provide a reasonable indication of patentability, it is not possible to guarantee that every relevant prior art record has been located and considered. As a result, any conclusions regarding the validity of the claims of a particular patent, based on patent office searches, should be regarded as indicative rather than conclusive.

Further, non-provisional patent applications are not normally published until at least 18 months from the earliest acceptable priority date. Accordingly, a patentability search would not normally identify any third party patent application that is potentially relevant to the assessment of patentability that has a priority date which is less than 18 months prior to the date of the patentability search. Delays between official publication and the incorporation of information into the relevant database can also occur, which means that some documents may not be located in a patentability search.

1.8.4 Freedom to Operate

The grant of patent rights as referred to in this Report provides no guarantee that Cleo Diagnostics is entitled to freely use and commercialise its products or methods. If additional third party patents or patent applications are identified that contain claims or have a scope that is infringed by Cleo Diagnostics and the claims are valid, Cleo Diagnostics may be unable to obtain licences to these patents or patent applications at a reasonable cost, if at all, and may also be unable to develop or obtain alternative technology. If such licences cannot be obtained at a reasonable cost, the business could be significantly impacted.

1.9 Statement of Independence

FB Rice is a firm of patent and trade mark attorneys that provide advice in relation to all aspects of intellectual property. FB Rice has extensive experience protecting and defending intellectual property

rights. FB Rice provides a comprehensive intellectual property service through its patent and trade mark attorney practices and through its partnership with a major international renewal service.

Neither FB Rice nor any of its directors has any interest or entitlement to securities in Cleo Diagnostics, other than fees for professional work done. FB Rice estimates it will be paid approximately AU\$5,500 excluding GST for the preparation of this Report. Over the past 24 months preceding the date of the Prospectus, FB Rice has provided services to Cleo Diagnostics in the amount of approximately AU\$16,000 (excluding GST) some of which were costs incurred by our foreign associates handling the prosecution of applications mentioned herein.

Consent for the inclusion of this Report in a Prospectus to be issued by Cleo Diagnostics, in the form in which it now appears, has been granted by FB Rice and has not been revoked, as at the date of this Report.

The person responsible for preparing this Report was Ian Rourke (B.Sc. (Hons), PhD, DipIPP, FIPTA, GAICD), Partner at FB Rice. Dr Rourke has been a Registered Australian Patent Attorney since 2000.



Ian Rourke
Partner

22 June 2023

Annexure B – Independent Limited Assurance Report

For personal use only





Tel: +61 3 9603 1700
Fax: +61 3 9602 3870
www.bdo.com.au

Collins Square, Tower Four
Level 18, 727 Collins Street
Melbourne VIC 3008
GPO Box 5099 Melbourne VIC 3001
Australia

The Directors
Cleo Diagnostics Ltd
Level 2, 480 Collins Street
Melbourne VIC 3000

22 June 2023

Dear Directors

INDEPENDENT LIMITED ASSURANCE REPORT

INTRODUCTION

BDO Corporate Finance (East Coast) Pty Ltd (**BDO**) has been engaged by Cleo Diagnostics Ltd (**Cleo** or the **Company**) to prepare this Independent Limited Assurance Report (**Report**) for inclusion in a prospectus proposed to be issued, in relation to the initial public offering of shares in Cleo, on or about 23 June 2023 (**Prospectus**) and listing on the Australian Securities Exchange (**ASX**) (the **Offer**).

Unless stated otherwise in this Report, expressions defined in the Prospectus have the same meaning in this Report.

This Report has been prepared for inclusion in the Prospectus. We disclaim any assumption of responsibility for any reliance on this Report or on the financial information to which it relates for any purpose other than that for which it was prepared.

SCOPE

You have requested BDO to perform a limited assurance engagement in relation to the financial information described below and disclosed in the Prospectus.

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 (**AAS**) or Australian equivalents to International Financial Reporting Standard (**AIFRS**) and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act 2001.

STATUTORY HISTORICAL FINANCIAL INFORMATION

You have requested BDO to review the following statutory historical financial information included in the Prospectus:

- The audited historical statement of profit or loss and other comprehensive income of the Company for the period from incorporation (30 November 2021) to 30 June 2022 (**FY22**) and half year period ended 31 December 2022 (**1HFY23**);
- The audited historical statement of cash flows of the Company for the period ended FY22 and 1HFY23; and
- The audited historical statement of financial position of the Company as at 31 December 2022;

together the **Historical Financial Information**.

For personal use only



The Historical Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in AAS and the Company's adopted accounting policies.

The Historical Financial Information has been extracted from the Audited Financial Statements of Cleo for FY22 and 1HFY23 (both periods audited by BDO Audit Pty Ltd (**BDO Audit**) in accordance with Australian Auditing Standards).

BDO Audit issued an unmodified opinion on the financial reports for the period ended 30 June 2022 and half year period ended 31 December 2022.

PRO FORMA HISTORICAL FINANCIAL INFORMATION

You have requested BDO review the following pro forma historical financial information included in the Prospectus:

- The pro forma historical statement of financial position of the Company as at 31 December 2022 reflecting the actual position as at that date; and
- The associated details of the pro forma adjustments.

together the **Pro Forma Financial Information**.

The Pro Forma Financial Information has been derived from the Historical Statement of Financial Position of Cleo, after adjusting for the effects of pro forma adjustments described in Section 5 of the Prospectus. The stated basis of preparation is the recognition and measurement principles contained in AAS applied to the Historical Statement of Financial Position and the event(s) or transaction(s) to which the pro forma adjustments relate, as described in Section 5 of the Prospectus, as if those event(s) or transaction(s) had occurred as at 31 December 2022. Due to its nature, the Pro Forma Financial Information does not represent the Company's actual or prospective financial position, financial performance, and/or cash flows.

DIRECTORS' RESPONSIBILITY

The directors of Cleo are responsible for the preparation of the Historical Financial Information and Pro Forma Financial Information, including the selection and determination of pro forma adjustments made to the Historical Financial Information and included in the Pro Forma Financial Information. This includes responsibility for such internal controls as the directors determine are necessary to enable the preparation of Historical Financial Information (as defined in Section 5 of the Prospectus) that are free from material misstatement, whether due to fraud or error.

OUR RESPONSIBILITY

Our responsibility is to express a limited assurance conclusion on whether anything has come to our attention that the Historical Financial Information, based on the procedures performed, and the evidence we have obtained, has not been properly compiled in all material respects by Cleo, in accordance with the stated basis of preparation.

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*.

The limited assurance procedures we performed were based on our professional judgement and included consideration of work papers, accounting records and other documents, including those dealing with the derivation of the Historical Financial Information of Cleo from its audited financial statements for the period ended 30 June 2022 and for the half year period ended 31 December 2023 respectively.



Our limited assurance procedures consist of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A limited assurance engagement 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.

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.

CONCLUSION

STATUTORY 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 Historical Financial Information, as described in Section 5 of the Prospectus, and comprising:

- The audited historical statement of profit or loss and other comprehensive income of the Company for FY22 and 1HFY23;
- The audited historical statement of cash flows of the Company for FY22 and 1HFY23; and
- The audited historical statement of financial position of the Company as at 31 December 2022

is not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 5 of the Prospectus.

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 Financial Information, as described in Section 5 of the Prospectus, and comprising:

- The pro forma historical statement of financial position of the Company as at 31 December 2022

is not presented fairly in all material respects, in accordance with the stated basis of preparation as described in Section 5 of the Prospectus.

SUBSEQUENT EVENTS

Apart from the matters dealt with in this Report, and having regard to the scope of this Report and the information provided by the Directors, to the best of our knowledge and belief no material transaction(s) or event(s) outside of the ordinary business of Cleo not described in the Prospectus, has come to our attention that would require comment on, or adjustment to, the information referred to in our Report or that would cause such information to be misleading or deceptive.

INDEPENDENCE

BDO is a member of BDO International Ltd. BDO does not have any interest in the outcome of the Prospectus other than in connection with the preparation of this Report and participation in due diligence procedures, for which professional fees will be received. From time to time, BDO provides Cleo with certain other professional services for which normal professional fees are received.

GENERAL ADVICE WARNING

This Report has been prepared, and included in the Prospectus, to provide investors with general information only and does not take into account the objectives, financial situation or needs of any specific investor. It is not



intended to be a substitute for professional advice and potential investors should not make specific investment decisions in reliance on the information contained in this Report. Before acting or relying on any information, potential investors should consider whether it is appropriate for their objectives, financial situation or needs.

Without modifying our conclusions, we draw attention to Section 5 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.

BDO 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. However, BDO has not authorised the issue of the Prospectus. Accordingly, BDO makes no representation regarding, and takes no responsibility for, any other statements or material in or omissions from the Prospectus.

FINANCIAL SERVICES GUIDE

Our Financial Services Guide follows this Report. This guide is designed to assist retail clients in their use of any general financial product advice in our Report.

As set out in the financial services guide, this Report provides general information only. It does not take into account the objectives, financial situation or needs of any specific investor. It is not intended to be a substitute for professional advice and potential investors should not make specific investment decisions in reliance on the information contained in this Report. Before acting or relying on any information, potential investors should consider whether it is appropriate for their objectives, financial situation or needs.

If you require any additional information and/or clarification on any matter please contact us.

Yours faithfully

BDO Corporate Finance (East Coast) Pty Ltd

DocuSigned by:
Stephen Seear
5B72002D14384EF...
Stephen Seear
Director

For personal use only



Tel: +61 3 9603 1700
 Fax: +61 3 9602 3870
 www.bdo.com.au

Collins Square, Tower Four
 Level 18, 727 Collins Street
 Melbourne VIC 3008
 GPO Box 5099 Melbourne VIC 3001
 Australia

FINANCIAL SERVICES GUIDE

Dated: 22 June 2023

This Financial Services Guide (FSG) helps you decide whether to use any of the financial services offered by BDO Corporate Finance (East Coast) Pty Ltd (BDO Corporate Finance, we, us, our).

The FSG includes information about:

- Who we are and how we can be contacted;
- The services we are authorised to provide under our Australian Financial Services Licence, Licence No: 247420
- Remuneration that we and/or our staff and any associates receive in connection with the financial services
- Any relevant associations or relationships we have
- Our complaints handling procedures and how you may access them.

FINANCIAL SERVICES WE ARE LICENSED TO PROVIDE

We hold an Australian Financial Services Licence which authorises us to provide financial product advice to retail and wholesale clients about securities and certain derivatives (limited to old law securities, options contracts and warrants). We can also arrange for customers to deal in securities, in some circumstances. Whilst we are authorised to provide personal and general advice to retail and wholesale clients, we only provide *general* advice to retail clients.

Any general advice we provide is provided on our own behalf, as a financial services licensee.

GENERAL FINANCIAL PRODUCT ADVICE

Our general advice is typically included in written reports. In those reports, we provide general financial product advice that is prepared without taking into account your personal objectives, financial situation or needs. You should consider the appropriateness of the general advice having regard to your own objectives, financial situation and needs before you act on the advice. Where the advice relates to the acquisition or possible acquisition of a financial product, you should also obtain a product disclosure statement relating to the product and consider that statement before making any decision about whether to acquire the product.

FEES, COMMISSIONS AND OTHER BENEFITS THAT WE MAY RECEIVE

We charge fees for providing reports. These fees are negotiated and agreed to with the person who engages us to provide the report. Fees will be agreed on an hourly basis or as a fixed amount depending on the terms of the agreement. In this instance, the Company has agreed to pay us a fee for preparing the Report.

Except for the fees referred to above, neither BDO Corporate Finance, nor any of its directors, employees or related entities, receive any pecuniary benefit or other benefit, directly or indirectly, for or in connection with the provision of general advice.

All our employees receive a salary. Our employees are eligible for bonuses based on overall company performance but not directly in connection with any engagement for the provision of a report.

REFERRALS

We do not pay commissions or provide any other benefits to any person for referring customers to us in connection with the reports that we are licensed to provide.

ASSOCIATIONS AND RELATIONSHIPS

BDO Corporate Finance is a member firm of the BDO network in Australia, a national association of separate entities (each of which has appointed BDO (Australia) Limited ACN 050 110 275 to represent it in BDO International). The general financial product advice in our report is provided by BDO Corporate Finance and not by BDO or its related entities. BDO and its related entities provide services primarily in the areas of audit, tax, consulting and financial advisory services.

We do not have any formal associations or relationships with any entities that are issuers of financial products. However, you should note that we and BDO (and its related entities) might from time to time provide professional services to financial product issuers in the ordinary course of business.

COMPLAINTS RESOLUTION

Internal Complaints Resolution Process

As the holder of an Australian Financial Services Licence, we are required to have a system for handling complaints from persons to whom we provide financial product advice. Complaints can be in writing, addressed to the Complaints Officer, BDO Corporate Finance, Level 11, 1 Margaret St, Sydney NSW 2001 or by telephone or email, using the contact details at the top of this FSG.

When we receive a complaint we will record the complaint, acknowledge receipt of the complaint within 15 days and investigate the issues raised. As soon as practical, and not more than **45 days** after receiving the written complaint, we will advise the complainant in writing of our determination.

Referral to External Dispute Resolution Scheme

If a complaint relating to general advice to a retail client is not satisfied with the outcome of the above process, or our determination, has the right to refer the matter to the Australian Financial Complaints Authority (AFCA). AFCA is an independent company that has been established to impartially resolve disputes between consumers and participating financial services providers.

BDO Corporate Finance is a member of AFCA (Member Number 11843).

Further details about AFCA are available at the AFCA website www.afca.org.au or by contacting them directly via the details set out below.

Australian Financial Complaints Authority
 GPO Box 3
 MELBOURNE VIC 3001
 Toll free: 1800 931 678
 Email: info@afca.org.au

COMPENSATION ARRANGEMENTS

BDO Corporate Finance and its related entities hold Professional Indemnity insurance for the purpose of compensating retail clients for loss or damage suffered because of breaches of relevant obligations by BDO Corporate Finance or its representatives under Chapter 7 of the Corporations Act 2001. These arrangements and the level of cover held by BDO Corporate Finance satisfy the requirements of section 912B of the Corporations Act 2001.

CONTACT DETAILS

You may provide us with instructions using the details set out at the top of this FSG or by emailing - cf.ecp@bdo.com.au

For personal use only

For personal use only

