

emerald
clinics

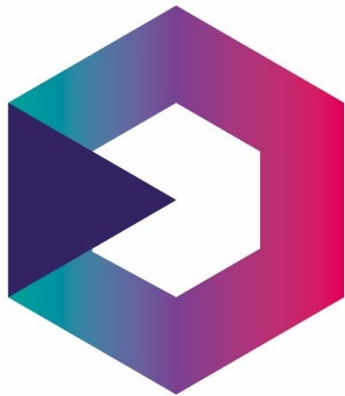
PROSPECTUS

For an initial offer of at least 30 million Shares and up to 40 million Shares
to be issued at a price of \$0.20 per Share
to raise at least \$6 million and up to \$8 million (before costs)

EMERALD CLINICS LIMITED
ACN 625 085 734

Lead manager:





emerald clinics

Emerald Clinics Limited
ACN 625 085 734

Prospectus

For an initial offer of up to 40 million Shares at an issue price of \$0.20 each to raise up to \$8 million (before costs)

This Prospectus has been issued to provide information on the offer of at least 30 million Shares and up to 40 million Shares to be issued at a price of \$0.20 per Share to raise at least \$6 million and up to \$8 million (before costs) (**Public Offer**).

This Prospectus also incorporates the offer of up to 20,625,000 Shares to be issued on conversion of the Convertible Notes (**Convertible Note Offer**).

It is proposed that the Public Offer and the Convertible Note Offer (together, **Offers**) will close at 5.00 pm (WST) on 17 January 2020. The Directors reserve the right to close the Offers earlier or to extend this date without notice. Applications must be received before that time.

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.

An investment in the Company under this Prospectus should be regarded as highly speculative in nature, and investors should be aware that they may lose some, or all, of their investment. Refer to Section 4 for a summary of the key risks associated with an investment in the Shares.

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Important Information

Prospectus

This Prospectus is dated, and was lodged with ASIC on 11 December 2019. 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. The expiry date of this Prospectus is 5.00 pm (WST) on that date which is 13 months after the date this Prospectus was lodged with ASIC. No Shares will be issued on the basis of this Prospectus after that expiry date.

Application will be made to ASX within 7 days of the date of this Prospectus for Official Quotation of the Shares the subject of the Offers.

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 or the Directors in connection with the Offers.

It is important that you read this Prospectus in its entirety and seek professional advice where necessary. The Shares the subject of this Prospectus should be considered highly speculative.

Exposure Period

This Prospectus will be circulated during the Exposure Period. 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.

Electronic Prospectus and Application Forms

This Prospectus will generally be made available in electronic form by being posted on the Company's website at www.emeraldclinics.com.au. Persons having received a copy of this Prospectus in its electronic form may obtain an additional paper copy of this Prospectus and the relevant Application Form (free of charge) from the Company's registered office during the Offer Period by contacting the Company as detailed in the Corporate Directory. The Offers constituted by this Prospectus in electronic form is only

available to persons receiving an electronic version of this Prospectus and the relevant Application Form within Australia.

Applications will only be accepted on the relevant Application Form attached to, or accompanying, this Prospectus or in its paper copy form as downloaded in its entirety from www.emeraldclinics.com.au. The Corporations Act prohibits any person from passing on to another person the Application Form unless it is accompanied by or attached to a complete and unaltered copy of this Prospectus.

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

No document or information included on the Company's website is incorporated by reference into this Prospectus.

Offers outside Australia

No action has been taken to register or qualify the Shares the subject of this Prospectus, or the Offers, or otherwise to permit the public offering of the Shares, in any jurisdiction outside Australia. The distribution of this Prospectus in jurisdictions outside of Australia 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. This Prospectus does not constitute an offer of Shares in any jurisdiction where, or to any person to whom, it would be unlawful to issue this Prospectus, except to the extent permitted by exemptions set out in Section 1.17.

Canada (select Provinces)

This Prospectus constitutes an offering of Shares only in the Provinces and to those persons to whom they may be lawfully distributed in the Provinces, and only by persons permitted to sell such Shares. This Prospectus is not, and under no circumstances is to be construed as, an advertisement or a public offering of securities in the Provinces. This Prospectus may only be distributed in the Provinces to persons that are "accredited investors" within the meaning of NI 45-106 – *Prospectus Exemptions*, of the Canadian Securities Administrators.

No securities commission or similar authority in the Provinces has reviewed or in any way passed upon this Prospectus, the merits of the

Shares or the offering of Shares and any representation to the contrary is an offence.

Hong Kong

WARNING: This Prospectus has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the SFO. No action has been taken in Hong Kong to authorise or register this Prospectus or to permit the distribution of this Prospectus or any documents issued in connection with it. Accordingly, the Shares have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

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

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

Malaysia

No approval from, or recognition by, the Securities Commission of Malaysia has been or will be obtained in relation to any offer of Shares. The Shares may not be offered or sold in Malaysia except pursuant to, and to persons prescribed under, Part I of Schedule 6 of the Malaysian Capital Markets and Services Act.

New Zealand

This Prospectus has not been registered, filed with or approved by any New Zealand regulatory authority under the FMC Act. The Shares 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.

Singapore

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

This Prospectus has been given to you on the basis that you are (i) an existing holder of the Company's shares, (ii) an "institutional investor" (as defined in the SFA) or (iii) an "accredited investor" (as defined in the SFA). In the event that you are not an investor falling within any of the categories set out above, please return this Prospectus immediately. You may not forward or circulate this Prospectus to any other person in Singapore.

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

United States

This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The Shares have not been, and will not be, registered under the US Securities Act of 1933 and may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

Speculative Investment

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

Prospective investors should carefully consider whether the Shares offered pursuant to this Prospectus are an appropriate investment for them in light of their personal circumstances,

including their financial and taxation position. Refer to Section 4 for details relating to the key risks applicable to an investment in the Shares.

Cooling off rights

Cooling off rights do not apply to an investment in Shares pursuant to the Offers. This means that, in most circumstances you cannot withdraw your Application once it has been accepted.

Using this Prospectus

Persons wishing to subscribe for Shares offered by this Prospectus should read this Prospectus in its entirety in order to make an informed assessment of the assets and liabilities, financial position and performance, profits and losses, and prospects of the Company and the rights and liabilities attaching to the Shares offered pursuant to this Prospectus. If persons considering subscribing for Shares offered pursuant to this Prospectus have any questions, they should consult their stockbroker, solicitor, accountant or other professional adviser for advice.

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 date of this Prospectus, are expected to take place.

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 management of the Company. Key risk factors associated with an investment in the Company are detailed in Section 4. These and other factors could cause actual results to differ materially from those expressed in any forward-looking statements.

The Company has no intention to update or revise forward-looking statements, or to 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.

The Company cannot and does 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.

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. Unless otherwise stated, all data contained in charts, graphs and tables is based on information available at the date of this Prospectus.

Third Party Publications

The Company Overview in Section 2 and the Industry Overview in Section 3 of 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.

Miscellaneous

All financial amounts contained in this Prospectus are expressed as Australian currency unless otherwise stated. Conversions may not reconcile due to rounding. All references to '\$' or 'A\$' are references to Australian dollars.

All references to time in this Prospectus are references to (WST), being the time in Perth, Western Australia, unless otherwise stated.

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

Corporate Directory

Directors	Dr Stewart Washer - Executive Chairman Dr Michael Winlo - Managing Director Dr Alistair Vickery - Executive Director Mr Matthew Callahan - Non-Executive Director
Proposed Director	Sir John Tooke - Proposed Non-Executive Director
Company Secretary	Mr Simon Robertson
Registered Office	50 Angove Street Level 1 NORTH PERTH WA 6006 Phone: 08 6559 2800 Email: admin@emeraldclinics.com.au Website: www.emeraldclinics.com.au
Share Registry*	Automic Pty Ltd Level 2, 267 St Georges Terrace PERTH WA 6000 Phone: (within Australia): 1300 288 664 (outside Australia): +61 2 9698 5414
Lead Manager	PAC Partners Securities Pty Ltd Level 10, 330 Collins Street MELBOURNE VIC 3000 a Corporate Authorised Representative of PAC Asset Management Pty Ltd holder of an Australian Financial Services Licence (AFSL No. 335 374)
Proposed Stock Exchange Listing	Australian Securities Exchange (ASX) Proposed ASX Code: EMD
Lawyers	HWL Ebsworth Level 20, 240 St Georges Terrace PERTH WA 6000
UK Lawyers	Fieldfisher LLP Free Trade Exchange Level 5, 37 Peter Street MANCHESTER M2 5GB UK

Investigating Accountant

BDO Corporate Finance (WA) Pty Ltd
38 Station Street
SUBIACO WA 6008

Auditor*

Stantons International Audit and Consulting Pty Ltd trading as Stantons
International
Level 2, 1 Walker Avenue
WEST PERTH WA 6005

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

Letter from the Chairman

Dear Applicant,

On behalf of the Board, I am pleased to offer you the opportunity to participate in an issue of Shares in Emerald Clinics Limited (**Emerald or the Company**). Emerald is an Australian company establishing and operating a network of patient-centred medical clinics that specialise in safe cannabinoid treatment and real-world clinical evidence generation (**Clinics**). The kind of evidence Emerald will gather is needed by licensed producers, regulators, prescribers and patients to ensure any potential benefits of cannabinoid medicines for patients can be realised.

Legalisation of medicinal cannabis has created a large therapeutics industry that is still in its infancy globally. Several companies hold manufacturing and production licences, however patient access to cannabinoid medicines may be restricted in some jurisdictions. In Australia, for example, cannabinoid medicines are only available to patients through either the Authorised Prescriber Scheme (**APS**) or the Special Access Scheme Part B (**SAS-B**) administered by the Therapeutic Goods Administration (**TGA**). Similar models are in place, or in development, in many other jurisdictions around the world. The Company believes the lack of high quality clinical evidence contributes to a restriction on patient access. Emerald sees the compilation of this evidence as an opportunity.

Emerald has established a network of specialist Clinics staffed and managed by experienced clinicians who have received training in cannabinoid medicine. Emerald's clinicians are also supported by a research team and a purpose-built technology platform that securely captures clinical data from consenting patients to generate a unique real-world clinical evidence data asset.

The clinical evidence Emerald will build has the potential to benefit patients by supporting drug development programs, payment coverage decisions, clinical decision support tools and more.

Emerald's strategy is to become the leading, independent operator of data-driven, patient-centric, specialist cannabinoid management clinics across Australia and the world. Emerald will provide, where appropriate, patient access to cannabinoid medicines under the guidance of a trained clinician. In addition, Emerald will continue to develop its data management platform to capture and generate a comprehensive real-world data asset that can be used as evidence to help evaluate the safety and efficacy of cannabinoid medicines.

To accomplish these goals, the Company intends to expand its existing Clinics in Perth, Sydney, Melbourne and regional New South Wales with further Clinics in 2020, as well as expand Emerald's care and data capture model internationally.

Emerald has already closed multiple anonymous patient data deals demonstrating both the strategic need for, and commercial potential of, Emerald's unique data assets and knowledge-generating care model.

The purpose of the Public Offer is to raise a minimum of \$6 million and up to \$8 million (before associated costs) by the issue of Shares at an issue price of \$0.20 each. The Lead Manager to the Public Offer is PAC Partners (see Section 7.1 for further details).

Proceeds raised under the Public Offer will enable the Company to:

- (a) operate the Clinics and expand the number of Clinics throughout Australia;
- (b) further develop and commercialise the Data Platform;
- (c) develop novel IP concerning the use of cannabinoid medicine;
- (d) attract and retain high quality clinical staff;

- (e) meet the costs of the Offers; and
- (f) meet the conditions to apply for Official Quotation of the Shares on the ASX.

The Company has established a Board and management team possessing skills and experience spanning clinical medicine, clinical trials, data science, learning health systems, digital health, medicinal cannabis, medical clinic operations, capital raising, corporate governance and administration.

The Board believes the Public Offer represents an attractive and timely opportunity to become a shareholder in a company that will own data-driven cannabinoid medicine Clinics providing patient care with a focus on building real-world data. Together with the expertise and experience of its personnel, Emerald's offering positions investors to capitalise on the current positive demand for real-world evidence to support the development and differentiation of cannabinoid medicines.

Potential investors should be aware that there are risks associated with the Emerald business and therefore there are risks associated with an investment in the Company. These risks include business risks related to the access and sale of medicinal cannabis, sourcing data from third parties, data collection risks and patient uptake. The key risks are identified in Section 4 of the Prospectus.

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

On behalf of the Board, I look forward to welcoming you as a shareholder of the Company.

Yours sincerely,



Dr Stewart Washer
Executive Chairman
Emerald Clinics Limited

Key Offer Details

Key Details of the Offers ¹	No. of Shares (Minimum Subscription)	No. of Shares (Maximum Subscription)	Options
Existing Securities on Issue ²	133,277,778	133,277,778	18,350,000
Shares offered under the Public Offer (at an Offer Price of \$0.20 per Share)	30,000,000	40,000,000	n/a
Convertible Note Offer ³	20,625,000	20,625,000	n/a
Total Securities on issue on completion of the Offers	183,902,778	193,902,778	18,350,000

Notes:

1. Please refer to Section 1.9 for further details relating to the proposed capital structure of the Company.
2. See Section 1.9 for further details of the current capital structure of the Company. See Section 8.3 for the terms and conditions of the Options.
3. See Section 7.7 for the terms and conditions of the Convertible Notes.

Indicative Timetable

Event	Date
Lodgement of this Prospectus with ASIC	11 December 2019
Opening Date for the Offers	19 December 2019
Closing Date for the Offers	17 January 2020
Allotment Date	23 January 2020
Despatch of holding statements	29 January 2020
Expected date for quotation on ASX	7 February 2020

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. In particular, the Company reserves the right to vary the Opening Date and the Closing Date without prior notice, which may have a consequential effect on the other dates. Applicants are therefore encouraged to lodge their Application Form as soon as possible after the Opening Date if they wish to invest in the Company.

Investment Overview

This Section is not intended to provide full information for investors intending to apply for Shares offered pursuant to this Prospectus. This Prospectus should be read and considered in its entirety. The Shares 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 Shares.

Topic	Summary	More Information
Introduction		
Who is the Company and what does it do?	Emerald Clinics Limited (ACN 625 085 734) (Company or Emerald) is an Australian incorporated company that operates a network of specialist medical clinics (Clinics) and uses purpose-built software and technology to gather high quality clinical data from informed and consenting patients. Emerald is a clinical services and healthcare technology company focussed on the provision of care for patients clinically determined to have exhausted conventional therapies and who may be suitable for cannabinoid-based medicines. In addition, Emerald uses technology to capture clinical data that can be used to generate clinical evidence relating to the safety and efficacy of cannabinoid-based medicines. Emerald has established four medical centres in Australia including one site each in West Leederville WA, Woolloomooloo NSW, Tintenbar NSW and Richmond VIC. Additional Clinics are planned across Australia within the next 12 months. Emerald is also considering the viability of expanding its operations to the United Kingdom.	Section 2
What is the Company's strategy?	Emerald provides patient-centric and independent specialist clinical expertise. All patients are referred to Emerald by a patient's treating doctor. As such, Emerald forms an integral part of a patient's care team. Emerald's Care Model (as described in Section 2.4) includes suitability screening and treatment planning as well as treatment safety and efficacy monitoring. All patients are invited to share their anonymous clinical data with the Emerald team via an informed consent process. Emerald's mission is to ensure that cannabinoid-based medicines are appropriately prescribed to suitable patients in order to improve health outcomes and quality-of-life. A core component of the Emerald Care Model is the capture of comprehensive real-world data (RWD), from consenting patients that can be used as real world evidence (RWE) to support innovation across the cannabinoid medicine industry (Emerald Data Platform). All data is captured, encrypted and stored in either an electronic health record (EHR) or an FDA-compliant electronic data capture system (EDC). In addition to organic growth within the clinical network, Emerald will also seek to acquire data from pharmaceutical companies, research organisations and country-specific health record agencies	Section 2.4

Topic	Summary	More Information																																			
	and regulators to further enrich the Data Platform and Emerald Care Model upon securing all appropriate consents. Ultimately, the combination of patient access, clinic and drug development customers, along with the revenue from the use of the Data Platform and Emerald Care Model will drive value for investors.																																				
What is the Company's financial position?	A summary of the financial history of the Company is in the financial information section and Independent Limited Assurance Report contained in Section 6 and Annexure A respectively. Investors should be aware that the Company has a limited operating history and is currently making a loss, meaning it is reliant on raising funds from investors to continue to fund its operations and development of its Data Platform.	Section 6 and Annexure A																																			
What is the proposed capital structure of the Company?	On the basis that the Company completes the Offers on the terms in this Prospectus, the Company's capital structure will be as follows: <table><tr><th></th><th>Shares (Min)</th><th>%</th><th>Shares (Max)</th><th>%</th><th>Options</th><th>%</th></tr><tr><td>Existing Securities</td><td>133,277,778</td><td>72.5</td><td>133,277,778</td><td>68.7</td><td>18,350,000</td><td>100</td></tr><tr><td>Public Offer</td><td>30,000,000</td><td>16.3</td><td>40,000,000</td><td>20.6</td><td>Nil</td><td>Nil</td></tr><tr><td>Convertible Note Offer</td><td>20,625,000</td><td>11.2</td><td>20,625,000</td><td>10.6</td><td>Nil</td><td>Nil</td></tr><tr><td>TOTAL</td><td>183,902,778</td><td>100</td><td>193,902,778</td><td>100</td><td>18,350,000</td><td>100</td></tr></table>		Shares (Min)	%	Shares (Max)	%	Options	%	Existing Securities	133,277,778	72.5	133,277,778	68.7	18,350,000	100	Public Offer	30,000,000	16.3	40,000,000	20.6	Nil	Nil	Convertible Note Offer	20,625,000	11.2	20,625,000	10.6	Nil	Nil	TOTAL	183,902,778	100	193,902,778	100	18,350,000	100	Section 1.9
	Shares (Min)	%	Shares (Max)	%	Options	%																															
Existing Securities	133,277,778	72.5	133,277,778	68.7	18,350,000	100																															
Public Offer	30,000,000	16.3	40,000,000	20.6	Nil	Nil																															
Convertible Note Offer	20,625,000	11.2	20,625,000	10.6	Nil	Nil																															
TOTAL	183,902,778	100	193,902,778	100	18,350,000	100																															
What is the proposed use of funds raised under the Public Offer?	The Company proposes to use the funds raised from the Public Offer towards the operation and expansion of the Clinics, developing the Data Platform, expenses of the Offers, and general administration fees and working capital.	Section 1.8																																			
Summary of key risks																																					
Prospective investors should be aware that subscribing for Shares in the Company involves a number of risks. The risk factors set out in Section 4, and other general risks applicable to all investments in listed securities, may affect the value of the Shares in the future. Accordingly, an investment in the Company should be considered highly speculative. This Section summarises the key risks which apply to an investment in the Company and investors should refer to Section 4 for a more detailed summary of the risks.																																					
Business strategy execution	The ability of the Company to achieve growth of its business is dependent on the successful implementation of the Company's growth strategies, business plans and strategic initiatives outlined in this Prospectus, which includes but is not limited to the attraction and retention of patients at the Clinics. There can be no assurance that the Company will be successful in implementing these plans. If the Company is unable to implement its business strategy, there may be adverse effects on its results of operations or financial condition.	Section 4.1(a)																																			

Topic	Summary	More Information
Limited operating history and future capital needs	Investors should be aware that the Company has a limited operating history and is currently making a loss, meaning it is reliant on raising funds from investors to continue to fund its operations and development of its Data Platform. The future capital requirements of the Company will depend on many factors, including the pace and magnitude of its development of its business. The Company believes that its available cash and the net proceeds of the Public Offer will be adequate to satisfy its anticipated current working capital and other capital requirements. Should the Company require additional funding, there can be no assurance that additional financing will be available on acceptable terms or at all. Any inability to obtain additional financing, if required, would have a material adverse effect on the Company's business, financial condition and results of operations.	Section 4.1(b)
Obtaining and retaining licences, permits and approvals	The Company's business model is reliant on obtaining and retaining any necessary registrations, approvals and accreditations as outlined in the Legal Opinion on Emerald's business operations in Annexure B of this Prospectus. As at the date of this Prospectus, the Company and its practitioners have the required licences, permits and approvals required in order to operate the Clinics. Where required, the Company will apply for any necessary additional registrations, approvals and accreditations, and undertake the necessary requirements for approval, however, there is no assurance that any such registrations, approvals and accreditations will be granted to the Company, or on terms anticipated by the Company. A failure to obtain any such registrations, approvals and accreditations will result in the Company being unable to continue to establish and/or further its business operations. The Company will comply with any approvals or conditions attaching to the relevant registrations, approvals and accreditations, and undertake continued maintenance of such registrations, approvals and accreditations. However, there is no guarantee that any registrations, approvals and accreditations granted by regulatory bodies will not be revoked during their term, or that they will be renewed for a further period of time or renewed on terms anticipated by the Company. Should any of these circumstances eventuate, it is likely to have a material adverse effect on the Company's proposed activities and operations, as well as its financial performance and prospects.	Section 4.1(c)
Liquidity	A large portion of the Company's Shares will be subject to ASX escrow and may not be able to be freely tradable for a period of time. The ability of an investor in the Company to sell their Shares on the ASX will depend on the turnover or liquidity of the Shares at the time of sale. Therefore, investors may not be able to sell their Shares at the time, in the volumes or at the price they desire.	Section 4.1(d)
Establishment and implementation of new legislative regime	The Company operates (and intends to operate) in an industry which has recently experienced key regulatory and legislative changes. The legislative amendments to key Australian legislation only came into effect fairly recently (for example, the legislative amendments to the NDA only came into effect in Australia in October 2016).	Section 4.1(e)

Topic	Summary	More Information
	The Office of Drug Control and TGA has published regulations and a series of guidelines which explain how the reforms are to operate. Although this guidance is quite prescriptive, as with any new legislative regime, there remains some uncertainty as to the interpretation of the new laws and regulations and the review methodology that the regulatory bodies will adopt.	
Change to laws or regulations	The operations and proposed operations of the Company are subject to a variety of laws, regulations and guidelines. The medicinal cannabis industries are evolving globally, including in Australia. It is likely that governments worldwide, including Australia, will continue to explore the benefits, risks and operations of companies involved in the medicinal cannabis sector. In particular, the regulation of medicinal cannabis is a partisan and divisive issue and, as a result, a change in government or increase in political lobbying may result in a change in government policy and an amendment of legislation and/or regulation. The introduction of new legislation or amendments to existing legislation by governments, or the respective interpretation of the legal requirements in any of the legal jurisdictions which govern the operations or contractual obligations of the Company, could impact adversely on the assets, operations and financial performance of the Company and the medicinal cannabis industry in general.	Section 4.1(f)
Prescription of Cannabis	The Company's practitioners prescribe medicinal cannabis products to patients. Whilst medicinal cannabis is legal for therapeutic use in Australia under the TG Act, there is still a scarcity of high quality level 1 evidence related to the use of medicinal cannabis. Whilst this provides a value proposition to the Company's Data Platform, it also may present a risk for prescribing doctors.	Section 4.1(g)
Sourcing data from third parties	The Company is dependent on its ability to source data from patients, and patients could take steps to block its access to data, which could impair the Company's ability to provide its data collection service or limit the effectiveness its data collection. As part of the Company's informed consent process, the Company provides patients with the ability to elect that the Company does not collect information relating to their care beyond the minimum requirement for safe medical record keeping.	Section 4.1(h)
Risk associated with clinical trials	Scientifically robust clinical trials have long lead-in times, can be expensive to conduct, and are, by definition of their purpose, uncertain as to outcome. Prior to conduct of clinical trials involving cannabis extracts/derivatives, a number of approvals, licences and/or permits are required. Delays in obtaining all necessary authorisations can impact upon downstream activities, including the potential introduction of scheduling issues. Prior to commencing a prospective clinical trial, a sponsor must submit to the HREC a study protocol, an investigator's brochure and a template informed consent for the clinical trial. Once a study is approved by the HREC, the sponsor is required to complete an online CTN form on the TGA Businesses Services website, which notifies the TGA that the HREC has evaluated and approved the scientific merit of the trial and approved it on ethical grounds. Once	Section 4.1(i)

Topic	Summary	More Information
	the notification is acknowledged (and a unique clinical trial number issued), the trial may commence. After commencement, clinical trials are also subject to suspension, delay or termination by regulatory bodies due to revocation of licences/permits to conduct research on unregistered medicinal products, and/ or importation or sourcing of trial material, and/or handling of material classified as poisons. Issues that may impact upon the aforementioned are set out in Section 4.1(i).	
Competition	The industry in which the Company is involved is subject to domestic and international competition. While the Company will undertake all reasonable due diligence in its business decisions and operations, it will have no influence or control over the activities or actions of its competitors, which activities or actions may, positively or negatively, affect the operating and financial performance of the Company. There may be new entrants and players in the medicinal cannabis sector, evidence generation sector and health care sector generally, including other clinics. Some of these parties may have greater financial, technological, managerial and research and development resources and experience than the Company, which may lead to reduced margins and loss of revenue or loss of market share. Further, revenues in the future may be reduced as the industry consolidates and seeks revenue accretion at the expense of profit margin. If the Company is unable to compete successfully, it may be unable to generate, grow and sustain its revenues and earnings.	Section 4.1(j)
Strategic relationship	The medicinal cannabis industry is undergoing rapid growth and change, which has resulted in increasing consolidation and formation of strategic relationships. It is expected that this consolidation and strategic partnering will continue as the industries continue to grow. Acquisitions or other consolidating transactions could harm the Company in a number of ways. The Company may lose strategic relationships if third parties with whom the Company has arrangements are acquired by or enter into relationships with a competitor (which could cause the company to lose access to necessary resources). The Company's current competitors could become stronger, or new competitors could form from consolidations. This could cause the Company to lose access to markets or expend greater resources in order to stay competitive.	Section 4.1(k)
Growth prospects and expansion plans	The Company's growth prospects are dependent upon a number of factors, including service and product offering take up. If the Company fails to execute any expansion plan, its financial performance is likely to be negatively affected. The Company's financial prospects are particularly dependant on there being sufficient demand for evidence generating care and medicinal cannabis products in Australia. There is a risk that the availability of specialist cannabinoid clinical services available in Australia will outstrip the demand for those services, which may result in lower service prices. This would have an adverse effect on the financial performance of the Company.	Section 4.1(l)

Topic	Summary	More Information
	The Company's ability to achieve its growth strategy is also dependent on the Company being able to commercialise the data and evidence it generates related to the use of, among other therapies, medicinal cannabis. The availability of data and evidence may outstrip the demand, which may result in lower prices. In order to expand to international markets, changes in the laws and regulations relating to medicinal cannabis may need to be passed and those laws would need to allow for the operation of the type of clinics operated by the Company. There are no guarantees that the laws and regulations of any of the target markets will be amended or that the Company will be able to access such markets.	
Brand establishment and maintenance	The Company believes that establishing and maintaining the Company's brand in the industry in which it operates is critical to growing its customer base and product and service acceptance. This will depend largely on the Company's ability to provide innovative and in-demand products and services. If the Company fails to successfully establish and maintain its brand, its business and operating results could be adversely affected.	Section 4.1(m)
Patient engagement	The Company relies on patients presenting to our clinics to sustain clinic revenue and, in part, to increase the volume of data in its RWE data platform. In addition, prior to seeing any patient, Emerald's preference is to require a referral from that patient's treating doctor. Several factors may impact Emerald's ability to engage patients: (a) failure to attract sufficient referrals from other clinicians; (b) the approval of more effective and or cheaper treatment alternatives; (c) patient participation in clinical trials; (d) the set-up of competitor clinics; (e) failure to expand its clinical network; (f) failure to attract, train and retain suitably qualified medical practitioners; and (g) changes to laws or regulations that substantially change the availability of unregistered medicines.	Section 4.1(n)
Protection of Intellectual Property	The Company's success will depend on, in part, its ability to protect its intellectual property, including its trade marks, copyright, trade secrets and know-how. To the extent the Company fails to protect its intellectual property or infringes a third party's intellectual property, the Company may face increased competition from similar products, have to cease using certain intellectual property or be liable for damages. In the event that this occurs, there is a risk that it has a materially adverse impact on the Company.	Section 4.1(o)
Business management risk	The Company proposes to establish a network of medical clinics that will provide high quality care using medical grade cannabis as a treatment option. There is a risk that establishing the network of clinics may take longer than anticipated or that costs may exceed original estimates, which could adversely impact the profitability of the Company.	Section 4.1(p)

Topic	Summary	More Information
Uncertainty of future revenue and profitability	Future revenues from the provision of care and commercialisation of data and evidence by the Company and the Company's future profitability are contingent on, amongst other things, the Company's ability to obtain and maintain the required registrations and approvals, entry into local and international markets, ability to attract and retain high quality clinicians, being able to maintain favourable prices for products and services being offered, demand for services and products being sold, general economic conditions, the results of further medical research and clinical trials in relation to medicinal cannabis. Consequently, the level of any future sales of medicinal cannabis by the Company cannot be accurately determined and the Company cannot provide any guarantee that future sales will be achieved. Even if future sales are achieved, they may not result in the Company being profitable.	Section 4.1(q)
Early stage risk	Investing in an early stage enterprise, such as the Company, should be considered highly speculative and involves several significant risks including under capitalisation and obstacles or delays in the implementation of the business plan or revenue generation coupled with existing and future legislative and regulatory risks. There are many risks inherent in the development of biotechnology and data products particularly where the products are in very early stages of development. Projects can be delayed or fail to demonstrate any benefit, or research may cease to be viable for a range of scientific and commercial reasons.	Section 4.1(r)
Healthcare insurers and reimbursement risks	In both domestic and foreign markets, sales of prescription pharmaceutical products and provision of specialist care are likely to depend in part; upon the availability and amounts of reimbursement from third party health care 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 pressure to reduce the cost of therapeutic products, 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 therapeutic products and service provision. No assurance can be given that reimbursement will be provided by such payers at all or without substantial delay, or, if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable Emerald to provide services on a profitable basis or enable patients to use the unregistered medical cannabis products the Company's practitioners prescribe.	Section 4.1(s)
Reliance on key personnel, clinicians and management	The Company is highly dependent on its management and key personnel including experienced clinicians, who are responsible for its day-to-day operations and strategic management. If one or more of these personnel cease his/her involvement with the Company, it could have a materially detrimental impact on its future financial performance.	Section 4.1(t)

Topic	Summary	More Information
	The ability to attract and retain highly qualified staff is crucial to the future success of the Company. There can be no assurance that the Company will be able to so attract and retain such staff.	
Fit and proper persons	The Company's success will depend on, in part, an ability for the Company to continue to support the appropriate use of therapies for patients, including the use of unregistered medicines through the SAS-B and Authorised Prescriber pathways administered by the TGA. The TGA at its absolute discretion may withhold or deny approval sought by a clinician. In assessing applications for the APS an ethics committee, or federal and state regulators may withhold or deny an application at their absolute discretion. The Company also relies on its clinicians to provide high quality care, in line with the Australian Health Practitioner Regulation Agency registration requirements, as well as any codes, standards or guidelines published by the Medical Board of Australia or relevant Specialist Colleges (such as RACGP) to maintain registration. Failure to maintain registration would preclude a clinician from practicing. Should any of these circumstances eventuate, it is likely to have a material adverse effect on the Company's proposed activities and operations, as well as its financial performance and prospects.	Section 4.1(u)
Data Collection Risk	It is likely that the Company will continue to collect, store and process highly sensitive, highly regulated and confidential information. The provision of secure and reliable information storage and processing services is integral to the businesses and operations of the Company. The Company has developed such policies prior to collecting sensitive and personal data. However, even with such policies in place, if the Company's systems or data are compromised for any reason there is a risk that the Company may become involved in legal action due to breaching data confidentiality agreements. If the Company's security measures are breached or unauthorised access to customer data is otherwise obtained, the Company may be perceived as not being secure, customers may reduce the use of or stop using the Company, and it may incur significant liabilities.	Section 4.1(v)

Topic	Summary	More Information																																																																		
Directors, Related Party Interest and Substantial Holders																																																																				
Who are the Directors?	The current Directors of the Company are as follows: (a) Dr Stewart Washer - Executive Chairman; (b) Dr Michael Winlo – Managing Director; (c) Mr Matthew Callahan – Non-Executive Director; and (d) Dr Alistair Vickery – Executive Director. Upon Admission, proposed Non-Executive Director Sir John Tooke will join the Board.	'Corporate Directory' and Section 5.1																																																																		
What interests do Directors have in the securities of the Company?	As at the date of the Prospectus, the Directors hold relevant interests in the Securities specified below. <table><tr><th>Director</th><th>Shares</th><th>%</th><th>Options</th><th>%</th></tr><tr><td>Dr Stewart Washer</td><td>48,000,000</td><td>36.0</td><td>1,500,000</td><td>8.2</td></tr><tr><td>Dr Michael Winlo</td><td>Nil</td><td>Nil</td><td>3,500,000</td><td>19.1</td></tr><tr><td>Dr Alistair Vickery</td><td>Nil</td><td>Nil</td><td>2,000,000</td><td>10.9</td></tr><tr><td>Matthew Callahan</td><td>19,600,000</td><td>14.7</td><td>Nil</td><td>Nil</td></tr><tr><td>Sir John Tooke</td><td>Nil</td><td>Nil</td><td>500,000</td><td>2.7</td></tr></table> Based on the intentions of the Directors at the date of this Prospectus in relation to the Offers, the Directors and their related entities will have the following interests in Securities on Admission: <table><tr><th>Director</th><th>Shares</th><th>% Min</th><th>% Max</th><th>Options</th><th>%</th></tr><tr><td>Dr Stewart Washer</td><td>48,300,000</td><td>26.3</td><td>24.9</td><td>1,500,000</td><td>8.2</td></tr><tr><td>Dr Michael Winlo</td><td>Nil</td><td>Nil</td><td>Nil</td><td>3,500,000</td><td>19.1</td></tr><tr><td>Dr Alistair Vickery</td><td>Nil</td><td>Nil</td><td>Nil</td><td>2,000,000</td><td>10.9</td></tr><tr><td>Matthew Callahan</td><td>19,600,000</td><td>10.7</td><td>10.1</td><td>Nil</td><td>Nil</td></tr><tr><td>Sir John Tooke</td><td>Nil</td><td>Nil</td><td>Nil</td><td>500,000</td><td>2.7</td></tr></table>	Director	Shares	%	Options	%	Dr Stewart Washer	48,000,000	36.0	1,500,000	8.2	Dr Michael Winlo	Nil	Nil	3,500,000	19.1	Dr Alistair Vickery	Nil	Nil	2,000,000	10.9	Matthew Callahan	19,600,000	14.7	Nil	Nil	Sir John Tooke	Nil	Nil	500,000	2.7	Director	Shares	% Min	% Max	Options	%	Dr Stewart Washer	48,300,000	26.3	24.9	1,500,000	8.2	Dr Michael Winlo	Nil	Nil	Nil	3,500,000	19.1	Dr Alistair Vickery	Nil	Nil	Nil	2,000,000	10.9	Matthew Callahan	19,600,000	10.7	10.1	Nil	Nil	Sir John Tooke	Nil	Nil	Nil	500,000	2.7	Section 5.4
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What benefits are being paid to the Directors?	The Company has entered into executive employment agreements with Dr Winlo and Dr Vickery who will each be paid \$350,000 (exclusive of superannuation) per annum on the terms set out in Sections 7.2(b) and 7.2(c) respectively. Dr Winlo and Dr Vickery are each also entitled to receive a cash bonus of \$50,000 and \$100,000 on Admission respectively. The Company has entered into a consultancy agreement with Biologica Ventures Pty Ltd (an entity controlled by Dr Stewart Washer) (Biologica) and Dr Stewart Washer, pursuant to which the Company has agreed to pay Biologica (or its nominee) a consultancy fee of \$200,000 per annum (plus GST) on the terms set out in Section 7.2(a).	Sections 5.6, 5.7 and 7.2																																																																		

Topic	Summary	More Information																		
	The Company has entered into a consultancy agreement with Academic Health Solutions Ltd (of which Sir John Tooke is a director) (Academic Health) and Sir John Tooke, pursuant to which the Company has agreed to pay Academic Health (or its nominee) a consultancy fee of £2,500 per day or part thereof on the terms set out in Section 7.2(e). The Company has entered into a consultancy agreement with Thylacine Consulting LLC (of which Mr Matthew Callahan is a director) (Thylacine), pursuant to which the Company has agreed to pay Thylacine a rate of US\$300 per hour (plus GST), for a maximum of 16 hours in any week on the terms set out in Section 7.2(f). The Company has entered into separate director letters of appointments with Sir John Tooke and Mr Matthew Callahan, who will each be paid \$50,000 per annum as set out in Section 7.2(d).																			
What important contracts with related parties is the Company a party to?	In addition to the agreements set out above, the Company has entered the following related party transactions on arms' length terms: (a) P Washer Agreement with Dr Patrizia Washer, a former Director (refer Section 7.2(g)); (b) deeds of indemnity, insurance and access with each of its Directors on standard terms (refer Section 7.9) for details).	Sections 5.7, 7.2(g) and 7.9																		
Who will be the substantial holders of the Company?	Those Shareholders holding an interest in 5% or more of the Shares on issue as at the date of this Prospectus are as follows. <table border="1"> <thead> <tr> <th>Name</th><th>Number of Shares</th><th>% of Shares</th></tr> </thead> <tbody> <tr> <td>Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust</td><td>28,400,000</td><td>21.3</td></tr> <tr> <td>Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director)</td><td>19,600,000</td><td>14.7</td></tr> <tr> <td>Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust</td><td>19,600,000</td><td>14.7</td></tr> <tr> <td>Craig Lawrence Darby</td><td>19,600,000</td><td>14.7</td></tr> <tr> <td>Gleneagle Asset Management Ltd as trustee for the Alium Alpha Fund Account</td><td>7,000,000</td><td>5.25</td></tr> </tbody> </table> Based on the information known as at the date of this Prospectus, on Admission the following persons will have an interest in 5% or more of the Shares on issue:	Name	Number of Shares	% of Shares	Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust	28,400,000	21.3	Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director)	19,600,000	14.7	Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust	19,600,000	14.7	Craig Lawrence Darby	19,600,000	14.7	Gleneagle Asset Management Ltd as trustee for the Alium Alpha Fund Account	7,000,000	5.25	Section 8.4
Name	Number of Shares	% of Shares																		
Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust	28,400,000	21.3																		
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Topic	Summary					More Information
	Name	Minimum Subscription		Maximum Subscription		
		Shares	%	Shares	%	
	Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust	28,700,000	15.6	28,700,000	14.8	
	Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director)	19,600,000	10.7	19,600,000	10.1	
	Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust	19,600,000	10.7	19,600,000	10.1	
	Craig Lawrence Darby	19,600,000	10.7	19,600,000	10.1	
What fees are payable to the Lead Manager?	PAC Partners (also referred to in this Prospectus as the "Lead Manager") has been appointed as Lead Manager to the Public Offer and is a party to the Lead Manager Mandate that is summarised in Section 7.1. Pursuant to the Lead Manager Mandate, the Company has agreed to pay the Lead Manager (or its nominees) a capital raising and selling fee of 6% of the total amount raised under the Public Offer. Pursuant to the Lead Manager Mandate, the Company has also issued to the Lead Manager 1,000,000 Shares at a nominal issue price of \$0.0001 each. A further 1,140,000 Shares have been issued to the Lead Manager and its associates, as follows: (a) 140,000 Shares issued at \$0.10 each as part of a seed raising; and (b) 1,000,000 Shares at a nominal issue price of \$0.0001 each. The Company has also paid the Lead Manager: (a) \$183,000 for services provided in connection with the Company's seed capital raising conducted in 2018; and (b) \$168,000 for services provided in connection with the issue of the Convertible Notes.					Sections 1.10 and 7.1
What are the Lead Manager's interests in the Securities of the Company?	As at the date of this Prospectus, the Lead Manager and its associates have a relevant interest in 2,140,000 Shares (a percentage shareholding of 1.6%). Based on the information available to the Company as at the date of this Prospectus regarding the intentions of the Lead Manager and its associates in relation to the Offers and assuming:					Sections 1.10 and 7.1

Topic	Summary	More Information
	(a) only the Minimum Subscription is achieved under the Public Offer; and (b) neither the Lead Manager nor its associates take up Shares under the Public Offer, the Lead Manager and its associates will have a relevant interest in 2,140,000 Shares (a percentage shareholding of 1.16% based on the Minimum Subscription).	
What is the Public Offer?		
What is the Public Offer?	The Public Offer is a public offering of up to 40 million Shares at an issue price of \$0.20 each to raise up to \$8 million (before costs).	Section 1.2
What is the Offer Price?	\$0.20 per Share.	Section 1.2
What is the minimum subscription amount under the Public Offer?	The minimum subscription under the Public Offer is \$6 million, being 30 million Shares.	Section 1.3
Will the Shares be quoted?	The Company will apply to the ASX for its admission to the official list of ASX and quotation of Shares on the ASX (expected to be under the code EMD) within 7 days of the date of this Prospectus.	'Corporate Directory' and Section 1.13
What is the purpose of this Prospectus?	The purposes of the Public Offer are to: (a) raise up to \$8 million (before associated costs); (b) operate and expand the number of Clinics throughout Australia; (c) further develop and commercialise the Data Platform; (d) develop novel IP concerning the use of cannabinoid medicine; (e) attract and retain high quality clinical staff; (f) meet the costs of the Offers; (g) meet the conditions to apply for Official Quotation of the Shares on the ASX; (h) 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 to the Official List; and (i) position the Company to seek to achieve the objectives detailed in Section 2.	Section 1.5
What are the conditions of the Public Offer?	The Offers under this Prospectus are conditional upon the following events occurring: (a) the Company raising the Minimum Subscription pursuant to the Public Offer; (b) to the extent required by ASX or the Listing Rules, certain persons entering into a restriction agreement imposing such	Section 1.7

Topic	Summary	More Information
	restrictions on trading on the Company's securities as mandated by the Listing Rules; and (c) ASX providing the Company with a list of conditions which, once satisfied, will result in ASX admitting the Company to the Official List. If these conditions are not satisfied then the Offers will not proceed and the Company will repay all Application Monies received under the Offers in accordance with the Corporations Act.	
Are there any escrow arrangements?	ASX will classify certain existing Securities on issue in the Company as being subject to the restricted securities provisions of the Listing Rules. Restricted securities would be required to be held in escrow for up to 24 months and would not be able 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 on the ability of a Shareholder to dispose of their Shares in a timely manner. Prior to the Company's Shares being admitted to quotation on the ASX, the Company will enter into escrow agreements with the recipients of any restricted securities in accordance with Chapter 9 of the Listing Rules, and the Company will announce to ASX full details (quantity and duration) of any Securities required to be held in escrow. As at the date of this Prospectus the Company expects approximately 99,999,700 Shares and 6,000,000 Options to be subject to 24 months escrow, and no Shares to be subject to 12 months escrow.	Section 1.18
What is the Offer period?	An indicative timetable for the Offers is set in the "Indicative Timetable" section of this Prospectus.	'Indicative Timetable'
Is the Public Offer underwritten?	No, the Public Offer is not underwritten.	Section 1.19
Additional information		
Will the Company be adequately funded after completion of the Public Offer?	The Board believes that the funds raised from the Public Offer will provide the Company with sufficient working capital to achieve its stated objectives as detailed in this Prospectus.	Section 1.8
What rights and liabilities attach to the Securities on issue?	A summary of the material rights and liabilities attaching to the Securities offered under the Offers and on issue is set out in Sections 8.1 and 8.3.	Sections 8.1 and 8.3

Topic	Summary	More Information
Who is eligible to participate in the Offers?	The Public Offer is open to all investors with a registered address in Australia. In addition, subject to the provisions in Section 1.17, certain investors located in Canada, Hong Kong Malaysia, New Zealand, Singapore and the United States are also eligible to participate in the Public Offer.	Sections 1.11 and 1.17
How do I apply for Shares under the Public Offer?	Applications under the Offers can be made by completing the relevant Application Form, in accordance with the instructions accompanying the relevant Application Form.	Sections 1.11
What is the allocation policy?	The Directors, in agreement with the Lead Manager, will allocate Shares at their sole discretion with a view to ensuring an appropriate Shareholder base for the Company going forward. There is no assurance that any Applicant will be allocated any Shares, or the number of Shares for which it has applied. The Company reserves the right to reject any Application or to issue a lesser number of Shares than those applied for. Where the number of Shares issued is less than the number applied for, surplus Application Monies will be refunded (without interest) as soon as reasonably practicable after the Closing Date.	Section 1.15
When will I receive confirmation that my Application has been successful?	Subject to the matters in Section 1.11, Shares under the Public Offer are expected to be allotted on the Allotment Date. It is the responsibility of Applicants to determine their allocation prior to trading in the Shares issued under the Public Offer. Applicants who sell Shares before they receive their holding statements do so at their own risk.	'Indicative Timetable'
What is the Company's dividend policy?	The Company does not expect to pay dividends in the near future as its focus will primarily be on growing the existing businesses. Any future determination as to the payment of dividends by the Company will be at the discretion of the Directors and will depend upon matters such as the availability of distributable earnings, the operating results and financial condition of the Company, future capital requirements, general business and other factors considered relevant by the Directors. No assurances are given in relation to the payment of dividends, or that any dividends may attach franking credits.	Section 2.5
How can I find out more about the Prospectus or the Offers?	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 Company Secretary at cosec@emeraldclinics.com.au	"Corporate Directory"

1. Details of Offers

1.1 Important information

This Prospectus contains details of the Public Offer to apply for Shares in the Company. You are encouraged to:

- (a) read the contents of this Prospectus carefully, including the risk factors in Section 4; and
- (b) obtain independent professional advice from your accountant, lawyer, financial advisor or any other party qualified to provide advice on the contents of this Prospectus.

1.2 Description of the Public Offer

This Prospectus invites investors to apply for up to 40 million Shares at an issue price of \$0.20 each to raise up to \$8 million (before associated costs) (**Public Offer**).

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

Applications must be for a minimum of 10,000 Shares (or \$2,000.00).

1.3 Minimum Subscription

The minimum subscription under the Public Offer is \$6 million, being 30 million Shares (**Minimum Subscription**).

None of the Shares offered under the Public Offer will be issued if Applications are not received for the Minimum Subscription. Should Applications for the Minimum Subscription not be received within 4 months from the date of this Prospectus, the Company 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).

1.4 Maximum subscription

The maximum subscription that the Company may raise under the Public Offer is \$8 million through the issue of 40 million Shares.

1.5 Purpose of the Public Offer

The purposes of the Public Offer are to:

- (a) raise up to \$8 million (before associated costs);
- (b) operate and expand the number of Clinics throughout Australia;
- (c) further develop and commercialise the Data Platform;
- (d) develop novel IP concerning the use of cannabinoid medicine;

- (e) attract and retain high quality clinical staff;
- (f) meet the costs of the Offers;
- (g) meet the conditions to apply for Official Quotation of the Shares on the ASX;
- (h) 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 to the Official List; and
- (i) position the Company to seek to achieve the objectives detailed in Section 2.

1.6 **Convertible Note Offer**

The Company has agreed to offer up to 20,625,000 Shares to third parties unrelated to the Company (being the Noteholders (or their nominees)) on conversion of the Convertible Notes. Details of the Convertible Notes are included in Section 7.7.

This Prospectus includes a separate offer of 20,625,000 Shares to the Noteholders (or their nominees) (**Convertible Note Offer**). No Application Monies are payable under the Convertible Note Offer.

The Company will not issue Shares under the Convertible Note Offer with the purpose of the Noteholders (or their nominees) selling or transferring those Shares, or granting, issuing or transferring interests in those Shares, within 12 months of the issue but this Prospectus provides them the ability to do so should they wish.

The Shares to be issued pursuant to the Convertible Note Offer are of the same class and will rank equally in all respects with the existing Shares in the Company. A summary of the rights and liabilities attaching to the Shares is set out in Section 8.1.

Only the Noteholders (or their nominees) may accept the Convertible Note Offer. A personalised Application Form in relation to the Convertible Note Offer will be issued to such persons and the Company will also provide those persons with a copy of this Prospectus.

1.7 **Conditional Offers**

The Offers under this Prospectus are conditional upon the following events occurring:

- (a) the Company raising the Minimum Subscription pursuant to the Public Offer;
- (b) 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; and
- (c) ASX providing the Company with a list of conditions which, once satisfied, will result in ASX admitting the Company to the Official List.

If these conditions are not satisfied then the Offers will not proceed and the Company will repay all Application Monies received under the Offers in accordance with the Corporations Act.

1.8 Proposed use of Funds

Following the Public Offer, it is anticipated that the following funds will be available to the Company:

Source of funds	Minimum Subscription (\$)	Maximum Subscription (\$)
Existing cash as at the date of this Prospectus	1,700,000	1,700,000
Proceeds from the Public Offer	6,000,000	8,000,000
Total funds available	7,700,000	9,700,000

The following table shows the intended use of funds together with the existing cash reserves in the one-year period following Admission:

Year 1	Minimum Subscription		Maximum Subscription	
	\$	%	\$	%
Clinic Operations - Existing	2,500,000	32.5	2,500,000	25.8
Develop Data Platform ²	800,000	10.4	1,600,000	16.5
Clinical Trials ²	800,000	10.4	1,100,000	11.3
Clinic Development – New and Existing	800,000	10.4	1,200,000	12.4
Corporate Overheads ³	1,600,000	20.8	1,600,000	16.5
Costs of the Offers	682,300	8.9	804,300	8.3
Working capital	517,700	6.7	895,700	9.2
Total Expenditure	7,700,000	100.0	9,700,000	100.0

Notes:

- Shareholders should note that the above estimated expenditures will be subject to modification on an ongoing basis depending on the results obtained from the Company's activities. Due to market conditions, the development of new opportunities and/or any number of other factors (including the risk factors outlined in Section 4), actual expenditure levels may differ significantly from the above estimates.
- For further information, see Section 2.4.
- Which includes, among other things, the salaries of Non-Executive Directors and Dr Stewart Washer, as well as a percentage of salaries payable to certain key management personnel.

The Board believes that the funds raised from the Public Offer will provide the Company with sufficient working capital to achieve its stated objectives as detailed in this Prospectus.

The use of further equity funding or Share placements will be considered by the Board where it is appropriate to accelerate a specific project or strategy.

Based on the intended use of funds detailed above, the amounts raised pursuant to the Public Offer will provide the Company sufficient funding for one year of operations. The Company may require further financing in the future. See Section 4.1(b) for further details about the risks associated with the Company's future capital requirements.

1.9 Capital Structure

On the basis that the Company completes the Public Offer on the terms in this Prospectus, the Company's capital structure will be as follows:

	Shares (Min)	%	Shares (Max)	%	Options	%
Existing Securities	133,277,778	72.5	133,277,778	68.7	18,350,000 ¹	100
Public Offer	30,000,000	16.3	40,000,000	20.6	Nil	Nil
Convertible Note Offer ²	20,625,000	11.2	20,625,000	10.6	Nil	Nil
TOTAL	183,902,778	100	193,902,778	100	18,350,000¹	100

Notes:

1. Comprising:
 - a. 17,750,000 Options with an exercise price of \$0.45 and an expiry date of 13 June 2023; and
 - b. 600,000 Options with an exercise price of \$0.45 and an expiry date of 26 September 2023.
2. The Convertible Notes will convert into 20,625,000 Shares at a deemed issue price of \$0.16 each upon Admission (refer to Section 7.7 for details).

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

Forecasts

The Directors have considered the matters detailed in ASIC Regulatory Guide 170 and believe that they do not have a reasonable basis to forecast future earnings on the basis that the operations of the Company are inherently uncertain. Accordingly, any forecast or projection information would contain such a broad range of potential outcomes and possibilities that it is not possible to prepare a reliable best estimate forecast or projection.

The Directors consequently believe that, given these inherent uncertainties, it is not possible to include reliable forecasts in this Prospectus.

Refer to Sections 2.3 and 2.4 for further information in respect to the Company's proposed activities.

1.10 Lead Manager's interests in Securities

PAC Partners (also referred to in this Prospectus as the "Lead Manager") has been appointed as Lead Manager to the Public Offer and is a party to the Lead Manager Mandate that is summarised in Section 7.1.

(a) Fees payable to the Lead Manager

Pursuant to the Lead Manager Mandate, the Company has agreed to pay the Lead Manager (or its nominees) a capital raising and selling fee of 6% of the total amount raised under the Public Offer.

Pursuant to the Lead Manager Mandate, the Company has also issued to the Lead Manager 1,000,000 Shares at a nominal issue price of \$0.0001 each.

A further 1,140,000 Shares have been issued to the Lead Manager and its associates, as follows:

- (i) 140,000 Shares issued at \$0.10 each as part of a seed raising; and
- (ii) 1,000,000 Shares at a nominal issue price of \$0.0001 each.

The Company has also paid the Lead Manager:

- (iii) \$183,000 for services provided in connection with the Company's seed capital raising conducted in 2018; and
- (iv) \$168,000 for services provided in connection with the issue of the Convertible Notes.

(b) Lead Manager's interests in Securities

As at the date of this Prospectus, the Lead Manager and its associates have a relevant interest in 2,140,000 Shares (a percentage shareholding of 1.6%).

Based on the information available to the Company as at the date of the Prospectus regarding the intentions of the Lead Manager and its associates in relation to the Offers and assuming:

- (i) only the Minimum Subscription is achieved under the Public Offer; and
- (ii) neither the Lead Manager nor its associates take up Shares under the Public Offer,

the Lead Manager and its associates will have a relevant interest in 2,140,000 Shares (a percentage shareholding of 1.16% based on the Minimum Subscription).

(c) Lead Manager's participation in previous placements

Other than as detailed below, the Lead Manager has not participated in a placement of Securities by the Company in the 2 years preceding lodgement of this Prospectus.

The Lead Manager (and its associates) have been issued Shares as follows:

Shares	Subscription Price	Date issued
2,000,000	\$0.0001	26 May 2018
140,000	\$0.10	22 June 2018

1.11 Applications

(a) General

Applications for Shares under the Offers can only be made using the relevant Application Form accompanying this Prospectus. For further information on how to complete the Application Form, Applicants should refer to the instructions set out on the form.

No brokerage, stamp duty or other costs are payable by Applicants. All Application Monies will be paid into a trust account. Applicants wishing to provide Application Monies via electronic funds transfer should follow the instructions on the Application Form or contact the Company.

(i) Option 1: Submit an Application form with a cheque

Investors may complete an Application Form which accompanies and forms part of this Prospectus and enclose a cheque, made payable to "Emerald Clinics Limited" and crossed "Not Negotiable". Investors must either mail or deliver both the Application Form (completed in accordance with the terms set out in the Application Form) and the cheque to the address set out on the Application Form by no later than the Closing Date.

(ii) Option 2: Submit an online Application Form and pay with BPAY

For online applications, investors can apply online with payment made electronically via BPAY®. Investors applying online will be directed to use an online Application Form and make payment by BPAY®. Applicants will be given a BPAY® biller code and a customer reference number (**CRN**) unique to the online Application once the online Application Form has been completed.

BPAY® payments must be made from an Australian dollar account of an Australian institution. Using the BPAY® details, Applicants must:

- (A) access their participating BPAY® Australian financial institution either via telephone or internet banking;
- (B) select to use BPAY® and follow the prompts;
- (C) enter the biller code and unique CRN that corresponds to the online Application;
- (D) enter the amount to be paid which corresponds to the value of Shares under the online Application Form;
- (E) select which account payment is to be made from;
- (F) schedule the payment to occur on the same day that the online Application Form is completed. Applications without payment will not be accepted; and
- (G) record and retain the BPAY® receipt number and date paid.

Investors should confirm with their Australian financial institution whether there are any limits on the investor's account that may limit the amount of any BPAY® payment and the cut off time for the BPAY® payment.

Investors can apply online by following the instructions at <https://investor.automic.com.au/#/ipo/emeraldclinics> and completing a BPAY® payment. If payment is not made via BPAY®, the Application will be incomplete and will not be accepted. The online Application Form and BPAY® payment must be completed and received by no later than the Closing Date.

Completed Application Forms and any accompanying cheques or BPAY® payment must be received by the Company before 5.00pm (WST) on the relevant Closing Date by either being posted or delivered to the following addresses:

By post	By hand delivery
Emerald Clinics Limited C/- Automic Pty Ltd GPO Box 5193 Sydney NSW 2001	Emerald Clinics Limited C/- Automic Pty Ltd Level 2, 267 St Georges Terrace PERTH WA 6000

An original, completed and lodged Application Form together with a cheque or BPAY® payment for any Application Monies, constitutes a binding and irrevocable offer to subscribe for the number of Shares specified in the Application Form. The Application Form does not need to be signed to be valid. If the Application Form is not completed correctly or if the accompanying payment is for the wrong amount, it may be treated by the Company as valid. The Directors' decision as to whether to treat such an Application as valid and how to construe amend or complete the Application Form is final, however an Applicant will not be treated as having applied for more Shares than is indicated by the amount of the cheque or BPAY® payment for the Application Monies.

It is the responsibility of Applicants outside Australia to obtain all necessary approvals for the allotment and issue of Shares pursuant to this Prospectus. 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:

- (a) agrees to be bound by the terms of the relevant Offer;
- (b) declares that all details and statements in the Application Form are complete and accurate;
- (c) 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;
- (d) authorises the Company and its respective officers or agents, to do anything on their behalf necessary for the Shares 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;
- (e) acknowledges that the information contained in, or accompanying, the Prospectus is not investment or financial product advice or a recommendation that Shares are suitable for them given their investment objectives, financial situation or particular needs; and
- (f) acknowledges that the Shares 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.

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.

(b) Public Offer

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).

Applications for Shares under the Public Offer must be made on the Application Form accompanying this Prospectus and received by the Company on or before the Closing Date. Persons wishing to apply for Shares should refer to Section 1.1(a) and the Application Form for further details and instructions.

(c) Convertible Note Offer

Only the Noteholders may accept the Convertible Note Offer. The Company will only provide an Application Form in relation to the Convertible Note Offer to the Noteholders, together with a copy of this Prospectus. No monies are payable for the Shares under the Convertible Note Offer.

1.12 CHESS and issuer sponsorship

The Company will apply to participate in CHESS. All trading on the ASX will be settled through CHESS. ASX Settlement, a wholly-owned subsidiary of the ASX, operates CHESS 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 CHESS 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 Shares on the issuer sponsored sub-register). The statements will set out the number of existing Shares (where applicable) and the number of Shares 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.

1.13 ASX Listing and Official Quotation

Within 7 days after the date of this Prospectus, the Company will apply to ASX for admission to the Official List and for the Shares, including those offered by this Prospectus, to be granted Official Quotation (apart from any Shares that may be designated by ASX as restricted securities).

If ASX does not grant permission for Official Quotation within three months after the date of this Prospectus (or within such longer period as may be permitted by ASIC) none of the Shares offered by this Prospectus will be allotted and issued. If no allotment and issue is made, all Application Monies will be refunded to Applicants (without interest) as soon as practicable.

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

1.14 Application Monies to be held in trust

Application Monies will be held in trust for Applicants until the allotment of the Shares under the Public Offer. Any interest that accrues will be retained by the Company.

If the Shares to be issued under this Prospectus are not admitted to quotation within a period of three months from the date of this Prospectus, the Company will either repay the Application Monies (without interest) as soon as practicable 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).

1.15 Allocation and issue of Shares

The Directors, in agreement with the Lead Manager, will allocate Shares at their sole discretion with a view to ensuring an appropriate Shareholder base for the Company going forward.

There is no assurance that any Applicant will be allocated any Shares, or the number of Shares for which it has applied. The Company reserves the right to reject any Application or to issue a lesser number of Shares than those applied for. Where the number of Shares issued is less than the number applied for, surplus Application Monies will be refunded (without interest) as soon as reasonably practicable after the Closing Date.

Subject to the matters in Section 1.11, Shares under the Public Offer are expected to be allotted on the Allotment Date. It is the responsibility of Applicants to determine their allocation prior to trading in the Shares issued under the Public Offer. Applicants who sell Shares before they receive their holding statements do so at their own risk.

1.16 Risks

Prospective investors should be aware that an investment in the Company should be considered highly speculative and involves a number of risks inherent in the various business segments of the Company. Section 4 details the key risk factors which prospective investors should be aware of. It is recommended that prospective investors consider these risks carefully before deciding whether to invest in the Company.

This Prospectus should be read in its entirety as it provides information for prospective investors to decide whether to invest in the Company. If you have any questions about the desirability of, or procedure for, investing in the Company please contact your stockbroker, accountant or other independent adviser.

1.17 Restrictions on Distribution

No action has been taken to register or qualify the Shares or the Offers in any jurisdiction outside Australia and New Zealand or otherwise to permit a public offering of the Shares in any jurisdiction outside Australia or New Zealand.

This Prospectus may not be released or distributed in the United States or elsewhere outside Australia and New Zealand, unless it has attached to it the selling restrictions applicable in the jurisdictions outside Australia and New Zealand, and may only be distributed to persons to whom the Offers may lawfully be made in accordance with the laws of any applicable jurisdiction.

The Prospectus does not constitute an offer or invitation in any jurisdiction where, or to any person to whom, the offer or invitation would be unlawful. The distribution of this Prospectus in jurisdictions outside Australia and New Zealand, except to the extent permitted under this Section 1.17, may be restricted by law and persons who come into possession of this Prospectus should seek advice on and observe any of those restrictions. Any failure to comply with the restrictions may constitute a violation of applicable securities laws.

Potential investors should refer to the relevant warning statements below and under 'Important Information' on page ii and iii of this Prospectus.

Each Applicant warrants and represents that:

- (a) they are an Australian or New Zealand citizen or resident in Australia or New Zealand, at the time of the application and are not acting for the account or benefit of any person in the United States or any other foreign person; or
- (b) they are an overseas Applicant that complies with all laws of any country relevant to his or her Application; and
- (c) they will not offer or sell the Shares in the United States or in any other jurisdiction outside Australia or New Zealand except in transactions exempt from registration under the US Securities Act 1933 as amended, and in compliance with all applicable laws in the jurisdiction in which the Shares are offered and sold.

Canada (British Columbia, Ontario and Quebec provinces)

This Prospectus constitutes an offering of Shares only in the Provinces of British Columbia, Ontario and Quebec (the **Provinces**) and to those persons to whom they may be lawfully distributed in the Provinces, and only by persons permitted to sell such Shares. This Prospectus is not, and under no circumstances is to be construed as, an advertisement or a public offering of securities in the Provinces. This Prospectus may only be distributed in the Provinces to persons that are "accredited investors" within the meaning of NI 45-106 – *Prospectus Exemptions*, of the Canadian Securities Administrators.

No securities commission or similar authority in the Provinces has reviewed or in any way passed upon this Prospectus, the merits of the Shares or the offering of Shares and any representation to the contrary is an offence.

No prospectus has been, or will be, filed in the Provinces with respect to the offering of Shares or the resale of such securities. Any person in the Provinces lawfully participating in the offer will not receive the information, legal rights or protections that would be afforded had a prospectus been filed and receipted by the securities regulator in the applicable Province. Furthermore, any resale of the Shares in the Provinces must be made in accordance with applicable Canadian securities laws which may require resales to be made in accordance with exemptions from dealer registration and prospectus requirements. These resale restrictions may in some circumstances apply to resales of the Shares outside Canada and, as a result, Canadian purchasers should seek legal advice prior to any resale of the Shares.

The Company as well as its directors and officers may be located outside Canada and, as a result, it may not be possible for purchasers to effect service of process within Canada upon the

Company or its directors or officers. All or a substantial portion of the assets of the Company and such persons may be located outside Canada and, as a result, it may not be possible to satisfy a judgment against the Company or such persons in Canada or to enforce a judgment obtained in Canadian courts against the Company or such persons outside Canada.

Any financial information contained in this Prospectus has been prepared in accordance with Australian Accounting Standards and also comply with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. Unless stated otherwise, all dollar amounts contained in this Prospectus are in Australian dollars.

Statutory rights of action for damages and rescission

Securities legislation in certain of the Provinces may provide purchasers with, in addition to any other rights they may have at law, rights of rescission or to damages, or both, when an offering memorandum that is delivered to purchasers contains a misrepresentation. These rights and remedies must be exercised within prescribed time limits and are subject to the defences contained in applicable securities legislation. Prospective purchasers should refer to the applicable provisions of the securities legislation of their respective Province for the particulars of these rights or consult with a legal adviser.

The following is a summary of the statutory rights of rescission or to damages, or both, available to purchasers in Ontario. In Ontario, every purchaser of the Shares purchased pursuant to this Prospectus (other than (a) a "Canadian financial institution" or a "Schedule III bank" (each as defined in NI 45-106), (b) the Business Development Bank of Canada or (c) a subsidiary of any person referred to in (a) or (b) above, if the person owns all the voting securities of the subsidiary, except the voting securities required by law to be owned by the directors of that subsidiary) shall have a statutory right of action for damages and/or rescission against the Company if this Prospectus or any amendment thereto contains a misrepresentation. If a purchaser elects to exercise the right of action for rescission, the purchaser will have no right of action for damages against the Company. This right of action for rescission or damages is in addition to and without derogation from any other right the purchaser may have at law. In particular, Section 130.1 of the Securities Act (Ontario) provides that, if this Prospectus contains a misrepresentation, a purchaser who purchases the Shares during the period of distribution shall be deemed to have relied on the misrepresentation if it was a misrepresentation at the time of purchase and has a right of action for damages or, alternatively, may elect to exercise a right of rescission against the Company, provided that (a) the Company will not be liable if it proves that the purchaser purchased the Shares with knowledge of the misrepresentation; (b) in an action for damages, the Company is not liable for all or any portion of the damages that the Company proves does not represent the depreciation in value of the Shares as a result of the misrepresentation relied upon; and (c) in no case shall the amount recoverable exceed the price at which the Shares were offered.

Section 138 of the *Securities Act* (Ontario) provides that no action shall be commenced to enforce these rights more than (a) in the case of any action for rescission, 180 days after the date of the transaction that gave rise to the cause of action or (b) in the case of any action, other than an action for rescission, the earlier of (i) 180 days after the purchaser first had knowledge of the fact giving rise to the cause of action or (ii) three years after the date of the transaction that gave rise to the cause of action. These rights are in addition to and not in derogation from any other right the purchaser may have.

Certain Canadian income tax considerations

Prospective purchasers of the Shares should consult their own tax adviser with respect to any taxes payable in connection with the acquisition, holding or disposition of the Shares as any discussion of taxation related matters in this Prospectus is not a comprehensive description and

there are a number of substantive Canadian tax compliance requirements for investors in the Provinces.

Language of documents in Canada

Upon receipt of this Prospectus, each investor in Canada hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the Shares (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Hong Kong

WARNING: This Prospectus has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the **SFO**). No action has been taken in Hong Kong to authorise or register this Prospectus or to permit the distribution of this Prospectus or any documents issued in connection with it. Accordingly, the Shares have not been and will not be offered or sold in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

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

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

Malaysia

No approval from, or recognition by, the Securities Commission of Malaysia has been or will be obtained in relation to any offer of Shares. The Shares may not be offered or sold in Malaysia except pursuant to, and to persons prescribed under, Part I of Schedule 6 of the Malaysian Capital Markets and Services Act.

New Zealand

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

- (a) is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- (b) meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;

- (c) is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- (d) is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act;
or
- (e) is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

Singapore

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

This Prospectus has been given to you on the basis that you are (i) an existing holder of the Company's shares, (ii) an "institutional investor" (as defined in the SFA) or (iii) an "accredited investor" (as defined in the SFA). In the event that you are not an investor falling within any of the categories set out above, please return this Prospectus immediately. You may not forward or circulate this Prospectus to any other person in Singapore.

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

United States

This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The Shares have not been, and will not be, registered under the US Securities Act of 1933 and may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

1.18 Escrow arrangements

ASX will classify certain existing Securities on issue in the Company as being subject to the restricted securities provisions of the Listing Rules. Restricted securities would be required to be held in escrow for up to 24 months and would not be able 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 on the ability of a Shareholder to dispose of their Shares in a timely manner.

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

As at the date of this Prospectus the Company expects approximately 99,999,700 Shares and 6,000,000 Options to be subject to 24 months escrow and no Shares subject to 12 months escrow.

1.19 Underwriting

The Public Offer is not underwritten.

1.20 Lead Manager

PAC Partners has been appointed as Lead Manager to the Public Offer on the terms and conditions summarised in Section 7.1 of this Prospectus.

1.21 Brokerage, commission and stamp duty

No brokerage, commission or stamp duty is payable by Applicants on acquisition of Shares under the Public Offer.

1.22 Withdrawal

The Directors may at any time decide to withdraw this Prospectus and the Public Offer in which case the Company will return all Application Monies (without interest) within 28 days of giving notice of their withdrawal.

1.23 Privacy disclosure

Persons who apply for Shares 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 Shareholders, 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.

1.24 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 from should be directed to the Company Secretary at cosec@emeraldclinics.com.au.

1.25 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 Company Secretary at cosec@emeraldclinics.com.au.

2. Company Overview

2.1 Company and Business Overview

Emerald Clinics Limited (**Emerald**) operates a network of specialist medical clinics (**Clinics**) and uses purpose-built software and technology to gather high quality clinical data from informed and consenting patients. The real-world data (**RWD**) generated across Emerald's clinical network is commercially valuable and, when anonymised and analysed, can be used as clinical evidence to improve cannabinoid and other medicine development, improve clinical trial design and delivery, develop clinical decision support tools for clinicians, guide pharmacovigilance programs, inform health economic and payment coverage decisions and, ultimately, aims to improve patient health outcomes.

Emerald has established four medical centres in Australia including one site each in West Leederville WA, Woolloomooloo NSW, Tintenbar NSW and Richmond VIC. Additional Clinics are planned across Australia within the next 12 months. Emerald is also considering the viability of expanding its operations in the United Kingdom.

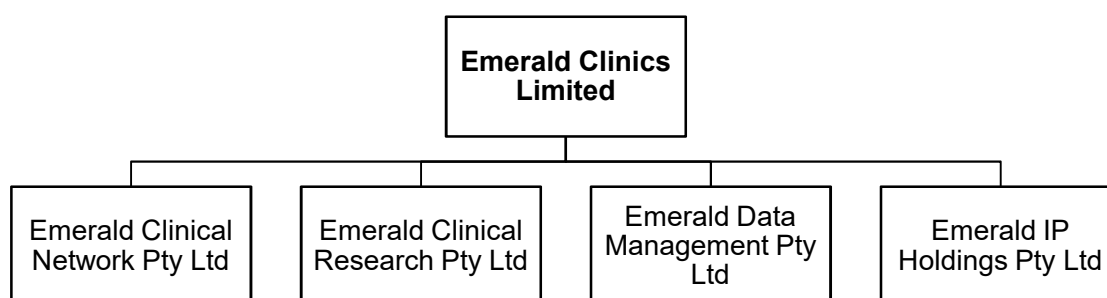
Emerald provides patient-centric and independent specialist clinical expertise. All patients are referred to Emerald by a patient's treating doctor. As such, Emerald forms an integral part of a patient's care team. Emerald's Care Model (as described in Section 2.4) includes suitability screening and treatment planning as well as treatment safety and efficacy monitoring. All patients are invited to share their anonymous clinical data with the Emerald team via an informed consent process.

Emerald's mission is to ensure that cannabinoid-based medicines are appropriately prescribed to suitable patients in order to improve health outcomes and quality-of-life. A core component of the Emerald Care Model is the capture of comprehensive RWD, from consenting patients that can be used as real world evidence (**RWE**) to support innovation across the cannabinoid medicine industry (**Emerald Data Platform**).

The Emerald Data Platform adheres to strict security, data governance and quality management standards and all data is captured, encrypted and stored in either an electronic health record (**EHR**) or an FDA-compliant electronic data capture system (**EDC**). This helps ensure that the RWE generated from Emerald's RWD could be presented to major global regulators such as the Food and Drug Administration (**FDA**) in the US and the European Medicines Agency (**EMA**) in Europe. Both the FDA and EMA are actively developing guidance to increase the use of RWE in support of "market authorisations". A market authorisation is an official approval given to a drug developer from a major regulator that allows that drug developer to promote and discuss the evidence-backed medical benefits of a new drug with clinicians. The Australian term for market authorisation is "inclusion" on the Australian Register of Therapeutic Goods, which is also called "registration". Market authorisations are only granted to drug developers after reviewing and assessing high quality clinical evidence. With the increasing acceptance of RWE as a compliment to, or in some cases, in lieu of, clinical evidence generated from clinical trials, RWE is sought after by biopharma companies as it can accelerate their treatment development programs, improve clinical trial designs and support pharmacovigilance programs. In addition, RWE is of interest to regulators to assist with policy development and monitoring, as well as to payers to help inform payment coverage decisions. As a result, RWE is of particular interest to producers of cannabinoid-based medicines (**Producers**) to support product differentiating market authorisations.

2.2 Corporate Structure

The Company has four wholly owned subsidiaries, which were all incorporated in Western Australia:



2.3 History of the Company

The Company was incorporated on 19 March 2018.

Initial Clinic Roll-Out

Emerald opened its first Clinic in Perth in December 2018, and has subsequently opened three more Clinics, one each in Sydney, Melbourne and Tintenbar.

The Clinics accept referrals from primary carers and specialists for patients who have exhausted conventional therapies. The Clinics are able to, but do not, accept patients who have not been referred, commonly referred to as 'walk ins'.

To date, in Australia, Emerald has focussed on treating patients assessed to be clinically suitable for cannabinoid medicines where other treatments have failed. The Clinics facilitate the screening, prescription and monitoring of cannabinoid medications by clinicians in a manner consistent with the *Therapeutic Goods Act 1989* (Cth) and applicable State poisons and medicines legislation.

Emerald received its first TGA approval for the prescription of medicinal cannabis on 28 December 2018. As of 18 November 2019, Emerald has received 811 successful initial approvals for the prescription of medicinal cannabis and Emerald has received referrals for 818 unique patients who are now considered Active Patients across its four Clinics.

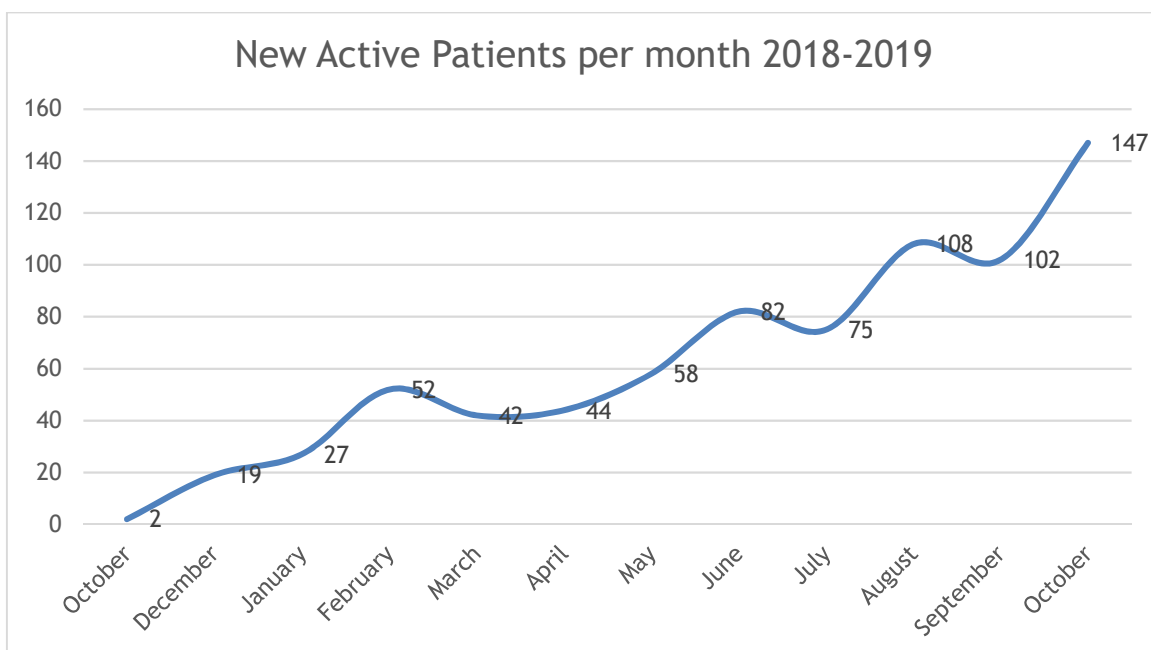


Figure 1 - Newly Active Emerald Patients By Month

Emerald Data Platform Development

Initially, Emerald focussed on developing the architecture, policies, processes and implementation plans for its clinical data capture approach, which underpins the Emerald Data Platform. During the start-up phase of product development, Emerald developed protocols for data collection and privacy protection with the intent of generating data focussed on the treatment of chronic and neuropathic pain with cannabinoid products.

Emerald has since secured fee-paying contracts for the use of the Emerald Data Platform.

Timeline of events

Set out below is a timeline of events and achievements since the Company was incorporated on 19 March 2018.

Date	Event
March 2018	Design and validation of Clinical Platform
April 2018	Design and validation of Data Platform
July 2018	Engaged medical advisors
December 2018	Opened Perth Clinic
April 2019	Opened Sydney Clinic
August 2019	Opened Melbourne Clinic First commercialisation of Data Platform
September 2019	Opened Tintenbar Clinic

2.4 Strategy of the Company

Commercialisation and Marketing Strategy

Cannabinoid medicine is a leading growth sector globally and patient demand is increasing rapidly in Australia. Many countries, including Australia, are legalising the use of cannabinoids for medical use and many new products are becoming available. In Australia, however, access to medicinal cannabis products is more tightly regulated than most prescription medicines. This tighter regulation occurs at both the Commonwealth level and the level of the States and Territories.

The main reason for this tighter regulation (especially at the Commonwealth level) is due to the lack of clinical evidence supporting the use of each specific medicinal cannabis product. The TGA has only approved the registration of one medicinal cannabis product to date (Sativex), for the specific indication of improving symptoms related to muscle stiffness (spasticity) in multiple sclerosis. Access to unregistered prescription medicines is limited to ad-hoc approvals by the TGA. There have been very few well designed clinical trials using medicinal cannabis, so there is limited evidence on its success in treating different medical conditions, or on effective forms and dosages, therefore to increase the number and range of indications of registered medicinal cannabis products in Australia, more clinical evidence is required to support the use of each specific medicinal cannabis product. This situation in other countries is similar.

For example, at the time of this Prospectus and to the best of the Company's knowledge, only three cannabis-based medicines have received a market authorisation from the FDA in the US.

The majority of cannabinoid-based medicines in Australia lack specific clinical indications and can only be prescribed via special access schemes. A lack of high-quality clinical evidence supporting the use of cannabinoid medicines has led to apprehension amongst patients, prescribers, regulators and Payers. This is preventing mainstream adoption of these treatments and constraining patient access.

Emerald's key, long-term value driver will be the RWE generated by the Emerald Data Platform in the course of providing specialist care to patients in its Clinics. Emerald's RWE can help address the current paucity of clinical evidence behind the safe and appropriate use of medicinal cannabis and is of value to Producers looking to improve their medical products and clarify their clinically relevant points of difference compared to alternatives.

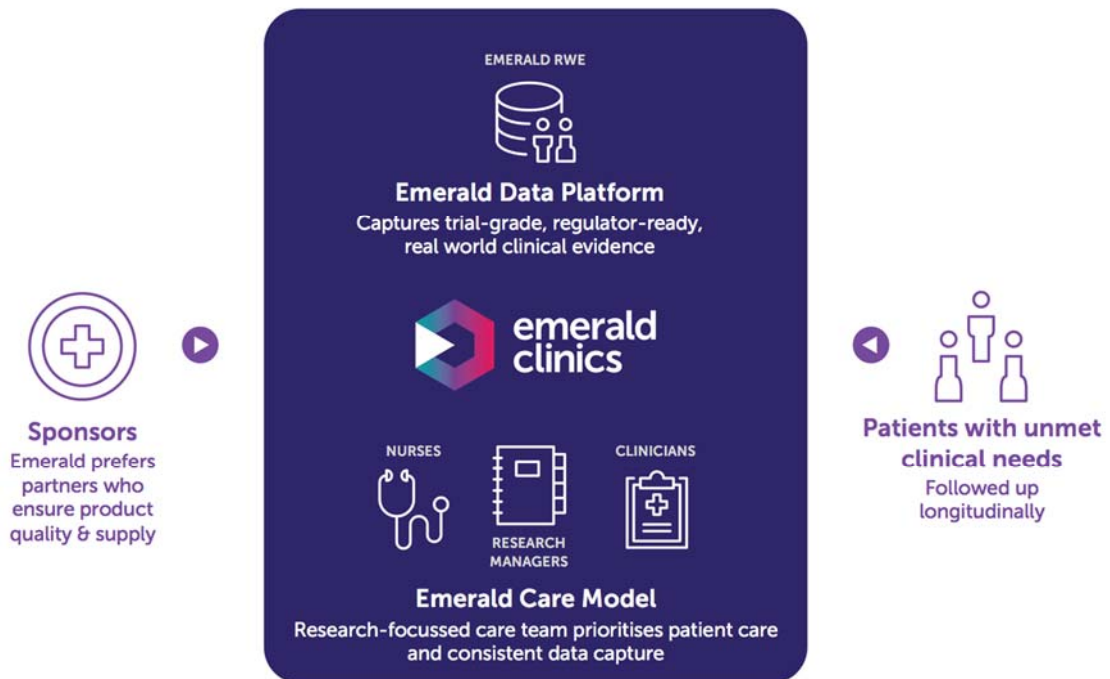


Figure 2 - Emerald Clinics Model

The Emerald Care Model

A schematic of Emerald's Care Model and the Data Platform is shown in Figure 2 above. The **"Emerald Care Model"** is a combination of clinical protocol (which determines the schedule of assessments and sequencing of when and how such assessments are performed), business processes and decision making affecting the patient experience.

Patients present to Emerald clinics with a referral from their primary care doctor or treating specialist. All patients undergo an initial medical screen to assess their needs and suitability for cannabinoid therapy. If deemed appropriate, an application will be made by the medical practitioner to the TGA under the SAS-B or, in limited instances, under the APS¹ and, if required, to the relevant state authority. If approved for cannabinoid therapy, Emerald's care team – which may comprise one or more nurses, research managers, pain specialists and general practitioners – invite patients to give their consent for treatment. The care team also supports patients with appropriate treatment plans as well as conducts regular follow-up using clinically validated assessments. The assessments help evaluate the safety, efficacy and quality-of-life impacts of the treatment program. Subject to patient consent, relevant patient data is entered into both an electronic health record (**EHR**) and an FDA-compliant electronic data capture system (**EDC**)² (see Figure 3). These components form the Emerald Data Platform. This clinical data helps guide the safe management of Emerald patients.

Patients are also invited to provide their consent to allow their anonymous clinical data to be aggregated and shared for research and commercial purposes thus helping develop Emerald's RWE asset.

¹ For further information, please see <https://www.tga.gov.au/access-medicinal-cannabis-products>. The TGA has not provided consent to be named in this Prospectus.

² Emerald's EDC is based on an off-the-shelf EDC called Medrio. Medrio has provide proof of compliance with both FDA (21 CFR (Code of Federal Regulations) Part 11) and EMA (Annexure 11).

The Clinics

The Clinics generate revenue and provide patient data. Consultations are billed directly to the patient or, on a case-by-case basis to a patient's insurer. The Clinics derive revenue in a manner consistent with other general practice and specialist medical centres, noting however, that as part of Emerald's governance model, doctors at the Clinics are remunerated on a per-day, rather than per-consult or prescription basis. This is designed to ensure that there is no financial incentive to prescribe cannabinoid products. Emerald does not accept inducements, rebates or incentives from any producer of cannabinoid medicines and has no pecuniary interest in any pharmacies that dispense cannabinoid medicines. Emerald's philosophy is that all prescription decisions are made in the best interests of every patient and in consideration of the best available clinical evidence and in consultation with the patient's referring doctor and, if required with the appropriate approvals from the relevant national and state-based regulatory authorities.

In Australia, all cannabinoid-based medicines must meet Good Manufacturing Practice (**GMP**) standards and the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*. This means cannabinoid-based medicine prescribed by Emerald clinicians can be considered pharmaceutical quality. The product stringency imposed in Australia helps ensure the veracity of the RWE generated by Emerald's Care Model. Each Clinic also provides training and clinical decision support to its doctors.

In addition to evaluating the available safety and efficacy data for each product, Emerald clinicians will also consider the long-term availability, stability and cost of the product, and the willingness of the Producer to engage in safety, monitoring or research programs. Emerald's patient population is diverse. To date, Emerald has received SAS-B approvals from the TGA for the following non-exhaustive indications:

- (a) chronic, non-cancer pain
- (b) chemotherapy-induced nausea and vomiting;
- (c) palliative care indications;
- (d) cancer pain;
- (e) neuropathic pain;
- (f) spasticity from neurological conditions; and
- (g) anorexia and wasting associated with chronic illness (such as cancer).

A majority of Emerald's patients have presented for the symptomatic treatment of chronic, non-cancer pain.

International Clinic Expansion Possibilities.

Emerald intends to expand its clinical network across Western Australia, New South Wales, Victoria, Queensland and South Australia and into the United Kingdom (**UK**) in the near term, where legal provisions for private clinics are in place. To operate a private, independent clinic in England, Emerald will register the service with the Care Quality Commission which regulates clinical services in England. The current regulations in the UK require a Specialist Clinician to make the decision to prescribe cannabis-based products for medicinal use (**CBPMs**). In order for Emerald to undertake a successful expansion in the UK, it will be reliant on Emerald's ability to attract and retain Specialist Clinicians, identify a viable site and attract sufficient patient referrals to generate RWE.

Tightly regulated access models are in place, or in development, in the UK.



Dr Alistair Vickery at the West Leederville Emerald Clinic

Paying for Medicinal Cannabis

At the time of this Prospectus, in Australia, the cost of medicinal cannabis is not covered by the federal pharmaceutical benefits scheme (**PBS**). This means that a majority of patients must pay out-of-pocket for any prescribed product.

Similarly, in the UK, the National Institute for Health and Care Excellence (**NICE**) recently published prescribing guidelines for CBPMs. NICE concluded that more research is needed before it can recommend the use of CBPMs for medical use reimbursed by the National Health Service (**NHS**). Only two naturally occurring products were approved for use and eligible for reimbursement under the NHS. They are:

- (a) Epidiolex®; and
- (b) Sativex® - for muscle spasms in multiple sclerosis.

Unless more suitable evidence is generated concerning the positive pharmacoeconomic benefits of medicinal cannabis, it is unlikely federal governments, or private health insurers will systematically reimburse patients for the cost of medicinal cannabis products.

The Emerald Data Platform

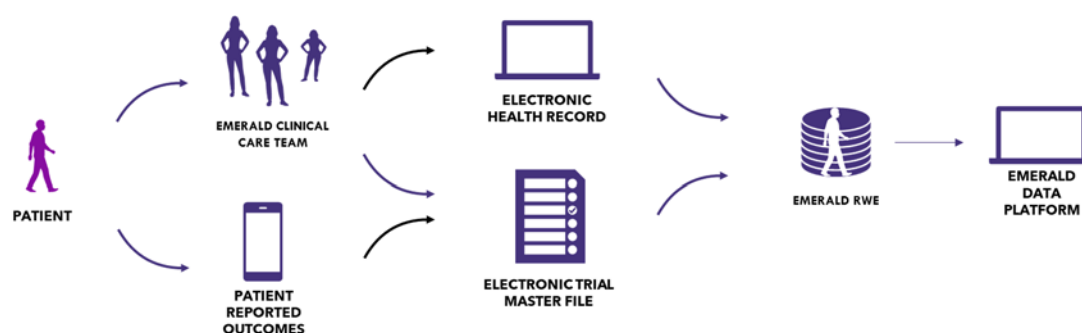


Figure 3 - Emerald Data Platform

As described above, Emerald’s clinicians and research team collect information from each consenting patient. This data comprises a demographic profile as well as specific safety and treatment outcomes as monitored via routine medical examinations and a suite of clinically validated measures and questionnaires designed to evaluate changes in specific medical conditions, adverse events, quality-of-life changes, physical and emotional functioning and sleep. Regular patient blood and pathology testing may also be required in certain circumstances, however is not routinely collected as part of the Data Platform. All data is captured, encrypted and stored in either an EHR or an FDA-compliant EDC (also known as an electronic trial master file).³

In addition, EDCs must provide secure access controls, clear data audit trails and an ability to support standardised data models. The Emerald Data Platform has therefore been developed to conform to these requirements. This allows Emerald’s data capture workflows and the resulting RWE generated to be considered both “trial-grade” and “regulator ready”.

Emerald has instituted a data governance framework that governs all use of data as well as Emerald’s de-identification process covering the removal of all personally identifiable information (PII).

All integrated data is de-identified (**De-identified Data**) and the De-identified Data is manually reviewed against baseline questions to confirm that all PII has been removed. The baseline questions include but are not limited to the following:

- (a) Does the De-identified Data contain a name, address, phone number or unique government identifiers?
- (b) Does the De-identified Data contain any unique identification numbers that associate the identity of an individual in one system to another (for example, a medical reference number that can be used to associate a set of De-identified Data in one database to a set of PII in another database)?
- (c) Can an individual be uniquely identified using the De-identified Data by any means including the combination of multiple data values (for example, the combination of a date of birth, postcode, and gender)?

(Together, the **Baseline Questions**).

³ Recommendations regarding the collection and utilisation of EHR data in clinical investigations for the FDA can be found in the guidance for industry Use of Electronic Health Record Data in Clinical Investigations (July 2018). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry>

In the event that the answer to the any of the Baseline Questions indicates that the relevant data has not been sufficiently de-identified, the data is stripped of the PII and re-tested.

Regulator Interest in RWE

Major international regulators are increasingly aware that, frequently, many of the purported clinical and pharmacoeconomic benefits suggested in the outcomes of randomised control clinical trials do not manifest in real-world patient populations. This is due to real-world variances across patient populations, prescriber behaviours and health systems. As such, there is growing interest from the world's most influential regulators such as the FDA and EMA to incorporate more RWE to support regulatory decision making.

A challenge limiting the potential for RWE in standard clinical practice is that most data capture technology prevalent in modern health systems is optimised for care delivery and not evidence generation.

This creates an opportunity to apply learnings from clinical trials – where evidence generation is the primary goal, to clinical care – where treatment is the goal. Emerald's model is to bring clinical-trial-grade data management to direct patient care in order to develop RWE on cannabinoid medicines. Due to the strict manner in which Emerald is developing its RWE asset and increasing acceptance of RWE by major regulators, Emerald believes it can be used as clinical evidence to help improve patient care and aid in the development of new treatments and diagnostics.

High quality RWE is highly valued by drug developers in order to accelerate the acceptance, development of, and patient access to, their treatments. Drug developers are prepared to pay for access to RWE that can help de-risk or accelerate their clinical development programs.

Therefore, it is Emerald's intention to market its RWD and RWE, collected in a robust, harmonised and consistent manner across its network, to drug developers. In addition, Emerald's RWD can be used to develop novel, Emerald-owned intellectual property related to clinical decision support tools, treatment efficacy biomarkers and general market intelligence.

Emerald has and intends to further monetise its De-identified Data and / or data-insights-as-a-service to qualified third parties. Emerald's patient-centric philosophy mandates that Emerald patients own their data and are openly invited to provide their consent for Emerald to use that data for research and commercial purposes. Patients are not remunerated and may withdraw their consent at any time, and if requested, Emerald will remove their De-identified Data from the Data Platform. To minimise the risk of data exposure, Emerald has developed a robust data governance framework and cyber security infrastructure in close collaboration with cyber security experts.

Emerald is not aware of any other group collecting a similar breadth of data to the data quality and integrity standards described above in any patient-facing clinics. Emerald believes that its system of generating RWE, and the feedback of this information into its Clinics, makes Emerald's data unique and commercially valuable. For further information on Emerald's competitors, please see Section 3.4.

Emerald has commercialised its RWE with a number of companies to date, for further information see Section 7.3.

Clinical Trials

Emerald aims to augment its Data Platform by supporting and conducting clinical trials. These trials may be self-sponsored (paid for by Emerald) in order to generate novel, Emerald-owned

intellectual property. Such trials will only be initiated following extensive due diligence including, but not limited to, internal analysis of Emerald-owned data, external market analysis, review of existing intellectual property and after obtaining appropriate human research ethics committee (**HREC**) and relevant regulatory approvals.

Emerald does not intend to undertake any trials in the near term that would require it to obtain a Schedule 8 licence in its own right, but it may choose to partner with third parties that hold such licences.

Emerald Clinics has and will continue to seek opportunities to conduct commercial, fee-for-service, clinical trials on behalf of drug developers.

Emerald will prepare its network to support the following clinical trials and development programs:

- (a) **Clinical Efficacy and Safety Studies** - in partnership with pharmaceutical/biotechnology companies, hospitals and / or research organisations, to deliver sponsor-initiated and investigator-initiated trials evaluating the clinical efficacy and safety of cannabinoid medicines, related combination-therapy regimes and how to best identify patients most likely to respond to treatment or not.
- (b) **Digital Health Platforms** – to support the development of digital health Apps and devices for patient monitoring, such as real-time monitoring of patient’s activity and sleep patterns during cannabinoid treatment and clinical decision support tools.
- (c) **Product Development** – to support novel treatment formulations and delivery methods in order to improve the bioavailability and efficacy of treatments across a range of therapeutic indications and patient cohorts.

Emerald has entered into one agreement to date in respect to its clinical trial model, for further information see Section 7.4.

Continued Growth

In addition to organic growth within the clinical network, Emerald will also seek to acquire data from pharmaceutical companies, research organisations and country-specific health record agencies and regulators to further enrich the Data Platform and Emerald Care Model upon securing all appropriate consents.

Ultimately, the combination of patient access, clinic and drug development customers, along with the revenue from the use of the Data Platform and Emerald Care Model will drive value for investors.

2.5 Dividend Policy

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

Any future determination as to the payment of dividends by the Company will be at the discretion of the Directors and will depend upon matters such as the availability of distributable earnings, the operating results and financial condition of the Company, future capital requirements, general business and other factors considered relevant by the Directors. No assurances are given in relation to the payment of dividends, or that any dividends may attach franking credits.

3. Industry Overview

3.1 Current legal position of medical cannabis in Australia

In February 2016, the Australian Government amended the *Narcotics Drugs Act 1967* (Cth) (**NDA**) to allow cultivation of cannabis for medicinal or scientific purposes under a national licensing scheme.

Australia has a national classification system, produced by the TGA, that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into schedules dependent on the level of regulatory control and are published in the Standard for the Uniform Scheduling of Medicines and Poisons (**SUSMP**). The SUSMP is referred to as the Poisons Standard and provides a legal framework for the States and Territories to adopt a uniform approach to control the availability, accessibility, and safety of poisons in Australia.

Poisons for therapeutic use (medicines) are mostly included in schedules 2, 3, 4, and 8 of the SUSMP. Schedule 8 substances are highly regulated, on the basis that it is considered that these have high potential for abuse and addiction.

Schedule 9 contains substances, including cannabis, that are prohibited and should only be available for teaching, training, medical or scientific research with the approval of Commonwealth and/or State and Territory health authorities.

On 1 November 2016, the TGA implemented a new Schedule 8 entry for medicinal cannabis products (when extracted from the cannabis plant) and only for human therapeutic use. Approval to prescribe medicinal cannabis to a patient can be sought from an authorised medical practitioner through an application to the TGA under the SAS. In addition to TGA approval, various states and territories impose additional approval steps before allowing a patient to receive medicinal cannabis.

On 30 July 2018, an online system was introduced by the TGA to support SAS application lodgement and notifications. The online SAS system allows prescribers in certain States and Territories to submit an application to both the TGA and the relevant State/Territory Health Department simultaneously.

The current regulation relating to the prescription of Schedule 8 medicinal cannabis substances in Australian states (excluding Tasmania) is summarised below:

State	Process
NSW	Approvals by the NSW Government are only required where a medical practitioner seeks to prescribe a Schedule 8 medicinal cannabis substance to a drug dependent person or child (under 16 years of age) or for use in a clinical trial.
WA	Approvals by the WA Government are required where a medical practitioner seeks to prescribe Schedule 8 medicinal cannabis substances. A medical practitioner may be designated a Cannabis-Based Product Prescriber in which case they may prescribe Schedule 8 medicinal cannabis substances without further approval as long as they notify the WA Government. However, a Cannabis-Based Product Prescriber will still need individual approvals to treat a

	patient under 18 years of age or a patient with a history of certain mental health disorders, drug dependence, or past illicit drug use.
VIC	Medical practitioners require a permit from the Victorian Government for each patient in order to prescribe a Schedule 8 medicinal cannabis substance to that patient.
QLD	Medical practitioners require approval from the Queensland Government to prescribe Schedule 8 medicinal cannabis substances. Registered specialists, such as general practitioners, do not require approval to prescribe Schedule 8 medicinal cannabis substances unless they seek to prescribe to a drug dependent person.
SA	Medical practitioners in South Australia may only prescribe Schedule 8 medicinal cannabis substances without approval if they prescribe to a patient for less than two months or the patient is 70 years or older or the patient is reasonably expected to live for less than 12 months. In all other cases medical practitioners require prior approval from the South Australian Government to prescribe Schedule 8 medicinal cannabis substances.

3.2 Licensing and approvals required for Company's proposed activities

In order to prescribe medicinal cannabis, approvals are required from both the TGA and the relevant State/Territory Health Departments.

The TGA is the Commonwealth authority responsible for ensuring that all therapeutic goods for supply in Australia are safe and fit for their intended purpose. The TGA administers the *Therapeutics Goods Act 1989* (Cth) (the **TG Act**), which establishes the regulatory framework for all medicines in Australia.

The TG Act provides a number of mechanisms to enable access to unapproved therapeutic goods. For medicinal cannabis products these include access via the following pathways:

- (a) **Authorised Prescriber:** a medical practitioner applies to the TGA to become an Authorised Prescriber of a medicinal cannabis product to a particular group of patients for a specific indication. An Authorised Prescriber does not need to notify the TGA when they are prescribing the medicinal cannabis product, however they must report on a six-monthly basis. Medical practitioners seeking to become Authorised Prescribers need to have their application approved by a HREC or endorsed by a specialist college. As at the date of the Prospectus, Emerald has two Authorised Prescribers focussed on treating patients with chronic, non-cancer pain.
- (b) **Special Access Scheme Category B (SAS-B):** SAS-B applications are submitted on a per patient basis and must be submitted by a medical practitioner. The applications need to include the patient diagnosis and clinical justification for the proposed prescription, including commentary regarding the seriousness of the relevant condition, justifying the supply of medicinal cannabis products and the way in which the medical practitioner will monitor the safety and efficacy of that product. The application also must identify the proposed medicinal cannabis product and any safety and efficacy data relevant to the proposed product.
- (c) **Clinical trials:** These applications as per the standard pathway of using therapeutic goods supplied for clinical trials in Australia need to follow the TGA:

- (i) Clinical Trial Notification (**CTN**) scheme; or
- (ii) Clinical Trial Exemption scheme (**CTX**).

Online SAS Application Process to Streamline TGA and State/Territory Approvals

On 13 April 2018, the Council of Australian Governments Health Ministers agreed to work together to streamline access to medicinal cannabis for Australian health practitioners. This announcement stated that prescribers of medicinal cannabis could provide the relevant information, through a single application process to fulfil both Commonwealth and jurisdictional requirements to enable access.

As of 30 July 2018 the online system has commenced by the TGA to enable the lodgement of SAS applications and notifications through the online system. Currently most states and territories (other than Tasmania) can be applied to simultaneously via this online system (Tasmania is to be included in the future). Only the prescribing medical practitioner can submit applications on behalf of the patient, while clinic administrators do not have the ability to submit SAS applications and notification to the TGA, they may have oversight of applications and notifications being made by their affiliated site. The chart below demonstrates the number of TGA approved applications from January 2018.

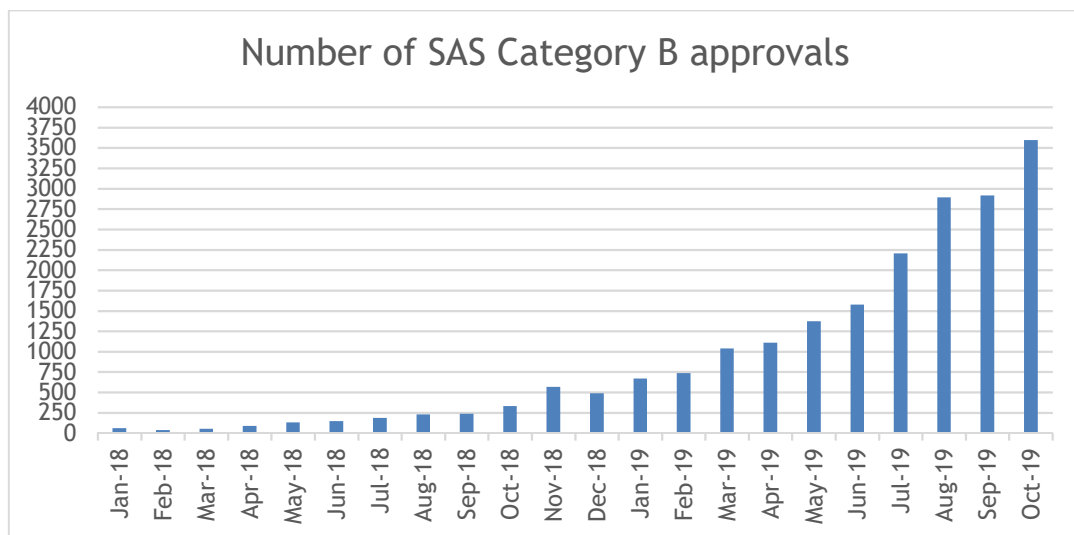


Figure 4. Source: <https://www.tga.gov.au/access-medicinal-cannabis-products-1#consumer>

Note: Approval numbers do not equal the actual number of patients receiving these medicines under the SAS. This is due to the possibility of repeat applications for the same patient.

Medicinal Cannabis Products Quality Standards

All medicinal cannabis products supplied in Australia as a therapeutic good whether imported into or manufactured in Australia must be manufactured in accordance with Good Manufacturing Practice standards. Suppliers of medicinal cannabis products must ensure that their products comply with all applicable quality standards. There are various standards that may apply to medicinal cannabis products, including *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* and *Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018*.

Clinics

Emerald is working towards Royal Australian College of General Practitioners (**RACGP**) accreditation of each Clinic solely operated by Emerald in line with best practice principles for operating medical practices across Australia as suggested by the RACGP. The RACGP encourages all services that provide primary health care to consider its standards as a template for quality improvement and risk management. RACGP accreditation for a clinic is not mandatory.

Clinics can be operating while working towards accreditation, which is completed by an independent third party. The process and requirements are well understood by the Emerald team, specifically the National Clinic Manager who is a registered Accreditation Surveyor with Australian General Practice Accreditation Ltd. No further licenses or government authorisations are required as Emerald will not be importing, manufacturing or dispensing cannabinoids medicines or any other Schedule 8 medications.

3.3 Real World Evidence Industry

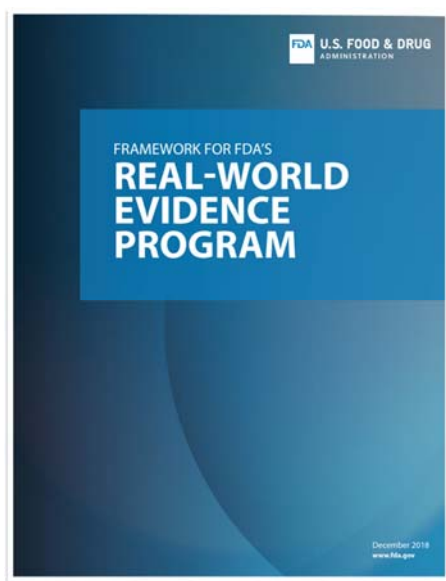
Real World Evidence

The FDA has defined RWE as 'clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.' RWD, according to FDA, consists of information relating to patient health status or the delivery of health care such as EHRs, insurance claims data, product or disease registries, or at-home patient monitoring devices, and can also include data on environmental exposures and socio-economic factors.

RWE studies can be prospective, retrospective or both—that is, they can be either based on pre-existing data, future data, or a combination of both. It is important, though, to note that RWE is subject to the same 'substantial evidence' standards required of randomised control trials (**RCTs**).

In June 2017, the FDA approved the first new indication for a medical device without requiring any substantive data from clinical trials. This approval signalled the beginning of a new era in drug and medical device regulation whereby the FDA based its approval on records of a product's actual patient use rather than on RCTs. The approval was granted using data collected in a product registry that contained 600 records relating to off label use of the product for a new procedure. Based on these records the FDA approved the new procedure and without requiring any further clinical trials, saving time, money and improving patient outcomes. This approval was a milestone in use of RWE.

In December 2018, the FDA issued guidance documents describing a framework for FDA's RWE program.



“As the breadth and reliability of RWE increases, so do the opportunities for FDA to make use of this information.”

Scott Gottlieb, FDA Commissioner
National Academies of Science, Engineering, and Medicine,
 Examining the Impact of RWE on Medical Product Development,
 September 19, 2017

Figure 5 - Framework for FDA's Real World Evidence Program

Since this time, FDA has shown an increasing propensity to consider RWD and RWE in the support of regulatory decisions.

RWE represents an opportunity for potentially faster and less expensive regulatory approvals compared with RCT's (the typical method of achieving an approval). RCT's are acknowledged to have some disadvantages such as participants failing to reflect the general population given strict inclusion exclusion criteria. RCT's also concentrate on the efficacy of a new treatment whereas RWE based approaches can help yield insights into the effectiveness cost of treatment.

In response to this opportunity, the global pharmaceutical sector has increased its investment in RWE with a 2017 survey by Deloitte finding that 54% of responding life sciences companies are investing in projects to significantly increase their RWE capabilities⁴. Survey participants also ranked market access and research and development as the two areas offering the greatest opportunities to secure benefits from RWE.

RWE represents an opportunity for potentially faster, less expensive, and more fit for purpose model for obtaining drug and device regulatory approvals. As regulators continue to develop frameworks for the safe use of cannabinoid-based medicines, (such as the FDA regulating CBD and the associated marketing and claims in the US), the need for companies to demonstrate the safety, efficacy and the pharmacoeconomic benefits of cannabinoid medicines they wish to promote, will increase.

Chronic Pain Market in Australia

A large proportion of patients referred to Emerald Clinics suffer from chronic pain that has not responded to standard treatment or for whom standard treatments are not appropriate.

The prevalence of chronic pain was around 3.2 million Australians in 2007 and is projected to increase to 5.0 million by 2050 as the population ages. Chronic pain is projected to increase in

⁴ <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-ls-2017-real-world-evidence-survey-031617.pdf> The author has not provided their consent for the statement to be included in the Prospectus.

prevalence for men from 13.9% to 15.4% and for women from 16.5% to 18.4% of the population from 2001 to 2050.⁵

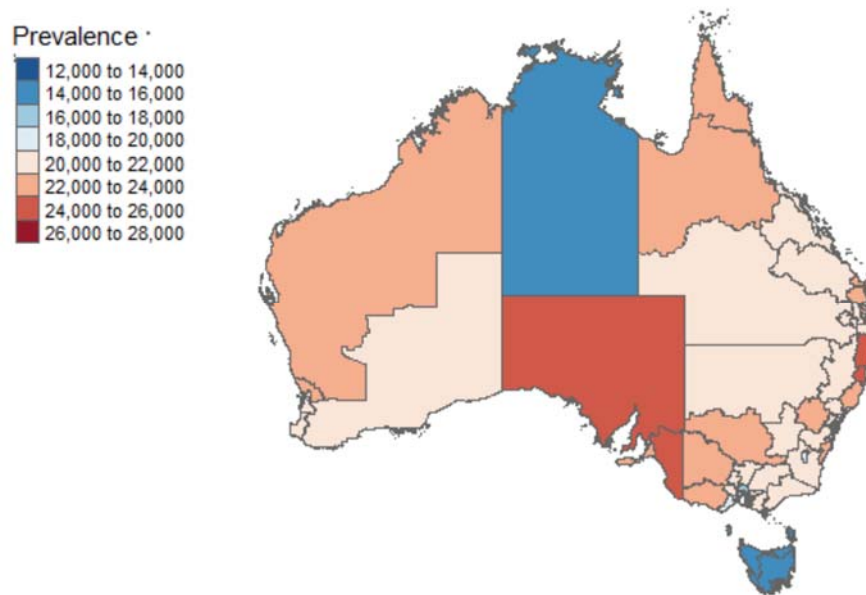


Figure 6 - Prevalence of chronic pain by electorate in 2018

Source: <https://www2.deloitte.com/au/en/pages/economics/articles/cost-pain-australia.html>

There have been a limited number of clinical trials evaluating cannabinoid medicine for the treatment of pain. These clinical trials have shown cannabinoid medicines can help with the intractable chronic pain condition known as 'neuropathic pain'. Neuropathic (nerve) pain has been reported to occur in 8% of the Australian population.⁶ Reports suggest that there is a higher prevalence of neuropathic pain amongst females.

More than 33,000 initial consultations with pain specialists were billed to Medicare in the 12 months prior to July 2018, indicating a significant market of patients seeking relief for unresolved pain⁷. During the period from January 2015 to March 2016, Medicare Australia reported PBS benefits for opioid medicines across Australia exceeded \$368,000,000⁸ across approximately 13,900,000 individual prescriptions indicating a significant requirement and acceptance of pharmacological pain therapies in Australian patient populations.

A recent report commissioned by Pain Australia and published by Deloitte Access Economics⁹ estimated that 3.2 million Australians were living with chronic pain in 2018, with 68.3% of those persons of working age. The report found that for 56% of Australians living with chronic pain, their pain restricts what activities they are able to undertake, reducing their quality of life and productivity. The total cost of chronic pain in Australia in 2018 was estimated to be \$73.2 billion, with the majority of this arising from health system costs and productivity losses. The opportunity

⁵ <http://fpm.anzca.edu.au/documents/thehighpriceofpainfinal-185.pdf> The author has not provided their consent for the statement to be included in the Prospectus.

⁶ <https://www.racgp.org.au/afp/2013/march/neuropathic-pain/> The author has not provided their consent for the statement to be included in the Prospectus.

⁷

http://medicarestatistics.humanservices.gov.au/statistics/do.jsp?_PROGRAM=/statistics/mbs_item_age_gender_report&VAR=services&STAT=count&PTYPE=finyear&START_DT=201707&END_DT=201806&RPT_FMT=by+state&GROUP=2801 The author has not provided their consent for the statement to be included in the Prospectus.

⁸ http://medicarestatistics.humanservices.gov.au/statistics/do.jsp?_PROGRAM=/statistics/mcl_pbs_item_report&WHE RE=999&SCHEME=PBS&RPT_FMT=without%20time%20period&PTYPE=quarter&START_DT=201501&END_DT=201603&DRILL=on&GROUP=N02A The author has not provided their consent for the statement to be included in the Prospectus.

⁹ <https://www.painaustralia.org.au/static/uploads/files/the-cost-of-pain-in-australia-final-report-12mar-wfxbrfyboams.pdf>

for new interventions, including cannabinoid-based medicines to improve the lives of chronic pain sufferers is significant and a focus for Emerald.

Medicinal Cannabis Market

Medicinal cannabis received legislative approval in Australia in November 2016 and legal importation for medicinal commenced in 2017. Accordingly, the Australian market is still in its infancy.

The TGA has developed a series of guidance documents based on reviews of published clinical studies to assist health professionals prescribe cannabis for medical conditions with varying levels of evidence. The conditions reviewed include epilepsy, multiple sclerosis, nausea and vomiting, palliative care and chronic non-cancer pain (see <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>).

Reviews of Clinical Evidence: Medicinal Cannabis for Chronic Pain

The TGA guidance document for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia summarised the meta-analysis conducted of all randomised studies in chronic non-cancer across all medicinal products. Overall this review indicated that medicinal cannabis was more likely than placebo to produce 30% and 50% reductions in pain scores. Furthermore, the review summarised that patients who used medicinal cannabis for (non-multiple sclerosis) neuropathic pain were more likely to experience a 50% reduction in pain and a reduction in pain scores compared with patients taking a placebo).¹⁰ However, the meta-analysis also found that those treated with cannabinoids were more likely to experience adverse events, including dizziness or vertigo, depressed mood, cognitive or attention disturbance, thought disturbance, nausea, and drowsiness.

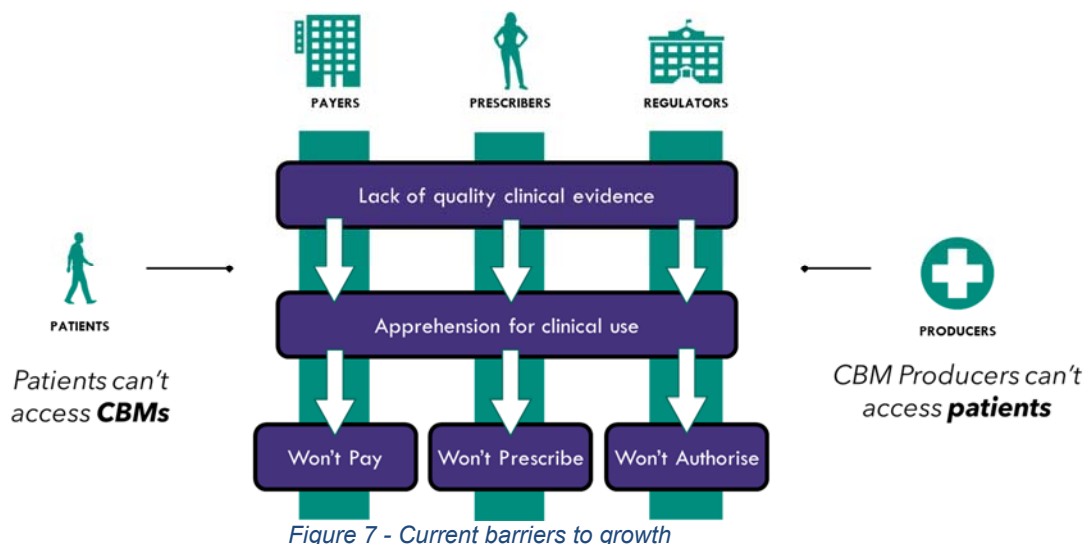
Australian Cannabinoid Medicine Suppliers

To enable Emerald's clinicians to make informed decision regarding the prescription of appropriate therapies for patients, Emerald evaluates locally available cannabinoid medicine product quality and supply reliability. As part of Emerald's internal quality assurance oversight, Emerald requests certificates of analysis for each batch of product available for prescription to Emerald patients. Emerald liaises with Producers regarding adverse events.

Efficacy Driven Market Growth

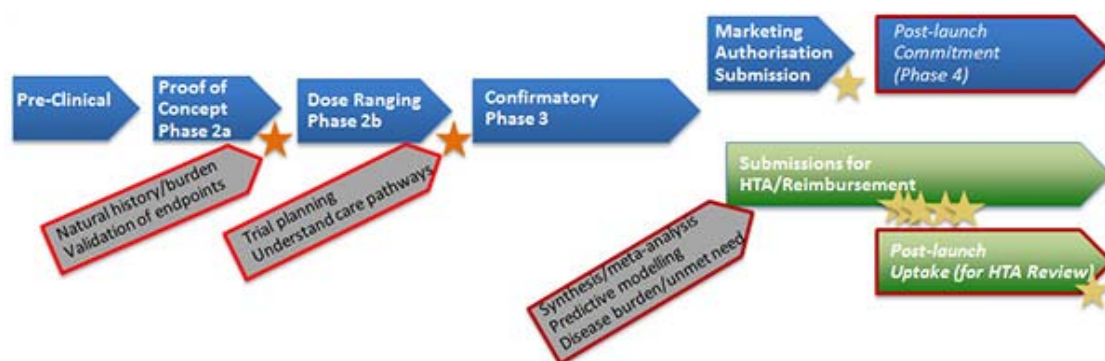
As the global market for cannabinoid-based medicines has expanded, large licensed Producers have adopted different strategies for market access across jurisdictions. Globally, growth has been hampered by a lack of quality evidence for the use of cannabis-based medicines resulting in regulators not authorising use beyond special-access pathways. Payers are regularly not reimbursing for the costs of cannabis-based treatments and clinicians limiting prescriptions.

¹⁰ <https://www.tga.gov.au/node/769205> The author has not provided their consent for the statement to be included in the Prospectus.

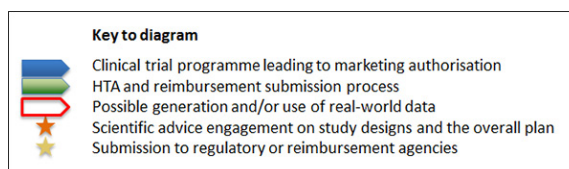


To overcome these barriers, companies are undertaking differing evidence generation strategies. Some companies are pursuing a traditional pharma pathway of RCTs to enable a market authorisation and reimbursement, others are relying on direct marketing to drive sales while others are developing innovative clinical evidence programs combining RWE and traditional clinical trial approaches that leverage the unique regulatory environment for medicinal cannabis products.

An illustrative example of the traditional RCT based model is set out below:



Source: <https://rwe-navigator.eu/background-supporting-material/evidence-development-pathways/>



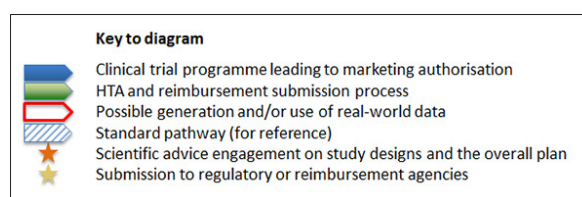
Direct patient marketing of unapproved therapeutic goods is not supported in Australia.

Some companies are pursuing a strategy that leverages the unique regulatory environment for cannabinoid medicines where they can be prescribed through specific access pathways (such as SAS-B in Australia) while also executing on a clinical program to execute an adaptive evidence strategy. These companies are seeking to accelerate the time to a market authorisation that comes with the benefits being captured by Figure 8, while also generating revenues and RWE from use through the available access pathways. An illustrative example of an adaptive evidence development pathway is provided below. Key to the success of this model is high quality RWE.



Figure 9 - Adaptive evidence development pathway example.

Source: <https://rwe-navigator.eu/background-supporting-material/evidence-development-pathways/>



The FDA is working to answer questions about the science, safety, and quality of products containing cannabis and cannabis-derived compounds, particularly CBD and has released consumer guidance updates.¹¹ In the UK, the NHS England and NHS Improvement released recommendations regarding the barriers to accessing CBPMs on NHS prescription. These recommendations accompanied draft guidance from the National Institute for Health and Care Excellence that found there was insufficient evidence to recommend the use of CBPMs for a number of conditions in the UK at the current price point. The NICE guidance recommended a number of evidence generating activities be undertaken. This shifting regulatory environment represents an opportunity to use RWE to support regulators, Payers and patients to safely and efficaciously use cannabis based medicines.

3.4 Competitors and other industry participants

Emerald operates in a market with other companies including those summarised below.

Company	Summary	Jurisdiction
CB2 Insights	Operates medical cannabis evaluation services, provides an EHR system and offers contract research services.	USA/Canada/UK
Southern Cannabis Holdings	Builds, integrates and operates brands across the cannabis value chain. SCH operates Cannabis Access Clinics, Freshleaf Analytics and Applied Cannabis Research. Cannabis Access Clinics are focussed on helping doctors and patients navigate the regulatory	Australia/UK/New Zealand

¹¹<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>; <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>. The author has not provided their consent for the statement to be included in the Prospectus.

	pathway for prescribing medicinal cannabis products in Australia and New Zealand. Freshleaf Analytics provides industry insights. Applied Cannabis Research offers contract research services.	
CDA Health	Operates Cannabis Doctors Australia, Burleigh Heads Cannabis, Healthy not high and Cannabis Doctors Aotearoa. Cannabis Doctors Australia is a provider of Patient Access to medicinal Cannabis. Burleigh Head Cannabis is a licensed importer, wholesaler and distributor of medicinal cannabis.	Australia/New Zealand
National Cannabinoid Clinics	Operates a clinic in NSW.	Australia
Cannvalate	Provides services to patients and doctors and operate a B2B model for pharmacy and licensed Producers. It provides contract research services, import and distribution services, licensing and market access services for Producers.	Australia

As the market for RWE increases, additional competitors may enter the market.

Emerald seeks to distinguish its products and services from its competitors by:

- (a) having in place strict product quality control, deep clinical assessment and EDC, with the aim of increasing the quality and value of the RWD collected; and
- (b) Emerald's Care Model and Data Platform, which supports long term patient engagement and the development of high quality evidence.

3.5 What this means for Emerald

Emerald aims to successfully commercialise the Data Platform and further develop its clinical network to support the development of its data assets. The achievement of this aim is subject to a number of risks as summarised in Section 4. This Section 3 does not represent any forecast or projection as to future revenue or profitability of the Company or penetration into markets. The Company provides this Section 3 as an overview of the medicinal cannabis industry in Australia, its use in the treatment of indications such as chronic pain, and the market demand for RWD and RWE generated by medicinal cannabis clinics.

4. Risk Factors

As with any investment, there are risks involved. This Section identifies the major areas of risk associated with an investment in the Company but should not be taken as an exhaustive list of the potential risk factors to which the Company and its Shareholders are exposed. Potential investors should read the entire Prospectus and consult their professional advisers before deciding whether to apply for Shares.

Any investment in the Company under this Prospectus should be considered highly speculative.

4.1 Risks specific to the Company

(a) Business strategy execution

The ability of the Company to achieve growth of its business is dependent on the successful implementation of the Company's growth strategies, business plans and strategic initiatives outlined in this Prospectus, which includes but is not limited to the attraction and retention of patients at the Clinics. There can be no assurance that the Company will be successful in implementing these plans. If the Company is unable to implement its business strategy, there may be adverse effects on its results of operations or financial condition.

(b) Limited operating history and future capital needs

Investors should be aware that the Company has a limited operating history and is currently making a loss, meaning it is reliant on raising funds from investors to continue to fund its operations and development of its Data Platform.

The future capital requirements of the Company will depend on many factors, including the pace and magnitude of its development of its business. The Company believes that its available cash and the net proceeds of the Public Offer will be adequate to satisfy its anticipated current working capital and other capital requirements. Should the Company require additional funding, there can be no assurance that additional financing will be available on acceptable terms or at all. Any inability to obtain additional financing, if required, would have a material adverse effect on the Company's business, financial condition and results of operations.

(c) Obtaining and retaining licences, permits and approvals

The Company's business model is reliant on obtaining and retaining any necessary registrations, approvals and accreditations as outlined in the Legal Opinion on Emerald's business operations in Annexure B of this Prospectus. As at the date of this Prospectus, the Company and its practitioners have the required licences, permits and approvals required in order to operate the Clinics.

Where required, the Company will apply for any necessary additional registrations, approvals and accreditations, and undertake the necessary requirements for approval, however, there is no assurance that any such registrations, approvals and accreditations will be granted to the Company, or on terms anticipated by the Company. A failure to obtain any such registrations, approvals and accreditations will result in the Company being unable to continue to establish and/or further its business operations.

The Company will comply with any approvals or conditions attaching to the relevant registrations, approvals and accreditations, and undertake continued maintenance of

such registrations, approvals and accreditations. However, there is no guarantee that any registrations, approvals and accreditations granted by regulatory bodies will not be revoked during their term, or that they will be renewed for a further period of time or renewed on terms anticipated by the Company. Should any of these circumstances eventuate, it is likely to have a material adverse effect on the Company's proposed activities and operations, as well as its financial performance and prospects.

(d) Liquidity

At Admission, the Company will have 183,902,778 Shares on issue (on a Minimum Subscription basis). The Company expects approximately 99,999,700 Shares to be subject to 24 months escrow in accordance with Chapter 9 of the Listing Rules, which would be equal to approximately 54.4% of the Company's issued capital at Minimum Subscription. This creates a liquidity risk as a large portion of issued capital may not be able to be freely tradable for a period of time. The ability of an investor in the Company to sell their Shares on the ASX will depend on the turnover or liquidity of the Shares at the time of sale. Therefore, investors may not be able to sell their Shares at the time, in the volumes or at the price they desire.

(e) Establishment and implementation of new legislative regime

The Company operates (and intends to operate) in an industry which has recently experienced key regulatory and legislative changes. The legislative amendments to key Australian legislation only came into effect fairly recently (for example, the legislative amendments to the NDA only came into effect in Australia in October 2016).

The Office of Drug Control and TGA has published regulations and a series of guidelines which explain how the reforms are to operate. Although this guidance is quite prescriptive, as with any new legislative regime, there remains some uncertainty as to the interpretation of the new laws and regulations and the review methodology that the regulatory bodies will adopt.

(f) Change to laws or regulations

The operations and proposed operations of the Company are subject to a variety of laws, regulations and guidelines. The medicinal cannabis industries are evolving globally, including in Australia. It is likely that governments worldwide, including Australia, will continue to explore the benefits, risks and operations of companies involved in the medicinal cannabis sector. In particular, the regulation of medicinal cannabis is a partisan and divisive issue and, as a result, a change in government or increase in political lobbying may result in a change in government policy and an amendment of legislation and/or regulation. The introduction of new legislation or amendments to existing legislation by governments, or the respective interpretation of the legal requirements in any of the legal jurisdictions which govern the operations or contractual obligations of the Company, could impact adversely on the assets, operations and financial performance of the Company and the medicinal cannabis industry in general.

In particular, the laws, regulations and guidelines in Australia in relation to medicinal cannabis are reasonably new, with the Federal government's legislative changes having come into full effect in late 2016 and the States and Territories having passed related legislation. Amendments to relevant laws, regulations and guidelines may be made as the regulatory processes are reviewed.

The Company's prospects are also dependent on how Australian Federal and State government policies evolve over time, and on legislative changes in other countries, for access to medicinal cannabis products.

(g) Prescription of Cannabis

The Company's practitioners prescribe medicinal cannabis products to patients. Whilst medicinal cannabis is legal for therapeutic use in Australia under the TG Act, there is still a scarcity of high quality level 1 evidence related to the use of medicinal cannabis. Whilst this provides a value proposition to the Company's Data Platform, it also may present a risk for prescribing doctors.

(h) Sourcing data from third parties

The Company is dependent on its ability to source data from patients, and patients could take steps to block its access to data, which could impair the Company's ability to provide its data collection service or limit the effectiveness its data collection. As part of the Company's informed consent process, the Company provides patients with the ability to elect that the Company does not collect information relating to their care beyond the minimum requirement for safe medical record keeping.

(i) Risk associated with clinical trials

Scientifically robust clinical trials have long lead-in times, can be expensive to conduct, and are, by definition of their purpose, uncertain as to outcome. Prior to conduct of clinical trials involving cannabis extracts/derivatives, a number of approvals, licences and/or permits are required. Delays in obtaining all necessary authorisations can impact upon downstream activities, including the potential introduction of scheduling issues.

Prior to commencing a prospective clinical trial, a sponsor must submit to the HREC a study protocol, an investigator's brochure and a template informed consent for the clinical trial. Once a study is approved by the HREC, the sponsor is required to complete an online CTN form on the TGA Businesses Services website, which notifies the TGA that the HREC has evaluated and approved the scientific merit of the trial and approved it on ethical grounds. Once the notification is acknowledged (and a unique clinical trial number issued), the trial may commence.

After commencement, clinical trials are also subject to suspension, delay or termination by regulatory bodies due to revocation of licences/permits to conduct research on unregistered medicinal products, and/ or importation or sourcing of trial material, and/or handling of material classified as poisons. Issues that may impact upon the aforementioned include:

- (i) participant recruitment not meeting trial timelines;
- (ii) lower than expected rates of compliance with the trial protocol by the participants;
- (iii) low rate of participant retention for the duration of the trial;
- (iv) lack of availability of the trial product for the duration of the trial due to manufacturing constraints, or regulatory constraints (including importation);
- (v) unfavourable results from third party pre-clinical or clinical studies which regulatory or ethical bodies believe are relevant; and

- (vi) failure of any key trial partners (e.g. contract research organisation) to provide their services in a quality and timely manner.

In addition to the above, all clinical trials are monitored and may be suspended or terminated by the ethical review board of the clinical institution due to matters outlined above as well as:

- (i) lack of efficacy of the trial product;
- (ii) number or severity of serious adverse events or unexpected side effects;
- (iii) non-compliance by the company, the contract research organisation, the clinician or any other partner organisation in the trial, with the agreed protocol and/or all applicable regulatory requirements;
- (iv) mishandling of clinical trial product, including labelling, storage, security and inventory;
- (v) mishandling of trial data, including security of participant information;
- (vi) mishandling of trial records; and
- (vii) complaints received by participants.

Any of the issues raised above has the potential to have an adverse and material effect on the business.

(j) Competition

The industry in which the Company is involved is subject to domestic and international competition. While the Company will undertake all reasonable due diligence in its business decisions and operations, it will have no influence or control over the activities or actions of its competitors, which activities or actions may, positively or negatively, affect the operating and financial performance of the Company.

There may be new entrants and players in the medicinal cannabis sector, evidence generation sector and health care sector generally, including other clinics. Some of these parties may have greater financial, technological, managerial and research and development resources and experience than the Company, which may lead to reduced margins and loss of revenue or loss of market share. Further, revenues in the future may be reduced as the industry consolidates and seeks revenue accretion at the expense of profit margin. If the Company is unable to compete successfully, it may be unable to generate, grow and sustain its revenues and earnings.

(k) Strategic relationships

The medicinal cannabis industry is undergoing rapid growth and change, which has resulted in increasing consolidation and formation of strategic relationships. It is expected that this consolidation and strategic partnering will continue as the industries continue to grow. Acquisitions or other consolidating transactions could harm the Company in a number of ways.

The Company may lose strategic relationships if third parties with whom the Company has arrangements are acquired by or enter into relationships with a competitor (which could cause the company to lose access to necessary resources). The Company's current competitors could become stronger, or new competitors could form from

consolidations. This could cause the Company to lose access to markets or expend greater resources in order to stay competitive.

Separately, the relationship between the Company and third parties may deteriorate organically, which may have an adverse impact on the Company's business.

(l) Growth prospects and expansion plans

The Company's growth prospects are dependent upon a number of factors, including service and product offering take up. If the Company fails to execute any expansion plan, its financial performance is likely to be negatively affected.

The Company's financial prospects are particularly dependant on there being sufficient demand for evidence generating care and medicinal cannabis products in Australia. There is a risk that the availability of specialist cannabinoid clinical services available in Australia will outstrip the demand for those services, which may result in lower service prices. This would have an adverse effect on the financial performance of the Company.

The Company's ability to achieve its growth strategy is also dependent on the Company being able to commercialise the data and evidence it generates related to the use of, among other therapies, medicinal cannabis. The availability of data and evidence may outstrip the demand, which may result in lower prices.

In order to expand to international markets, changes in the laws and regulations relating to medicinal cannabis may need to be passed and those laws would need to allow for the operation of the type of clinics operated by the Company. There are no guarantees that the laws and regulations of any of the target markets will be amended or that the Company will be able to access such markets.

(m) Brand establishment and maintenance

The Company believes that establishing and maintaining the Company's brand in the industry in which it operates is critical to growing its customer base and product and service acceptance. This will depend largely on the Company's ability to provide innovative and in-demand products and services. If the Company fails to successfully establish and maintain its brand, its business and operating results could be adversely affected.

(n) Patient engagement

The Company relies on patients presenting to our clinics to sustain clinic revenue and, in part, to increase the volume of data in its RWE Data Platform. In addition, prior to seeing any patient, Emerald's preference is to require a referral from that patient's treating doctor.

Several factors may impact Emerald's ability to engage patients, such as:

- (i) failure to attract sufficient referrals from other clinicians;
- (ii) the approval of more effective and or cheaper treatment alternatives;
- (iii) patient participation in clinical trials;
- (iv) the set-up of competitor clinics;
- (v) failure to expand its clinical network;

- (vi) failure to attract, train and retain suitably qualified medical practitioners; and
- (vii) changes to laws or regulations that substantially change the availability of unregistered medicines.

(o) Protection of Intellectual Property

The Company's success will depend on, in part, its ability to protect its intellectual property, including its trade marks, copyright, trade secrets and know-how. To the extent the Company fails to protect its intellectual property or infringes a third party's intellectual property, the Company may face increased competition from similar products, have to cease using certain intellectual property or be liable for damages. In the event that this occurs, there is a risk that it has a materially adverse impact on the Company.

(p) Business management risk

The Company has established a network of medical clinics that provide high quality care using medical grade cannabis as a treatment option and plans to expand this network. There is a risk that expanding the network of clinics may take longer than anticipated, which could adversely impact the profitability of the Company. Additionally:

- (i) the Company has limited operating history under the current business model;
- (ii) the Clinics may be operating on systems that are not integrated, which may adversely impact on the ability of the Company to obtain essential information required for the management of the Company;
- (iii) the performance of the Clinics may be adversely affected by changes such as increased overheads, reduced revenues or management changes; and
- (iv) the profitability of the clinics cannot be guaranteed and there is no guarantee that relationships with suppliers or potential clients will eventuate.

(q) Uncertainty of future revenue and profitability

Future revenues from the provision of care and commercialisation of data and evidence by the Company and the Company's future profitability are contingent on, amongst other things, the Company's ability to obtain and maintain the required registrations and approvals, entry into local and international markets, ability to attract and retain high quality clinicians, being able to maintain favourable prices for products and services being offered, demand for services and products being sold, general economic conditions, the results of further medical research and clinical trials in relation to medicinal cannabis.

Consequently, the level of any future sales of medicinal cannabis by the Company cannot be accurately determined and the Company cannot provide any guarantee that future sales will be achieved. Even if future sales are achieved, they may not result in the Company being profitable.

(r) Early stage risk

Investing in an early stage enterprise, such as the Company, should be considered highly speculative and involves several significant risks including under capitalisation and obstacles or delays in the implementation of the business plan or revenue generation coupled with existing and future legislative and regulatory risks.

The Company cannot be sure that any of its research and development activities will be successful, that its internal development milestones will be achieved, or that products will be developed that are commercially exploitable.

There are many risks inherent in the development of biotechnology and data products particularly where the products are in very early stages of development. Projects can be delayed or fail to demonstrate any benefit, or research may cease to be viable for a range of scientific and commercial reasons.

(s) Healthcare insurers and reimbursement risks

In both domestic and foreign markets, sales of prescription pharmaceutical products and provision of specialist care are likely to depend in part; upon the availability and amounts of reimbursement from third party health care 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 pressure to reduce the cost of therapeutic products, 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 therapeutic products and service provision. No assurance can be given that reimbursement will be provided by such payers at all or without substantial delay, or, if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable Emerald to provide services on a profitable basis or enable patients to use the unregistered medical cannabis products the Company's practitioners prescribe.

(t) Reliance on key personnel, clinicians and management

The Company is highly dependent on its management and key personnel including experienced clinicians, who are responsible for its day-to-day operations and strategic management. If one or more of these personnel cease his/her involvement with the Company, it could have a materially detrimental impact on its future financial performance.

The ability to attract and retain highly qualified staff is crucial to the future success of the Company. There can be no assurance that the Company will be able to so attract and retain such staff.

(u) Fit and proper persons

The Company's success will depend on, in part, an ability for the Company to continue to support the appropriate use of therapies for patients, including the use of unregistered medicines through the SAS-B and Authorised Prescriber pathways administered by the TGA. The TGA at its absolute discretion may withhold or deny approval sought by a clinician.

In assessing applications for the APS an ethics committee, or federal and state regulators may withhold or deny an application at their absolute discretion.

The Company also relies on its clinicians to provide high quality care, in line with the Australian Health Practitioner Regulation Agency registration requirements, as well as any codes, standards or guidelines published by the Medical Board of Australia or relevant Specialist Colleges (such as RACGP) to maintain registration. Failure to maintain registration would preclude a clinician from practicing at Emerald.

Should any of these circumstances eventuate, it is likely to have a material adverse effect on the Company's proposed activities and operations, as well as its financial performance and prospects.

(v) Data Collection Risk

It is likely that the Company will continue to collect, store and process highly sensitive, highly regulated and confidential information. The provision of secure and reliable information storage and processing services is integral to the businesses and operations of the Company. The Company has developed policies in relation to collecting sensitive and personal data. However, even with such policies in place, if the Company's systems or data is compromised for any reason there is a risk that the Company may become involved in legal action due to breaching data confidentiality agreements.

The collection, use, storage and disclosure of personal and sensitive information within the data and analytics industry in Australia is governed by the *Privacy Act 1988* (Cth) (**Privacy Act**) and the Australian Privacy Principles contained at Schedule 1 of the Privacy Act (**Australian Privacy Principles**). Various changes to the regulatory framework have been introduced in recent years, including as a result of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* (Cth), key provisions of which came into effect in March 2014. Any future adverse changes in privacy legislation (including changes to the Privacy Act and the Australian Privacy Principles), or changes in the way privacy laws are interpreted in the future could render any of the Company's services and products (or the ways in which such services and products are currently implemented or delivered) less attractive or contrary to law, which could have a material adverse effect on its business, operations and financial performance, and the price of the Shares. If the Company operates in jurisdictions outside of Australia, it will need to develop appropriate policies, guidelines and systems to comply with local legislation, guidelines and best practice.

If the Company's security measures are breached or unauthorised access to customer data is otherwise obtained, the Company may be perceived as not being secure, customers may reduce the use of or stop using the Company, and it may incur significant liabilities.

(w) Contractual disputes

As with any contract, there is a risk that the business could be disrupted in situations where there is a disagreement or dispute in relation to a term of the contract. Should such a disagreement or dispute occur, this may have an adverse impact on the Company's operations and performance generally. It is not possible for the Company to predict or protect itself against all such risks.

(x) Commercial agreements risk

Some of the Company's key commercial agreements are indicative only, are not binding on the parties and require a formal agreement to be negotiated and signed in order to bind the parties (for example, see Section 7.4 and 7.5).

There is a significant risk that formal agreements may not be agreed and signed by the Company in respect of these arrangements. If the Company is unable to sign binding agreements with its anticipated operators, customers or suppliers, the Company would not be able to derive any financial or other benefit from any of those relationships and the relevant commercial agreements disclosed to the market would be of no effect.

(y) Legal Proceedings

Legal proceedings may arise from time to time in the course of the business of the Company. As at the date of this Prospectus, there are no material legal proceedings affecting the Company and the Directors are not aware of any legal proceedings pending or threatened against or affecting the Company.

4.2 General Risks

(a) General economic climate

Factors such as inflation, currency fluctuations, interest rates, legislative changes, political decisions and industrial disruption have an impact on operating costs. The Company's future income, asset values and share price can be affected by these factors and, in particular, by exchange rate movements.

(b) Policies and legislation

Any material adverse changes in government policies or legislation of Australia, or any other country that the Company has economic interests in, may affect the viability and profitability of the Company.

The Federal and State Governments have only recently legalised the use of medicinal cannabis by Australian patients and legislation is still evolving. Unexpected changes to the regulatory environment may delay medicine importation, doctor registration and/or other factors that may have a material effect on the Company's business.

(c) Enforcement of contracts in foreign jurisdictions

From time to time, as part of its business, the Company may enter into contracts which are governed by the laws of countries other than Australia.

Should a contractual dispute result in court action or should the Company be required to enforce its rights, the procedure of the courts in the various foreign jurisdictions may be different to those in Australia.

(d) Negative publicity may adversely affect the Share price

Any negative publicity or announcement relating to any of the Company's substantial Shareholders, key personnel or activities may adversely affect the stock performance of the Company, whether or not this is justifiable. Examples of such negative publicity or announcements may include involvement in legal or insolvency proceedings, failed attempts in takeovers, joint ventures or other business transactions.

(e) Stock market conditions

As with all stock market investments, there are risks associated with an investment in the Company. Share prices may rise or fall and the price of Shares might trade below or above the Offer Price. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company. Further, the stock market is prone to price and volume fluctuations. There can be no guarantee that trading prices will be sustained. These factors may materially affect the market price of the Shares, regardless of Company's operational performance.

General factors that may affect the market price of Shares include without limitation; economic conditions in Australia and internationally, investor sentiment, local and international share market conditions, changes in interest rates and the rate of inflation, variations in commodity prices, the global security situation and the possibility of terrorist disturbances, changes to government regulation, policy or legislation, changes which may occur to the taxation of companies as a result of changes in Australian and foreign taxation laws, changes to the system of dividend imputation in Australia, and changes in exchange rates.

(f) Foreign Currency and exchange rate risks

The Company conducts business in other jurisdictions and is therefore exposed to the effects of changes in currency exchange rates. Unhedged, unfavourable movements in foreign exchange rates may have an adverse effect of the Company's revenue and/or cost of operating and therefore affect the market price of the Shares. The most common currencies to be used are Australian dollars.

(g) Speculative investment

The above list of risk factors ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of the Company and the value of the Shares offered under this Prospectus.

Therefore, the Shares 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 Shares.

Potential investors should consider that the investment in the Company is highly speculative and should consult their professional advisers before deciding whether to apply for Shares pursuant to the Public Offer.

5. Board, Management and Corporate Governance

5.1 Board of Directors

As at the date of this Prospectus, the Board comprises of:

- (a) Dr Stewart Washer – Executive Chairman;
- (b) Dr Michael Winlo – Managing Director
- (c) Mr Matthew Callahan – Non-Executive Director; and
- (d) Dr Alistair Vickery – Executive Director.

Sir John Tooke has also agreed to join the Board as a Non-Executive Director upon Admission.

5.2 Directors' and Officers' Profiles

The names and details of the Directors in office at the date of this Prospectus are:

(a) Dr Stewart Washer – Executive Chairman

Stewart has 25 years of CEO and Board experience in medical and agrifood biotech companies. He is currently the Executive Chairman of Emerald Clinics Ltd, Chairman of Orthocell Ltd (ASX:OCC), a regenerative medicine company and Director of Cynata Therapeutics Ltd (ASX:CYP) stem cell therapies.

Stewart has held a number of Board positions in the past, including Chairman of Hatchtech Pty Ltd that was sold in 2015 for A\$279m and was a Director of iCeutica that was sold to a US Pharma. He was also a Senator with Murdoch University and was a Director of AusBiotech Ltd. Stewart was previously Chairman of Minomic International Ltd cancer diagnosis and treatment and Director of Zelira Therapeutics Ltd (ASX:ZLD) medical cannabis clinical studies and research.

Stewart resigned from the board of Zelira Therapeutics Ltd on 2 December 2019.

(b) Dr Michael Winlo – Managing Director

Michael has a Bachelor of Medicine and Bachelor of Surgery with Honours from the University of Western Australia as well as a Master of Business Administration from Stanford University. Prior to Emerald, Michael was CEO at Linear Clinical Research Ltd (**Linear**) until October 2019 – a registered not-for-profit company providing clinical trial services for US- and Asia-based biotech companies. Linear was the first site in Australia and one of only a few in the world to successfully adopt electronic data capture technology. Under Michael's leadership, Linear's revenues grew over 300% in just over

three years (to over \$23 million per year). Prior to Linear, Michael was Health Lead at Palantir Technologies – a Big Data company based in Silicon Valley California.

Michael is a non-executive director of Linear.

(c) Dr Alistair Vickery - Executive Director

Alistair is a specialist general practitioner with over 30 years' experience in general practice. He is a Clinical Professor of Primary Health Care at the University of Western Australia and the clinical lead of the research group CHASM (The Collaborative for Health Care Analysis and Statistical Modelling) - providing high-level analysis and statistical modelling to inform clinical service planning and service evaluation. Alistair is Chair of Black Swan Health, one of the largest primary health care service providers in Western Australia and he is a Fellow of the Australasian College of Health Service Management and an AICD graduate. Previously, Alistair was the Deputy Chair of the Postgraduate Medical Council of WA.

(d) Mr Matthew Callahan - Non-Executive Director

Matthew is an experienced life sciences executive based in Philadelphia. He is the founding CEO of iCeutica Inc. and a co-inventor of some of the technologies that comprise the SoluMatrix Fine Particle Technology drug delivery platform that iCeutica uses to develop new pharmaceuticals. iCeutica has developed 3 products to date that have received FDA approval. He has more than 20 years' legal, intellectual property and investment management experience and is also a director of Orthocell Limited (ASX:OCC) and Botanix Pharmaceuticals Limited (ASX:BOT).

Matthew worked as an investment director for 2 venture capital firms in life sciences and was general manager and general counsel with technology and licensing company Ipernica Limited, now Nearmap Limited (ASX:NEA), where he was responsible for licensing programs that generated more than \$120,000,000 in revenue.

(e) Sir John Tooke - Proposed Non-Executive Director

Sir John is a non-executive director at BUPA Chile and was recently a non-executive director of the BUPA main Board and the Chair of the Medical Advisory Council. He is the Chair of Collaboration for the Advancement of Sustainable Medical Innovation (CASMI) UCL and Chaired the Oversight Group for the Academy of Medical Sciences project 'How we best use scientific evidence to judge the benefits and harms of medicines'. He also served as an Independent review Board Member for Google DeepMind Health (UK). Sir John was Head of the School of Life and Medical Sciences at University College London (UCL) as Vice Provost (Health) and Academic Director of UCL Partners. He is the Immediate Past President of the Academy of Medical Sciences in the UK.

Sir John is a clinician scientist with 30 years' experience as a consultant physician specialising in diabetes, endocrinology, vascular medicine and internal medicine with broad research experience (basic biomedical, experimental medicine, and applied health research including improvement science) recognised through Fellowship of the Academy of Medical Sciences. He held a Board position at the Francis Crick Institute (2011 -2015) and was a Member of the Council for Science & Technology (2011-2015) reporting to the Prime Minister (UK). It is proposed that Sir John will join the Board upon Emerald's Admission.

5.3 Key Management Personnel

Other than the Directors, the Company's Key Management Personnel are as follows:

(a) Mr Adam James – COO

Adam has over 10 years' experience across health systems reform, public and private health service administration and research commercialisation. Adam has led private and public clinical services focused on sleep medicine in Australia and is a Fellow of the Collaboration for the Advancement of Sustainable Medical Innovation (CASMI) UCL.

Prior to Emerald Clinics, Adam supported research institutions, clinician researchers and corporates to commercialise novel life science technologies. Adam holds a degree in Neuroscience (Pharmacology), an MBA and is a WA committee member for Ausbiotech; the representative body for the life sciences sector in Australia.

(b) Su-Mei Sain – Chief Financial Officer

Su-Mei is a member of Certified Practicing Accountants Australia since 2008 with eighteen years' experience in public practice and company accounting. Her finance knowledge and skills are predominantly within the mining resources sector with such companies as Apex Minerals NL, Consolidated Minerals Limited, Sirius Resources NL and recently Chief Financial Officer at S2 Resources Ltd. She is currently Chief Financial Officer of Todd River Resources Ltd.

(c) Dr Patrizia Washer – Research Director

Dr Washer holds a doctorate in microbiology from The University of Western Australia with postdoctoral experience in cancer research. She has over ten years' experience in business development managing the commercialisation of technologies from early stage research and development through to clinical development within the university and medical technology sector. Patrizia has previously worked as a clinical trial consultant for a medical device company, a medical cannabis research and development company and has been a board member of two medical start-up companies. Patrizia is the wife of Dr Stewart Washer and was previously a director of the Company, resigning on 28 October 2019.

(d) Mr Simon Robertson – Company Secretary

Simon gained a Bachelor of Business from Curtin University in Western Australia and a Master of Applied Finance from Macquarie University in New South Wales. He is a member of the Institute of Chartered Accountants and Chartered Secretaries Australia. Simon currently holds the position of company secretary for a number of publicly listed companies and has experience in corporate finance, accounting and administration, capital raising and ASX compliance and regulatory requirements.

5.4 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 date of this Prospectus, any interests in:

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

(c) the Offers, and

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:

(d) any Director to induce him or her to become, or to qualify as, a Director; or

(e) any Director of the Company for services which he or she (or an entity in which they are 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 and as follows.

5.5 Security holdings of Directors

The Directors and their related entities have the following interests in Securities as at the date of this Prospectus:

Director	Shares	% ¹	Options ²	% ¹
Dr Stewart Washer ³	48,000,000	36.0	1,500,000	8.2
Dr Michael Winlo ⁴	Nil	Nil	3,500,000	19.1
Dr Alistair Vickery	Nil	Nil	2,000,000	10.9
Matthew Callahan ⁵	19,600,000	14.7	Nil	Nil
Sir John Tooke ⁶	Nil	Nil	500,000	2.7

Notes:

1. Based on a total of 133,277,778 Shares and 18,350,000 Options being on issue at the date of this Prospectus.
2. Options are exercisable at \$0.45 each on or before 13 June 2023 issued on the terms and conditions set out in Section 8.3.
3. Dr Stewart Washer holds 28,400,000 Shares and 1,500,000 Options jointly with associate Dr Patrizia Washer as trustees for the Washer Family Account and 19,600,000 Shares are held by Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director).
4. Dr Winlo holds his interest in the Securities indirectly through an associated entity as trustee for the Winlo Trust.
5. Mr Callahan holds his interest in the Securities indirectly through associated entity Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust.
6. Sir Tooke holds his interest in the Securities indirectly through associated entity, Academic Health Solutions Ltd.

Based on the intentions of the Directors at the date of this Prospectus in relation to the Offers, the Directors and their related entities will have the following interests in Securities on Admission:

Director	Shares	% Min¹	% Max²	Options³	%¹
Dr Stewart Washer ⁴	48,300,000	26.3	24.9	1,500,000	8.2
Dr Michael Winlo ⁵	Nil	Nil	Nil	3,500,000	19.1
Dr Alistair Vickery	Nil	Nil	Nil	2,000,000	10.9
Matthew Callahan ⁶	19,600,000	10.7	10.1	Nil	Nil
Sir John Tooke ⁷	Nil	Nil	Nil	500,000	2.7

Notes:

1. Assuming that there are a total of 183,902,778 Shares and 18,350,000 Options on issue at Admission (based on the Minimum Subscription under the Public Offer).
2. Assuming that there are a total of 193,902,778 Shares and 18,350,000 Options on issue at Admission (based on the Maximum Subscription under the Public Offer).
3. Options are exercisable at \$0.45 each on or before 13 June 2023 issued on the terms and conditions set out in Section 8.3.
4. It is Dr Washer's intention as at the date of this Prospectus to subscribe for up to 300,000 Shares under the Public Offer. Dr Washer will hold 28,700,000 Shares and 1,500,000 Options jointly with associate Dr Patrizia Washer as trustees for the Washer Family Account and 19,600,000 shares will be held by Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director).
5. Dr Winlo holds his interest in the Securities indirectly through an associated entity as trustee for the Winlo Trust.
6. Mr Callahan holds his interest in the Securities indirectly through associated entity Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust.
7. Sir Tooke holds his interest in the Securities indirectly through associated entity, Academic Health Solutions Ltd.

5.6 Remuneration of Directors

The Directors have received, or accrued, the following remuneration since incorporation of the Company.

Director ¹	1 July 2018 – 30 June 2019	1 July 2019 - present
Dr Stewart Washer	\$300,000	\$125,000
Dr Michael Winlo	-	\$216,607
Dr Alistair Vickery	\$132,359	\$176,107
Matthew Callahan	-	\$20,833
Sir John Tooke ²	\$30,019	\$49,316
Dr Patrizia Washer ³	\$230,526	\$133,970

Notes:

- The Company has entered into the:
 - Biologica Agreement with Dr Stewart Washer;
 - Winlo Agreement with Dr Michael Winlo;
 - Vickery Agreement with Dr Alistair Vickery; and
 - consultancy agreements and letters of appointments with the Non-Executive Directors, as set out in Section 7.2.
- Upon Admission, proposed Director Sir John Tooke will join the Board. The Company has entered into the Academic Health Agreement with Academic Health Solutions Ltd (of which Sir John Tooke is a director) and Sir John Tooke as set out in Section 7.2(e).
- The Company has entered into the P Washer Agreement with Dr Patrizia Washer, who resigned as a Director of the Company on 28 October 2019 but continues to act as a consultant to the Company.

5.7 Related Party Transactions

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

- Executive services or consultancy agreements with its Executive Directors and Non-Executive Directors (refer Section 7.2);
- letters of appointment with Sir John Tooke and Mr Matthew Callahan on standard terms (refer Section 7.2(d) for details); and
- P Washer Agreement with Dr Patrizia Washer, a former Director (refer Section 7.2(g));
- Academic Health Agreement with Academic Health Solutions Ltd, of which Sir John Tooke is a director (refer to Section 7.2(e) for details);
- Thylacine Agreement with Thylacine Consulting LLC, of which Matt Callahan is a director (refer to Section 7.2(f) for details); and

- (f) deeds of indemnity, insurance and access with each of its Directors on standard terms (refer Section 7.9) for details).

The Company has also entered into agreements with the following:

- (g) Collaboration Agreement with Zelira Therapeutics Limited (ASX:ZLD), of which Stewart Washer is a former director (refer Section 7.3 for details);
- (h) Linear Agreement with Linear Clinical Research Limited, a registered not-for-profit company, of which Dr Michael Winlo is a director (refer Section 7.8(a) for details);

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

5.8 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 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 date of this Prospectus 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 www.emeraldclinics.com.au/corporate-governance.

(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 Executive Directors;
- (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.

(b) Composition of the Board

Election of Board members is substantially the province of the Shareholders in general meeting. The Board currently consists of Executive Directors Stewart Washer, Michael Winlo and Alistair Vickery and Non-Executive Director Matthew Callahan. Upon Admission, proposed Director Sir John Tooke will join the Board and be considered an independent Director. 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.

(c) 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. A Risk Committee has been established by the Board.

(d) Ethical standards

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

(e) Independent professional advice

Subject to the Chairman's approval in certain circumstances, the Directors, at the Company's expense, may obtain independent professional advice on issues arising in the course of their duties.

(f) 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.

A Non-Executive Director may be paid fees or other amounts in accordance with any consultancy agreement in which they have an interest or as the Directors determine from time to time where a Director performs special duties or otherwise performs services outside the scope of the ordinary duties of a Director or any consultancy agreement in place.

In addition, subject to any necessary Shareholder approval Directors may receive non-cash performance incentives such as options or performance rights. 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.

(g) 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 other designated persons). The policy generally provides that the written acknowledgement of the Chairman (or the Board in the case of the Chairman) must be obtained prior to trading.

(h) 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 matters including gender, age, cultural background and ethnicity.

(i) 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, 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.

(j) 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.

5.9 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 departures from the Recommendations as at the date of this Prospectus are detailed in the table below.

Principles and Recommendations	Explanation for Departure
Recommendation 1.5 A listed entity should: (a) have and disclose a diversity policy; (b) through its board or a committee of the board, set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally; and (c) disclose in relation to each reporting period: (i) the measurable objectives for that period to achieve gender diversity; (ii) the entity's progress towards achieving those objectives; and (iii) either: (A) the respective proportions of men and women on the board, in senior executive positions and across the whole workforce (including how the entity has defined 'senior executive' for these purposes); or (B) if the entity is a 'relevant employer' under the Workplace Gender Equality Act, the entity's most recent 'Gender Equality Indicators', as defined in and published under that Act.	The Company has adopted a policy addressing the achievement of gender diversity, however, given the current size of the Company's operations, the Company has not set measurable objectives for achieving gender diversity. Should the setting of such measurable objectives be considered appropriate for the Company in the future due to increases in size of the organisation, the Company will look to adopt such objectives. The Company's corporate code of conduct provides a framework for undertaking ethical conduct in employment.
Recommendation 2.1 The board of a listed entity should: (a) have a nomination committee which: (i) has at least three members, a majority of whom are independent directors; and (ii) is chaired by an independent director, and disclose:	The Company is not yet of a relevant size to consider formation of a nomination committee to deal with the selection and appointment of new Directors and as such a nomination committee has not been formed. Nominations of new Directors are considered by the full Board. If any vacancies arise on the Board, all directors are involved in the search and recruitment of a replacement. The Board is confident that this process for selection, including undertaking appropriate checks before appointing a person, or putting forward to security holders a

Principles and Recommendations	Explanation for Departure
(iii) the charter of the committee; (iv) the members of the committee; and (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 (b) 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.	candidate for election, and review is stringent and full details of all Directors will be provided to Shareholders in the annual report and on the Company's website.
Recommendation 2.4 A majority of the board of a listed entity should be independent directors.	Due to the size and scale of the Company's current activities, the Board does not consist of a majority of independent directors. The Board considers the composition of the Board, post listing, is appropriate given the size and current operations of the Company. To further facilitate independent decision-making, the Board has agreed procedures for directors to have access in appropriate circumstances to independent professional advice. As the Company grows, the Board will consider the appointment of additional independent Directors.
Recommendation 2.5 The chair of the board of a listed entity should be an independent director and, in particular, should not be the same person as the CEO of the entity.	The Board has formed the view that, given the size and nature of the business of the Company, and the knowledge and experience Dr Stewart Washer brings to the Company, that Dr Washer is the most appropriate person to hold the position of Chairman of the Company even though he is not independent by reason of being an Executive Director. The Chairman is not the same person as the CEO of the entity.
Recommendation 4.1 The board of a listed entity should: (a) have an audit committee which: (i) has at least three members, all of whom are non-executive directors and a majority of whom are independent directors; and	The full Board carries out the duties that would ordinarily be assigned to the Audit Committee. The Board considers that the Company is not currently of a size, nor are its affairs of such complexity requiring the formation of a separate Audit Committee.

Principles and Recommendations	Explanation for Departure
(ii) is chaired by an independent director, who is not the chair of the board, and disclose: (iii) the charter of the committee; (iv) the relevant qualifications and experience of the members of the committee; and (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 (b) if it does not have an audit committee, disclose that fact and the processes it employs that independently verify and safeguard the integrity of its corporate reporting, including the processes for the appointment and removal of the external auditor and the rotation of the audit engagement partner.	
Recommendation 4.2 The board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.	The Company will, before it approves the entity's financial statements for a full year and half year financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively. The Board has formed the view that, given the size and nature of the business of the Company, such a process is not required in relation to the Company's quarterly cash flow reports.

Principles and Recommendations	Explanation for Departure
Recommendation 8.1 The board of a listed entity should: (a) have a remuneration committee which: (i) has at least three members, a majority of whom are independent directors; and (ii) is chaired by an independent director, and disclose: (iii) the charter of the committee; (iv) the members of the committee; and (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 (b) if it does not have a remuneration committee, disclose that fact and the processes it employs for setting the level and composition of remuneration for directors and senior executives and ensuring that such remuneration is appropriate and not excessive.	The Board as a whole performs the function of the Remuneration committee which includes setting the Company's remuneration structure, determining eligibilities to incentive schemes, assessing performance and remuneration of senior management and determining the remuneration and incentives of the Board. The Board considers that the Company is not currently of a size, nor are its affairs of such complexity requiring the formation of a separate Remuneration Committee. The Board may obtain external advice from independent consultants in determining the Company's remuneration practices, including remuneration levels, where considered appropriate.

6. Financial Information

6.1 Financial information

The Independent Limited Assurance Report contained in Annexure A sets out:

- (a) the audited historical statement of profit or loss and other comprehensive income and historical statement of cash flows for the year ended 30 June 2019 and the period from incorporation (19 March 2018) to 30 June 2018; and
- (b) the audited historical statement of financial position as at 30 June 2019.

Investors are urged to read the Independent Limited Assurance Report in full.

Investors should be aware that the Company has a limited operating history and is currently making a loss, meaning it is reliant on raising funds from investors to continue to fund its operations and development of its Data Platform.

6.2 Forecast financial information

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.

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 making an assessment of whether to apply for Shares under the Public Offer. The provisions of such material contracts are summarised in this Section.

7.1 Lead Manager Mandate

The Company has entered into a mandate with PAC Partners dated 27 March 2018 (and amended on 22 October 2019) to appoint PAC Partners to act as Lead Manager in relation to the Public Offer (**Lead Manager Mandate**).

Pursuant to the Lead Manager Mandate, PAC Partners is engaged to provide lead manager services to the Company, including but not limited to:

- (a) lead managing the Public Offer;
- (b) providing advice and recommendations on the structure of the Public Offer;
- (c) providing advice on and coordinating the marketing of the Company and the Public Offer to potential investors and/or participants in the Public Offer; and
- (d) participating in the due diligence process undertaken by the Company in the preparation of this Prospectus.

Pursuant to the Lead Manager Mandate, the Company has agreed to:

- (a) pay the Lead Manager (or its nominees) a capital raising and selling fee of 6% of the total amount raised under the Public Offer.
- (b) issue to the Lead Manager (or its nominees) 1,000,000 Shares at a nominal issue price of \$0.0001 each, which have been issued.

Separately to the Lead Manager Mandate, the Company has:

- (a) issued to the Lead Manager and its associates:
 - (i) 140,000 Shares at \$0.10 each as part of a seed raising; and
 - (ii) 1,000,000 Shares at a nominal issue price of \$0.0001 each as consideration for lead manager services in connection with a pre-IPO seed raising; and
- (b) paid the Lead Manager:
 - (i) \$183,000 (excluding GST) for lead managing a pre-IPO seed raising; and
 - (ii) \$168,000 (excluding GST) for lead managing the issue of the Convertible Notes.

Please see Section 1.10 for further information regarding the Lead Manager's interests in the Public Offer.

7.2 Executive services, consultancy and employment agreements

(a) Consultancy Agreement – Biologica Ventures Pty Ltd and Dr Stewart Washer

The Company has entered into a consultancy agreement with Biologica Ventures Pty Ltd (an entity controlled by Dr Stewart Washer) (**Biologica**) and Dr Stewart Washer dated 27 July 2018 (and amended on 2 December 2019), pursuant to which Biologica and Dr Stewart Washer are engaged to provide consultancy services to the Company, reporting to the Board (**Biologica Agreement**). Pursuant to the Biologica Agreement, it is acknowledged that Dr Stewart Washer is appointed to the Board as Executive Chairman, is responsible along with the Board for the strategic direction and control of the business of the Company, and must exercise such other powers and perform such other duties from time to time vested in him by the Board.

Pursuant to the Biologica Agreement, the Company has agreed to pay Biologica (or its nominee) a consultancy fee of \$200,000 per annum (plus GST).

The Biologica Agreement is for an indefinite term, continuing until terminated by the Company giving not less than 6 months' written notice of termination or by Biologica giving not less than 3 months' notice of termination (or shorter period in limited circumstances).

The parties to the Biologica Agreement are also subject to restrictions in relation to the use of confidential information during and after the term of the Biologica Agreement, on terms which are considered standard for agreements of this nature.

The Biologica Agreement contains additional provisions considered standard for agreements of this nature. The Biologica Agreement does not include any change of control provisions.

(b) Executive Employment Agreement – Dr Michael Winlo

The Company has entered into an executive employment agreement with Dr Michael Winlo dated 17 June 2019 and amended on 26 November 2019 (**Winlo Agreement**), pursuant to which Dr Winlo serves as Managing Director and is responsible for (amongst other things) the overall management and supervision of the activities, operations and affairs of the Company, subject to the overall control and direction of the Board (**Winlo Services**).

The remuneration payable to Dr Winlo for the Winlo Services is \$350,000 per annum (excluding statutory superannuation), payable from 17 June 2019. Dr Winlo is entitled to receive an annual cash bonus of \$87,500 subject to the satisfaction of short term incentive hurdles to be determined by the Board and a \$50,000 cash bonus upon Admission. In addition, the Company has issued Dr Winlo 3,500,000 Options exercisable at \$0.45 each and expiring on 13 June 2023 and otherwise on the terms and conditions set out in Section 8.3.

The Board may, in its absolute discretion, invite Dr Winlo to participate in other bonus and/or incentive schemes in the Company that it may implement from time to time, subject to Shareholder approval.

The Winlo Agreement is for an indefinite term, continuing until terminated by the Company giving not less than three months' written notice of termination (or shorter period in limited circumstances) or by Dr Winlo giving not less than six months' notice of termination.

Dr Winlo is also subject to restrictions in relation to the use of confidential information and intellectual property during and after his employment with the Company ceases and being directly or indirectly involved in a competing business during 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.

The Winlo Agreement contains additional provisions considered standard for agreements of this nature. The Winlo Agreement does not include any change of control provisions.

(c) Executive Employment Agreement – Dr Alistair Vickery

The Company has entered into an executive employment agreement with Dr Alistair Vickery dated 18 March 2019 (**Vickery Agreement**), pursuant to which Dr Vickery serves as Medical Director and is responsible for (amongst other things) providing medical direction and administration oversight, supervising clinicians, providing education and training, and advising the management team on clinical trials and the clinical research platform (**Vickery Services**).

The remuneration payable to Dr Vickery for the Vickery Services is \$350,000 per annum (excluding statutory superannuation), payable from 18 March 2019. Dr Vickery is entitled to receive a cash bonus of \$87,500 payable subject to the satisfaction of short term incentive hurdles to be determined by the Board and a \$100,000 cash bonus upon Admission. In addition, the Company has issued Dr Vickery 2,000,000 Options exercisable at \$0.45 each and expiring on 13 June 2023 and otherwise on the terms and conditions set out in Section 8.3.

The Board may, in its absolute discretion, invite Dr Vickery to participate in other bonus and/or incentive schemes in the Company that it may implement from time to time, subject to Shareholder approval.

The Vickery Agreement is for an indefinite term, continuing until terminated by the Company giving not less than 24 months' written notice of termination (or shorter period in limited circumstances) or by Dr Vickery giving not less than 12 months' notice of termination.

In the event Dr Vickery is removed from his position as a Director, Dr Vickery will be deemed to have provided notice of termination of the Vickery Agreement, which will terminate upon 1 month from the date of such notice.

Dr Vickery is also subject to restrictions in relation to the use of confidential information and intellectual property during and after his employment with the Company ceases and being directly or indirectly involved in a competing business during 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.

The Vickery Agreement contains additional provisions considered standard for agreements of this nature. The Vickery Agreement does not include any change of control provisions.

(d) Non-Executive Director Letters of Appointment – Sir John Tooke and Mr Matthew Callahan

The Company has entered into separate Non-Executive Director letters of appointment with Sir John Tooke and Mr Matthew Callahan, pursuant to which the Company has agreed to pay:

- (i) Sir John Tooke \$50,000 per annum for services provided to the Company as Non-Executive Director, payable from Admission; and
- (ii) Mr Matthew Callahan \$50,000 per annum for services provided to the Company as Non-Executive Director, payable from 1 July 2019.

The appointment of Sir John Tooke as Non-Executive Director is effective from Admission, and the appointment of Mr Matthew Callahan as Non-Executive Director took effect on 23 March 2018.

Each Non-Executive Director letter of appointment contains additional provisions considered standard for agreements of this nature.

(e) Consultancy Agreement – Academic Health Solutions Ltd and Sir John Tooke

The Company has entered into a consultancy agreement with Academic Health Solutions Ltd (of which Sir John Tooke is a director) (**Academic Health**) and Sir John Tooke dated 14 November 2019, pursuant to which Academic Health and Sir John Tooke are engaged 1 day per month to provide consultancy services to the Company, including but not limited to, advising on the management of the Company's clinical registry and related services, reporting to the Board (**Academic Health Agreement**).

Pursuant to the Academic Health Agreement, the Company has agreed to pay Academic Health (or its nominee) a consultancy fee of £2,500 per day or part thereof.

The Academic Health Agreement is for a 12 month term commencing on 1 April 2019, continuing until terminated by the Company giving not less than 1 months' written notice of termination or by Academic Health giving not less than 1 months' notice of termination (or shorter period in limited circumstances).

The parties to the Academic Health Agreement are also subject to restrictions in relation to the use of confidential information during and after the term of the Academic Health Agreement, on terms which are considered standard for agreements of this nature.

The Academic Health Agreement contains additional provisions considered standard for agreements of this nature.

(f) Consultancy Agreement – Thylacine Consulting LLC and Mr Matthew Callahan

The Company has entered into a consultancy agreement with Thylacine Consulting LLC (of which Mr Matthew Callahan is a director) (**Thylacine**) dated 4 November 2019, pursuant to which Thylacine and Mr Matthew Callahan are engaged to provide consultancy services to the Company, including other duties over and above his role as a Non-Executive Director as may be required by the Board from time to time (**Thylacine Agreement**).

Pursuant to the Thylacine Agreement, the Company has agreed to pay Thylacine a rate of US\$300 per hour (plus GST), for a maximum of 16 hours in any week.

The Thylacine Agreement is for a 3 year term expiring on 4 November 2022 unless terminated earlier by any party giving not less than 6 months' written notice of termination to the other parties (or shorter period in limited circumstances).

The parties to the Thylacine Agreement are also subject to restrictions in relation to the use of confidential information and intellectual property during and after the term of the

Thylacine Agreement, on terms which are considered standard for agreements of this nature.

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

(g) Consultancy Agreement – Dr Patrizia Washer

The Company has entered into a consultancy agreement with Dr Patrizia Washer dated 1 July 2018 (**P Washer Agreement**), pursuant to which Dr Patrizia Washer is engaged to provide consultancy services to the Company up to 4 days per week (or part thereof), including but not limited to developing and implementing clinical activities as required by the management team and the Board, assisting with strategic planning, budgeting and operations, providing general advice to the Company on matters relating to the business of the Company and performing other duties as may be required by the Board from time to time.

Pursuant to the P Washer Agreement, the Company has agreed to pay Dr Patrizia Washer a consultancy fee of \$1,500 per day worked, or part thereof (which includes superannuation).

The P Washer Agreement is for an indefinite term, continuing until terminated by either party giving 1 months' notice of termination to the other party (or shorter period in limited circumstances).

The parties to the P Washer Agreement are also subject to restrictions in relation to the use of confidential information and intellectual property during and after the term of the Washer Agreement, on terms which are considered standard for agreements of this nature.

The P Washer Agreement contains additional provisions considered standard for agreements of this nature.

7.3 Collaboration Agreements

The Company has entered into three collaboration agreements, pursuant to which the Company has established non-exclusive commercial relationships for the purposes of developing evidence to support the use of cannabinoids and understanding the performance of certain prescribed medicines in a clinical setting (**Collaboration Agreements**).

Under the first Collaboration Agreement, the Company has successfully commercialised its De-identified Data via a data-sharing arrangement involving the grant of a non-exclusive licence to use its De-identified Data in consideration for an upfront cash payment.

Under the second Collaboration Agreement, the Company has the ability to obtain third party De-identified Data pertaining to patients (other than patients of the Company) that have been prescribed or treated using cannabinoid products.

Under the third Collaboration Agreement, the Company has established a collaborative research project to facilitate collection of De-identified Data.

The Collaboration Agreements acknowledge that all ownership rights relating to the existing intellectual property of each party are reserved to that party, and specify how intellectual property developed under the respective Collaboration Agreements will be owned and licenced.

The parties to the Collaboration Agreements are also subject to restrictions in relation to the use of confidential information during and after the relevant term, on terms which are considered standard for agreements of this nature.

The Collaboration Agreements contain additional provisions considered standard for agreements of this nature.

One of the Collaboration Agreements has been entered into with Zelira Therapeutics Limited (ASX:ZLD), of which Dr Stewart Washer is a former director. Stewart resigned from the board of Zelira, effective from 2 December 2019. This agreement was negotiated on arm's length terms.

7.4 Letter of Intent - Zelira Therapeutics Limited

The Company has entered into a binding letter of intent to support a clinical trial with Zelira Therapeutics Limited (**Zelira**). Under the letter of intent, Zelira must pay Emerald up to \$99,920 to recruit up to 8 patients to participate in a clinical trial. Of this:

- (a) a \$30,650, non-refundable fee is payable up-front and includes fees in respect of 2 patients;
- (b) each subsequent patient will be billed at \$11,345 at time of enrolment, with a maximum of up to six more patients to be recruited; and
- (c) at the end of study, a close-out fee of \$1,200 is payable.

The study is expected to run until April 2020. All intellectual property rights created as a result of the clinical trial will be owned by Zelira. Zelira will be responsible for obtaining HREC approval.

The Executive Chairman of the Company, Dr Stewart Washer, is a former director of Zelira. The letter of intent has been negotiated on arm's length terms.

Investors are reminded that there is a risk that formal agreements may not be agreed and signed by the Company, as set out in Section 4.1(x).

7.5 Letter of Intent - Spectrum Biomedical UK Limited

The Company has entered into a letter of intent with Spectrum Biomedical UK Limited (**SBUK**), under which SBUK agrees to pay Emerald the following amounts as consideration for Emerald conducting an observational study:

- (a) £150,000 upon execution into a formal agreement, and
- (b) subject to a maximum aggregate payment of £400,000, a fixed fee per patient enrolled into an observational study, payable upon the enrolment of the 50th patient into a study and then payable on each subsequent enrolment of 50 patients into a study.

The payments under the letter of intent are subject to entry into a formal agreement, and investors are reminded that there is a risk that no formal agreement will be agreed, as set out in Section 4.1(x).

7.6 Medical practitioner and advisor agreements

(a) Medical Practitioner Agreements

The Company has entered into numerous medical practitioner agreements (**Medical Practitioner Agreements**), pursuant to which certain medical practitioners have agreed to provide medical services to clients of the Company for a minimum of one day per week, undertake training and education offered by the Company and participate in clinical quality processes such as case conferences and audits.

The fee payable by the Company to each medical practitioner ranges between \$1,200 per day and \$1,800 per day (plus GST). The Medical Practitioner Agreements are for an indefinite term, continuing until terminated by either the medical practitioner or the Company giving 1 months' written notice (or shorter period in limited circumstances).

The parties to the Medical Practitioner Agreements are also subject to restrictions in relation to the use of confidential information and intellectual property during and after the term of each Medical Practitioner Agreement, and each medical practitioner is restricted from being directly or indirectly involved in a competing business during their engagement with the Company and for a period of up to 12 months after their engagement with the Company ceases, on terms which are otherwise considered standard for agreements of this nature.

Each Medical Practitioner Agreement contains additional provisions considered standard for agreements of this nature.

(b) Medical Advisor Agreements

The Company has entered into two medical advisor agreements (**Medical Advisor Agreements**), pursuant to which two medical practitioners, being pain specialists, have agreed to provide advice and clinical governance and related services to the general practitioners and staff of the Company.

The remuneration payable by the Company to each medical adviser is \$50,000 each per annum (excluding GST). The Medical Practitioner Agreements are for a fixed term, continuing until 30 September 2020 unless terminated by either the medical practitioner or the Company giving 1 months' written notice.

Each Medical Advisor Agreement contains additional provisions considered standard for agreements of this nature.

7.7 Convertible Note Deeds

The Company is a party to a number of convertible note deeds (**Convertible Note Deeds**), with certain sophisticated and professional investors (unrelated to the Company) which were entered into during March and April 2019 in connection with the Company's capital raising of \$3,300,000 (before costs) via the issue of convertible notes (**Convertible Notes**). The Convertible Notes are convertible into Shares in the Company at a deemed issue price of \$0.16 each on Admission into a maximum of 20,625,000 Shares, being the Shares the subject of the Convertible Note Offer. No interest is payable pursuant to the Convertible Note Deeds on the basis that all Convertible Notes will convert into Shares on Admission.

The Convertible Note Deeds contain additional provisions considered standard for agreements of this nature.

7.8 Other material contracts

(a) Services Agreement - Linear Clinical Research

The Company has entered into a services agreement with Linear Clinical Research Ltd, a registered not-for-profit company (**Linear**) (**Linear Agreement**) dated on or about 25 November 2019 pursuant to which Linear has agreed to provide clinical research services to the Company as requested from time to time, including but not limited to, the deployment and management of a digital patient database and related data management services (**Linear Services**).

Pursuant to the Linear Agreement, the Company has agreed to pay Linear a total of \$86,625 (plus GST) in consideration for the Linear Services.

The Linear Agreement is for a fixed term, expiring on 30 September 2021 unless terminated by the Company providing 60 business days' notice or by Linear giving 20 business days' notice of termination (or shorter period in limited circumstances).

The Linear Agreement acknowledges that all rights relating to the existing intellectual property of either party are reserved to that party, and that ownership of any intellectual property rights in any modification or adaptation of existing intellectual property rights arising pursuant to the Linear Agreement vest in the respective owner of the underlying intellectual property rights. Ownership of all intellectual property rights in any work product (including data, results and information generated by Linear in providing the Linear Services, as well as clinical information and samples obtained from participants participating in the research activities contemplated under the Linear Agreement) shall remain with the Company.

The parties to the Linear Agreement are also subject to restrictions in relation to the use of confidential information during and after the term of the Linear Agreement, on terms which are considered standard for agreements of this nature.

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

Dr Michael Winlo is a current director of Linear. The Linear Agreement was negotiated on arm's length terms.

(b) Lease Agreements

The Company has entered into various commercial lease agreements for the lease of commercial properties used for the operation of the Company's offices and Clinics (**Leases**). The Leases for the Clinics all have initial terms ranging between two to three years with options to extend, save for the lease at Tintenbar, which has a six month term, renewable by mutual agreement.

The Leases are on terms which are considered standard for agreements of this nature.

7.9 Deeds of indemnity, insurance and access

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

Directors and officers to inspect board papers in certain circumstances. The deeds are considered standard for documents of this nature.

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 date of this Prospectus, 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.

Shareholders may be paid interim dividends or bonuses at the discretion of the Directors. 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 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. If the assets are insufficient to repay the whole of the paid up capital of members, they will be distributed in such a way that the losses borne by members are in proportion to the capital paid up.
- (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 Summary of the Company's Employee Securities Incentive Plan

The Emerald Clinics Limited Employee Securities Incentive Plan (**Plan**) was adopted by the Board on 28 November 2019. The full terms of the Plan may be inspected at the registered office of the Company during normal business hours. It is intended that both the Executive and Non-Executive Directors will participate in the Plan. As at the date of this Prospectus, the Directors do not participate in the Plan.

A summary of the terms of the Plan is set out below:

(a) Eligible Participant

Eligible Participant means a person that:

- (i) is an 'eligible participant' (as that term is defined in ASIC Class Order 14/1000) in relation to the Company or an Associated Body Corporate (as that term is defined in ASIC Class Order 14/1000); and
- (ii) has been determined by the Board to be eligible to participate in the Plan from time to time.

(b) 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 Company, by providing an opportunity to Eligible Participants to receive an equity interest in the Company in the form of Securities.

(c) 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. The Board may delegate its powers and discretion.

(d) Eligibility, invitation and application

- (i) 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 Shares on such terms and conditions as the Board decides.
- (ii) 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.
- (iii) 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.

(e) Grant of Securities

The Company will, to the extent that it has accepted a duly completed application, grant the 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.

(f) 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.

(g) 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.

(h) 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.

An invitation may specify that at the time of exercise of the Convertible Securities, 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.

(i) 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.

(j) 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 Company, 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.

(k) 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.

(l) 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.

(m) Disposal restrictions on Plan Shares

If the invitation provides that any Plan Shares 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.

For so long as a Plan Share is subject to any disposal restrictions under the Plan, the Participant will not:

- (i) transfer, encumber or otherwise dispose of, or have a security interest granted over that Plan Share; or
- (ii) take any action or permit another person to take any action to remove or circumvent the disposal restrictions without the express written consent of the Company.

(n) 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.

(o) 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.

(p) 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.

(q) 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.

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.

8.3 Options Terms

The following terms and conditions apply to the Options:

(a) Entitlement

Each Option entitles the holder to subscribe for one fully paid ordinary share in the capital of the Company (**Share**) upon exercise of the Option.

(b) Exercise Price, Expiry Date and Vesting

The Options have an exercise price (**Exercise Price**), expiry date (**Expiry Date**) and vesting conditions as follows:

Number	Exercise Price	Expiry Date	Vesting Condition / Vesting Date
17,750,000 Options	\$0.45 per Option	5:00pm (WST) on 13 June 2023	7,583,333 Options vested immediately on issue. 5,083,333 Options vest on 13 June 2020. 5,083,334 Options vest on 13 June 2021.
600,000 Options	\$0.45 per Option	5:00pm (WST) on 26 September 2023	200,000 Options vested immediately on issue. 200,000 Options vest on 26 September 2020. 200,000 Options vest on 26 March 2021

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

(c) Exercise Period

The Options are exercisable at any time after the Vesting Date (if applicable) and before the Expiry Date.

(d) Quotation of the Options

The Options will be unquoted.

(e) Transferability of the Options

The Options are not transferable, except with the prior written approval of the Company.

(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.

(g) Cashless exercise

A holder of Options 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 issue to the holder that number of Shares equal in value to the positive difference between the then Market Value of the Shares at the date of the Notice 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).

Where Market Value means:

- (i) If the Company is listed on ASX the volume weighted average price per Share traded on the ASX over the five (5) trading days immediately preceding the date of the Notice of Exercise; or
- (ii) If the Company is not listed on ASX the value per share determined by the Directors if their absolute discretion, acting reasonably.

(h) Lapse

- (i) Any Option not meeting the Vesting Condition in Section 8.3(b) (if applicable) will lapse on the Vesting Date.
- (ii) Any vested Option not exercised before the Expiry Date will automatically lapse on the Expiry Date.

(i) Shares Issued on Exercise

Shares issued on exercise of the Options rank equally with the then Shares of the Company.

(j) Quotation of Shares on Exercise

Application will be made by the Company to ASX, on the Business Day the Shares are issued, for quotation of the Shares issued upon the exercise of the Options.

(k) Timing of Issue of Shares

Within 15 business days after the later of the following:

- (i) receipt of a Notice of Exercise given in accordance with these terms and conditions and payment of the Exercise Price for each Option being exercised; and
- (ii) when excluded information in respect to the Company (as defined in section 708A(7) of the Corporations Act) (if any) ceases to be excluded information,

the Company will:

- (iii) issue the Shares pursuant to the exercise of the Options;
- (iv) give ASX a notice that complies with section 708A (5) (e) of the Corporations Act; and
- (v) apply for official quotation on ASX of Shares issued pursuant to the exercise of the Options.

If the Company is unable to give ASX a notice that complies with section 708A(5)(e) of the Corporations Act within 5 days after the issue of the Shares, 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. For the period of time whilst Shares issued on exercise of the Options are unable to be traded, a holding lock will be applied by the Company's share registry.

(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. However, the Company will ensure that for the purposes of determining entitlements to any such issue, the record date will be at least 3 business days after the issue is announced. This will give the holders of Options the opportunity to exercise their Options 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 Optionholder would have received if the Optionholder 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 Entitlements Issue

If the Company makes an issue of Shares pro rata to existing Shareholders (other than as a bonus issue, to which Section 8.3(m) will apply) there will be no adjustment of the Exercise Price of an Option or the number of Shares over which the Options are exercisable.

(o) Adjustments for Reorganisation

If there is any reorganisation of the issued share capital of the Company, the rights of the Optionholders will be varied in accordance with the Listing Rules.

(p) Change in control

Any unvested Options will immediately vest in the event that:

- (i) a court orders a meeting to be held in relation to a proposed compromise or arrangement for the purposes of, or in connection with, a scheme for the reconstruction of the Company or its amalgamation with any other company or companies and the shareholders of the Company approve the proposed compromise or arrangement at such meeting;
- (ii) a Takeover Bid (as defined in the Corporations Act):
 - (A) is announced;
 - (B) has become unconditional; and
 - (C) the person making the Takeover Bid has a Relevant Interest (as defined in the Corporations Act) in 50% or more of the Shares; or
- (iii) any person acquires a Relevant Interest in 50.1% or more of the Shares by any other means.

8.4 Effect of the Offers on control and substantial Shareholders

Those Shareholders holding an interest in 5% or more of the Shares on issue as at the date of this Prospectus are as follows.

Name	Shares	%
Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust	28,400,000	21.3
Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director)	19,600,000	14.7
Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust	19,600,000	14.7
Craig Lawrence Darby	19,600,000	14.7
Gleneagle Asset Management Ltd as trustee for the Alium Alpha Fund Account	7,000,000	5.25

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

Name	Minimum Subscription		Maximum Subscription	
	Shares	%	Shares	%
Stewart James Washer and Patrizia Derna Washer as trustees for the Washer Family Trust	28,700,000	15.6	28,700,000	14.8
Mal Washer Nominees Pty Ltd as trustee for the Mal Washer Family Trust No 1 (an entity of which Dr Stewart Washer is a director)	19,600,000	10.7	19,600,000	10.1
Mercator Shipwrights Pty Ltd as trustee for the Mercator Trust	19,600,000	10.7	19,600,000	10.1
Craig Lawrence Darby	19,600,000	10.7	19,600,000	10.1

8.5 Interests of Promoters, Experts and Advisers

(a) No interest except as disclosed

Other than as set out below or elsewhere in this Prospectus, no 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 holds at the date of this Prospectus, or held at any time during the last 2 years, any interest in:

- (i) the formation or promotion of the Company;
- (ii) property acquired or proposed to be acquired by the Company in connection with its formation or promotion, or the Offers; or
- (iii) 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

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

(c) Auditor

Stantons International Audit and Consulting Pty Ltd (**Stantons International**) has been appointed to act as auditor to the Company. The Company has paid Stantons International a total of \$22,599 (excluding GST) for these services during the 24 months preceding lodgement of this Prospectus. During the 24 months preceding lodgement of this Prospectus with ASIC, Stantons International has also been paid \$3,500 (excluding GST) for professional services relating to valuation services.

(d) Legal adviser

HWL Ebsworth has acted as the Australian solicitors to the Company in relation to the Offers and has prepared the Legal Opinion which is included in Annexure B of this Prospectus. The Company estimates it will pay HWL Ebsworth \$115,000 (excluding GST) for these services. During the 24 months preceding lodgement of this Prospectus with ASIC, HWL Ebsworth has not provided services to the Company.

(e) UK Legal adviser

Fieldfisher LLP has acted as the UK solicitors to the Company in relation to the regulation of cannabinoid medicines in the UK, which is referred to in Sections 2.4 and 3.3 of this Prospectus. The Company estimates it will pay Fieldfisher LLP \$1,300 (excluding GST) for these services. During the 24 months preceding lodgement of this Prospectus with ASIC, Fieldfisher LLP has not provided services to the Company.

(f) Investigating Accountant

BDO Corporate Finance (WA) Pty Ltd has acted as Investigating Accountant and has prepared the Independent Limited Assurance Report which is included in Annexure A of

this Prospectus. The Company estimates it will pay BDO Corporate Finance (WA) Pty Ltd a total of \$15,000 (excluding GST) for these services. During the 24 months preceding lodgement of this Prospectus with ASIC BDO Corporate Finance (WA) Pty Ltd has not provided services to the Company.

(g) Lead Manager

PAC Partners has acted as the Lead Manager to the Public Offer. Details of the payments to be made to the Lead Manager are set out in Section 7.1. During the 24 months preceding lodgement of this Prospectus with ASIC, the Lead Manager has acted for the Company and has invoiced fees in the amount of \$351,000 (excluding GST).

8.6 Consents

(a) General

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

Each of the parties referred to below:

- (i) does not make 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

Automatic 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

Stantons International Audit and Consulting 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) Legal adviser

HWL Ebsworth 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 Australian legal adviser 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 Legal Opinion in the form and context in which it is included.

(e) UK Legal adviser

Fieldfisher LLP 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 UK legal adviser to the Company in relation to the regulation of cannabinoid medicines in the UK in the form and context in which it is named.

(f) Investigating Accountant

BDO Corporate Finance (WA) 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.

(g) Lead Manager

PAC Partners 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 Lead Manager to the Public Offer in the form and context in which it is named.

8.7 Expenses of Offers

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

Fees	Minimum Subscription \$	Maximum Subscription \$
ASIC Lodgement Fee	3,300	3,300
ASX Quotation Fee	104,000	106,000
Legal and Preparation Fees	140,000	140,000
Investigating Accountant Fees	15,000	15,000
Capital Raising Fee ¹	360,000	480,000
Printing, Postage and Administration Fees	5,000	5,000
Share Registry Fees	15,000	15,000
Investor relations and other costs	40,000	40,000
Total estimated expenses	682,300	804,300

Notes:

1. Refer to Section 7.1 for a summary of the terms of the Lead Manager Mandate.

8.8 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.

8.9 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 is directly or indirectly concerned which is likely to have a material adverse effect on the business or financial position of the Company.

8.10 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 Shares 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 relevant 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 relevant 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.

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 8.6 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 A, 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:



Dr Stewart Washer
Executive Chairman

Dated: 11 December 2019

10. Glossary of Terms

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

\$ or A\$ means Australian dollars.

Active Patient means any living patient who has been referred to Emerald for care and attended a Clinic and has not provided explicit instruction that they intend to cease using Emerald's services.

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

Allotment Date means the date, as determined by the Directors, on which the Shares offered under this Prospectus are allotted, which is anticipated to be the date identified in the Indicative Timetable.

Applicant means a person who submits an Application Form.

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

Application Form means the application form for the Public Offer or Convertible Note Offer (as applicable).

Application Monies means application monies for Shares under the Public Offer received and banked by the Company.

APS means the Authorised Prescriber Scheme, a scheme administered by the TGA.

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 Stantons International Audit and Consulting Pty Ltd ACN 144 581 519.

Australian Privacy Principles means the privacy principles contained in Schedule 1 of the Privacy Act.

Authorised Prescriber means a medical practitioner who is approved by the TGA to prescribe unapproved therapeutic goods for a particular condition or class of patients in their immediate care, without further TGA approval.

Biologica Agreement has the meaning given in Section 7.2(a).

Board means the board of Directors of the Company as at the date of this Prospectus.

CBD means cannabidiol.

CBPMs means cannabis-based products for medicinal use, as defined by paragraph 5 of part 1 of Schedule 4 of the amended *Misuse of Drugs Regulations 2001* (UK).

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

Clinical Platform means the back-end system to facilitate the screening, prescription and monitoring of cannabinoid medications by clinicians.

Clinics means Emerald's specialist medical clinics.

Closing Date means the date that the Offers close which is 5.00pm (WST) on 17 January 2020 or such other time and date as the Board determines.

Collaboration Agreement has the meaning given in Section 7.3.

Company or **Emerald** means Emerald Clinics Limited ACN 625 085 734.

Commonwealth or **Cth** means the Commonwealth of Australia.

Constitution means the constitution of the Company.

Convertible Note Deeds means the Convertible Note Deeds entered into by the Company, the terms of which are summarised in Section 7.7.

Convertible Note Offer has the meaning given in Section 1.6.

Convertible Notes means the convertible notes issued by the Company pursuant to the Convertible Note Deeds.

Corporations Act means the *Corporations Act 2001* (Cth).

CTN means clinical trial notification.

De-identified Data means fully anonymised patient data, that has undergone the systemic removal of PII.

Directors means the directors of the Company.

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

EDC means electronic data capture.

EHR means electronic health record.

EMA means the European Medicines Agency, a regulatory authority for medicinal products in the European Union.

Emerald Care Model has the meaning given in Section 2.4.

Emerald Data Platform or **Data Platform** means the comprehensive RWD obtained by Emerald from consenting patients.

Exercise Price means the price at which Options may be exercised, as set out in the table in Section 8.3.

Expiry Date means the date upon which Options expire as set out in the table in Section 8.3.

Exposure Period means the period of 7 days after the date of lodgement of this Prospectus, which period may be extended by the ASIC by not more than 7 days pursuant to section 727(3) of the Corporations Act.

FDA means the Food and Drug Administration, the United States' federal regulatory authority for food and drugs.

GST means Goods and Services Tax.

HREC means the Human Research Ethics Committee.

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

Investigating Accountant means BDO Corporate Finance (WA) Pty Ltd ACN 124 031 045.

Independent Limited Assurance Report means the report contained in Annexure A.

Lead Manager means PAC Partners Securities Pty Ltd ACN 623 653 912.

Lead Manager Mandate has the meaning given in Section 7.1.

Legal Opinion means the legal opinion contained in Annexure B.

Linear means Linear Clinical Research Limited ACN 142 055 749.

Linear Agreement has the meaning given in Section 7.8(a).

Listing Rules means the listing rules of ASX.

Minimum Subscription has the meaning given in Section 1.3.

NDA means the *Narcotics Drugs Act 1967* (Cth).

NHS means the National Health Service, via NHS England, Clinical Commissioning Groups, and devolved administrations in Scotland, Wales and Northern Ireland commission, the publicly funded national healthcare system for the UK.

NICE means the National Institute for Health and Care Excellence, a non-departmental public body that is sponsored by the UK Government's Department of Health and Social Care and which reviews the clinical and cost effectiveness of treatments providing Guidance on treatments which will be eligible for NHS reimbursement.

Noteholders means a holder of a Convertible Note.

Notice of Exercise has the meaning given in Section 8.3.

Offers means the Public Offer and the Convertible Note Offer.

Offer Price means \$0.20 per Share under the Public Offer.

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 to acquire a Share.

P Washer Agreement has the meaning given in Section 7.2(g).

Payers means the payers of healthcare costs, and includes but is not limited to insurance companies and state and federal governments.

PBS means the Pharmaceutical Benefits Scheme, part of Australia's broader National Medicines Policy, overseen by the Commonwealth's Department of Health.

PII means personally identifiable information.

Plan means the Emerald Clinics Limited Employee Incentive Plan.

Privacy Act means the *Privacy Act 1988* (Cth).

Producers means producers of cannabinoid-based medicines.

Prospectus means this prospectus dated 11 December 2019.

Provinces means the Provinces of British Columbia, Ontario and Quebec in Canada.

Public Offer has the meaning given in Section 1.2.

RACGP means the Royal Australian College of General Practitioners.

RCTs means randomised control trial, where subjects are randomly assigned to two groups, one (the experimental group) receiving the intervention that is being tested, and the other (the comparison or control group) receiving an alternative (conventional) treatment.

RWD means real-world clinical data, being information relating to patient health status or the delivery of health care such as EHRs, insurance claims data, product or disease registries, or at-home patient monitoring devices, and can also include data on environmental exposures and socio-economic factors.

RWE means real-world clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.

SAS means the Special Access Scheme, an application pathway that is evaluated by the TGA.

SAS-B means Category B of the SAS and has the meaning set out in Section 3.2(b).

SBUK means Spectrum Biomedical UK Limited, company number 11544382, a private limited company incorporated in the UK.

Schedule 8 means schedule 8 of the SUSMP.

Section means a section of this Prospectus.

Securities means any securities, including Shares, Options, performance shares or other convertible securities, issued or granted by the Company.

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

Share Registry means Automic Pty Ltd ACN 152 260 814.

Shareholder means a holder of one or more Shares.

SFA has the meaning given in Section 1.17.

SFO has the meaning given in Section 1.17.

Specialist Clinician means a medical practitioner on the Specialist Register of the General Medical Council in the UK. The General Medical Council requires the practitioner to have a specialist interest in the condition and be working within their own area of practice and training and within the limits of their competence.

Stantons International means Stantons International Audit and Consulting Pty Ltd ACN 144 581 519.

SUSMP means the Standard for the Uniform Scheduling of Medicines and Poisons, Australia's national classification system that controls how medicines and poisons are made available to the public, which is produced by the TGA.

TGA means the Therapeutic Goods Administration. Australia's regulatory authority for therapeutic goods.

TG Act means the *Therapeutic Goods Act 1989* (Cth). The legislative framework that provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia.

Vickery Agreement has the meaning given in Section 7.2(c).

Winlo Agreement has the meaning given in Section 7.2(b).

WST means Western Standard Time, being the time in Perth, Western Australia.

Annexure A Independent Limited Assurance Report

EMERALD CLINICS LIMITED
Independent Limited Assurance Report

6 December 2019

6 December 2019

The Directors
Emerald Clinics Limited
50 Angove Street
NORTH PERTH 6006

Dear Directors

INDEPENDENT LIMITED ASSURANCE REPORT

1. Introduction

BDO Corporate Finance (WA) Pty Ltd (**'BDO'**) has been engaged by Emerald Clinics Limited (**'Emerald'** or **'the Company'**) to prepare this Independent Limited Assurance Report (**'Report'**) in relation to certain financial information of Emerald, for the Initial Public Offering of shares in Emerald, for inclusion in the Prospectus. Broadly, the Prospectus will offer up to 40 million Shares at an issue price of \$0.20 each to raise up to \$8 million before costs (**'the Offer'**). The Offer is subject to a minimum subscription level of 30 million shares to raise \$6 million.

Expressions defined in the Prospectus have the same meaning in this Report. BDO Corporate Finance (WA) Pty Ltd (**'BDO'**) holds an Australian Financial Services Licence (AFS Licence Number 316158).

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.

2. Scope

You have requested BDO to perform a limited assurance engagement in relation to the historical and pro forma historical financial information described below and disclosed in the Prospectus.

The historical and pro forma historical financial information is presented in the Prospectus in an abbreviated form, insofar as it does not include all of the presentation and disclosures required by Australian Accounting Standards and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act 2001.

You have requested BDO to review the following historical financial information (together the **‘Historical Financial Information’**) of Emerald included in the Prospectus:

- the audited historical Statements of Profit or Loss and Other Comprehensive Income and historical Statement of Cash Flows for the year ended 30 June 2019 and the period from incorporation (19 March 2018) to 30 June 2018; and
- the audited historical Statement of Financial Position as at 30 June 2019.

The Historical Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in Australian Accounting Standards and the Company’s adopted accounting policies. The Historical Financial Information has been extracted from the financial report of Emerald for the year ended 30 June 2019 and for the period from incorporation to 30 June 2018, which was audited by Stantons International in accordance with the Australian Auditing Standards. Stantons International issued unmodified audit opinions on the financial reports.

Pro Forma Historical Financial Information

You have requested BDO to review the following pro forma historical financial information (the **‘Pro Forma Historical Financial Information’**) of Emerald included in the Prospectus:

- the pro forma historical Statement of Financial Position as at 30 June 2019.

The Pro Forma Historical Financial Information has been derived from the historical financial information of Emerald, after adjusting for the effects of the subsequent events described in Section 6 of this Report and the pro forma adjustments described in Section 7 of this Report. The stated basis of preparation is the recognition and measurement principles contained in Australian Accounting Standards applied to the historical financial information and the events or transactions to which the pro forma adjustments relate, as described in Section 7 of this Report, as if those events or transactions had occurred as at the date of the historical financial information. Due to its nature, the Pro Forma Historical Financial Information does not represent the Company’s actual or prospective financial position or financial performance.

The Pro Forma Historical Financial Information has been compiled by Emerald to illustrate the impact of the events or transactions described in Section 6 and Section 7 of the Report on Emerald’s financial position as at 30 June 2019. As part of this process, information about Emerald’s financial position has been extracted by Emerald from Emerald’s financial statements for the year ended 30 June 2019.

3. Directors’ responsibility

The directors of Emerald are responsible for the preparation and presentation of the Historical Financial Information and Pro Forma Historical Financial Information, including the selection and determination of pro forma adjustments made to the Historical Financial Information and included in the Pro Forma Historical Financial Information. This includes responsibility for such internal controls as the directors determine are necessary to enable the preparation of Historical Financial Information and Pro Forma Historical Financial Information are free from material misstatement, whether due to fraud or error.

4. Our responsibility

Our responsibility is to express limited assurance conclusions on the Historical Financial Information and the Pro Forma Historical Financial Information. 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*.

Our limited assurance procedures consisted 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 a reasonable assurance engagement. Accordingly, we do not express an audit opinion.

Our engagement did not involve updating or re-issuing any previously issued audit or limited assurance reports on any financial information used as a source of the financial information.

5. Conclusion

Historical Financial Information

Based on our limited assurance engagement, which is not an audit, nothing has come to our attention that causes us to believe that the Historical Financial Information, as described in the Appendices to this Report, and comprising:

- the Statement of Profit or Loss and Other Comprehensive Income and Statement of Cash Flows of Emerald for the year ended 30 June 2019 and for the period from incorporation to 30 June 2018; and
- the Statement of Financial Position of Emerald as at 30 June 2019,

is not presented fairly, in all material respects, or as adjusted in the pro forma, in accordance with the stated basis of preparation, as described in Section 2 of this Report.

Pro Forma Historical Financial information

Based on our limited assurance engagement, which is not an audit, nothing has come to our attention that causes us to believe that the Pro Forma Historical Financial Information as described in the Appendices to this Report, and comprising:

- the pro forma historical Statement of Financial Position of Emerald as at 30 June 2019,

is not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 2 of this Report.

6. Subsequent Events

The pro-forma statement of financial position reflects the following events that have occurred subsequent to the year ended 30 June 2019:

- The Company completed a capital raising prior to the initial public offer ('IPO') raise of \$500,000 at \$0.18 per share in December 2019 ('pre-IPO Raise'). Cash and cash equivalents and share capital has been increased based on the amount raised.
- The Company received a research and development ('R&D') refund for the financial year ended 30 June 2019 in November 2019 of \$409,078. This was not recognised as a receivable at 30 June 2019, therefore cash and cash equivalents has increased and accumulated losses decreased to recognise the refund being earned and received.
- The Company granted Options to employees and consultants subsequent to year end. The value of these Options has been reflected in other reserves and expensed through accumulated losses. These Options have been valued using the Black Scholes Option

Pricing Model, with the terms and valuations of these Options detailed in the “Other reserves” note in Appendix 4. We note that pursuant to AASB 2: Share Based Payments, Options are expensed over the vesting period. Given that one third of the Options vested immediately on issue, the adjustment to the pro-forma balance sheet reflects one third of the total value of the Options. The remaining Options will be expensed over the vesting period, therefore as at the pro-forma date, there is no adjustment required.

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 other material transactions or events outside of the ordinary business of Emerald not described above, 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.

7. Assumptions Adopted in Compiling the Pro-forma Statement of Financial Position

The pro forma historical Statement of Financial Position is shown in Appendix 2. This has been prepared based on the financial statements as at 30 June 2019, the subsequent events set out in Section 6, and the following transactions and events relating to the issue of Shares under this Prospectus:

- The issue of a minimum of 30 million Shares at an offer price of \$0.20 each to raise \$6 million before costs and a maximum of 40 million Shares at an offer price of \$0.20 each to raise \$8 million before costs pursuant to the Prospectus.
- Cash costs of the Offer are estimated to be \$682,300 under the minimum subscription and \$804,300 under the maximum subscription. Of these costs, \$493,650 and \$614,650 under the minimum and maximum subscription respectively are directly attributable to the capital raising and have therefore been offset against contributed equity. The remaining cash costs of the Offer which are not directly attributable to the capital raising have been expensed through accumulated losses. These costs amount to \$188,650 under the minimum and \$189,650 under the maximum subscriptions.
- The convertible note liability has been adjusted to nil to reflect the conversion of the notes at \$0.16, being 80% of the listing price. On conversion, the Company will issue 20,625,000 shares. The shares have been valued at \$0.20, with the difference between the value of the shares issued and the debt and equity value of the Convertible Notes at 30 June 2019, representing a financing charge. This financing charge amounts to \$1,003,045 and is reflected in accumulated losses.
- The options issued prior to 30 June 2019 (**‘Existing Options’**) have been revalued using an underlying share price of \$0.10 per share based on the price of the most recent capital raising as at the grant date of the options. The revaluation of the Existing Options results in an adjustment to accumulated losses and reserves at 30 June 2019 of \$104,515. We have therefore increased accumulated losses and reserves by this amount as a pro forma adjustment. Further information on these valuations can be found in Note 5, contained in Appendix 4.

8. Independence

BDO is a member of BDO International Ltd. BDO does not have any interest in the outcome of the proposed IPO other than in connection with the preparation of this Report and participation in due diligence procedures, for which professional fees will be received.

9. Disclosures

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 2 of this Report, 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.

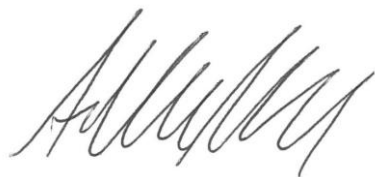
BDO has consented to the inclusion of this Report in the Prospectus in the form and context in which it is included. At the date of this Report this consent has not been withdrawn. However, BDO has not authorised the issue of the Prospectus. Accordingly, BDO makes no representation regarding, and takes no responsibility for, any other statements or material in or omissions from the Prospectus.

10. 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.

Yours faithfully

BDO Corporate Finance (WA) Pty Ltd

A handwritten signature in black ink, appearing to read 'Adam Myers', written in a cursive style.

Adam Myers

Director

APPENDIX 1
EMERALD CLINICS LIMITED
PRO FORMA STATEMENT OF FINANCIAL POSITION

	Notes	Audited as at 30-Jun-19 \$	Subsequent events \$	Pro-forma adjustments Min \$	Pro-forma adjustments Max \$	Pro-forma adjustments Min \$	Pro-forma adjustments Max \$
CURRENT ASSETS							
Cash and cash equivalents	2	2,658,814	909,078	5,317,700	7,195,700	8,885,592	10,763,592
Trade and other receivables		59,883	-	-	-	59,883	59,883
Restricted cash		56,258	-	-	-	56,258	56,258
TOTAL CURRENT ASSETS		2,774,955	909,078	5,317,700	7,195,700	9,001,733	10,879,733
NON CURRENT ASSETS							
Property plant & equipment		749,953	-	-	-	749,953	749,953
TOTAL NON CURRENT ASSETS		749,953	-	-	-	749,953	749,953
TOTAL ASSETS		3,524,908	909,078	5,317,700	7,195,700	9,751,686	11,629,686
CURRENT LIABILITIES							
Trade and other payables		231,089	-	-	-	231,089	231,089
Provision for employee benefits		41,659	-	-	-	41,659	41,659
TOTAL CURRENT LIABILITIES		272,748	-	-	-	272,748	272,748
NON CURRENT LIABILITIES							
Convertible Notes	3	2,752,621	-	(2,752,621)	(2,752,621)	-	-
TOTAL NON CURRENT LIABILITIES		2,752,621	-	(2,752,621)	(2,752,621)	-	-
TOTAL LIABILITIES		3,025,369	-	(2,752,621)	(2,752,621)	272,748	272,748
NET ASSETS		499,539	909,078	8,070,321	9,948,321	9,478,938	11,356,938
EQUITY							
Contributed equity	4	2,872,738	500,000	9,631,350	11,510,350	13,004,088	14,883,088
Reserves	5	374,069	46,800	(264,819)	(264,819)	156,050	156,050
Accumulated losses	6	(2,747,268)	362,278	(1,296,210)	(1,297,210)	(3,681,200)	(3,682,200)
TOTAL EQUITY		499,539	909,078	8,070,321	9,948,321	9,478,938	11,356,938

The cash and cash equivalents balance above does not account for working capital movements over the period from 1 July 2019 until completion. We have been advised that the Company's net operating costs subsequent to 30 June 2019 were \$1,451,430.

The pro forma statement of financial position after the Offer is as per the statement of financial position before the Offer adjusted for any subsequent events and the transactions relating to the issue of Shares pursuant to this Prospectus. The statement of financial position is to be read in conjunction with the notes to and forming part of the Historical Financial Information set out in Appendix 4.

APPENDIX 2
EMERALD CLINICS LIMITED
STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Statement of Profit or Loss and Other Comprehensive Income	Audited for the year ended 30-Jun-19 \$	Audited for the period ended 30-Jun-18 \$
Sales revenue	109,909	-
Operating costs	(646,301)	-
Gross loss	(536,392)	-
Other revenue		
Interest	28,747	-
Expenses		
Research and development expenses	(221,487)	-
Employee wages and director fees	(985,177)	(18,500)
Travel and conference expenses	(224,518)	-
Corporate compliance costs	(207,383)	(27,713)
Administration costs	(182,330)	-
IT consultancy fees	(165,297)	(18,112)
Occupancy costs for head office	(46,484)	-
Consultancy fees	(38,982)	-
Finance costs	(4,044)	(15)
Share based payments	(4,735)	-
Depreciation	(94,846)	-
Total expenses	(2,175,283)	(64,340)
Loss from continuing operations before income tax	(2,682,928)	(64,340)
Income tax expense	-	-
Loss from continuing operations after income tax	(2,682,928)	(64,340)
Other comprehensive income for the year		
Other comprehensive income for the year, net of tax	-	-
Total comprehensive loss for the year	(2,682,928)	(64,340)

This statement of profit or loss and other comprehensive income shows the historical financial performance of the Company and is to be read in conjunction with the notes to and forming part of the historical financial information set out in Appendix 4. Past performance is not a guide to future performance.

APPENDIX 3
EMERALD CLINICS LIMITED
HISTORICAL STATEMENT OF CASH FLOWS

Consolidated Statement of Cash Flows	Audited for the year ended 30-Jun-19 \$	Audited for the period ended 30-Jun-18 \$
Cash flows from operating activities		
Receipts from customers	109,909	-
Interest received	28,747	-
Payments to suppliers and employees	(2,731,878)	(20,816)
Net cash (used in) operating activities	(2,593,222)	(20,816)
Cash flows from investing activities		
Payments for plant and equipment	(844,800)	-
Payments for security deposits	(56,258)	-
Net cash (used in) investing activities	(901,058)	-
Cash flows from financing activities		
Proceeds from issue of shares	-	3,060,308
Net proceeds from convertible note	3,113,602	-
Net cash from financing activities	3,113,602	3,060,308
Net increase/(decrease) in cash and cash equivalents	(380,678)	3,039,492
Cash and cash equivalents at the beginning of the year	3,039,492	-
Cash and cash equivalents at the end of the year	2,658,814	3,039,492

APPENDIX 4
EMERALD CLINICS LIMITED
NOTES TO AND FORMING PART OF THE HISTORICAL FINANCIAL INFORMATION

1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies adopted in the preparation of the historical financial information included in this Report have been set out below.

a) Basis of preparation of historical financial information

The historical financial information has been prepared in accordance with the recognition and measurement, but not all the disclosure requirements of the Australian equivalents to International Financial Reporting Standards ('AIFRS'), other authoritative pronouncements of the Australian Accounting Standards Board, Australian Accounting Interpretations and the Corporations Act 2001.

The financial information has also been prepared on a historical cost basis, except for derivatives and available-for-sale financial assets that have been measured at fair value. The carrying values of recognised assets and liabilities that are hedged are adjusted to record changes in the fair value attributable to the risks that are being hedged. Non-current assets and disposal group's held-for-sale are measured at the lower of carrying amounts and fair value less costs to sell.

b) Going Concern

The historical financial information has been prepared on a going concern basis, which contemplates the continuity of normal business activity and the realisation of assets and the settlement of liabilities in the normal course of business.

The Directors are satisfied they will be able to raise additional funds as required and thus it is appropriate to prepare the financial statements on a going concern basis. If necessary the Company can delay research and development expenditures and directors can also institute cost saving measures to further reduce corporate and administrative costs or explore other opportunities to sell data and/or its clinics. In the event that the Company is unable to obtain sufficient funding for ongoing operating and capital requirements, there is a material uncertainty that may cast significant doubt as to whether the Company will continue as a going concern and therefore proceed with realising its assets and discharging its liabilities in the normal course of business at the amounts stated in the financial report. The financial statements do not include any adjustment relating to the recoverability or classification of recorded asset amounts or to the amounts or classification of liabilities that may be necessary should the Company not be able to continue as a going concern.

However, should the fundraising under the Prospectus be unsuccessful, the entity may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of liabilities that might be necessary should the Company not continue as a going concern.

c) Reporting Basis and Conventions

The report is also prepared on an accrual basis and is based on historic costs and does not take into account changing money values or, except where specifically stated, current valuations of non-current assets.

The following is a summary of the material accounting policies adopted by the company in the preparation of the financial report. The accounting policies have been consistently applied, unless otherwise stated.

d) New accounting policies adopted

During the financial year ended 30 June 2019, the Company adopted the following accounting standards from 1 July 2018:

- AASB 15: Revenue from Contracts with Customers
- AASB 9 - Financial Instruments

AASB 15: Revenue from Contracts with Customers

This standard replaces the current accounting requirements applicable to revenue with a single, principles-based model. Except for a limited number of exceptions, including leases, the new revenue model in AASB 15 applies to all contracts with customers as well as non-monetary exchanges between entities in the same line of business to facilitate sales to customers and potential customers. AASB 15 establishes a five-step model to account for revenue arising from contracts with customers and requires that revenue to be recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The five-step process outlined in AASB 15 are as follows:

1. identify the contract(s) with a customer;
2. identify the performance obligations in the contract(s);
3. determine the transaction price;
4. allocate the transaction price to the performance obligations in the contract(s); and
5. recognise revenue when (or as) the performance obligations are satisfied.

The Company has applied the new Standard effective from 1 July 2018 using the modified retrospective approach. Under this method, the cumulative effect of all contracts that are not completed as at 1 July 2018 is recognised at the date of initial application as an adjustment to the opening balance of retained earnings. However, the Company does not have any revenue in prior year, hence, no adjustment to the opening retained earnings have been made and the comparative information was not restated.

Revenue is recognised when or as a performance obligation in the contract with customer is satisfied, i.e. when the control of the goods or services underlying the particular performance obligation is transferred to the customer. A performance obligation is a promise to transfer a distinct goods or service (or a series of distinct goods or services that are substantially the same and that have the same pattern of transfer) to the customer that is explicitly stated in the contract and implied in the Company's customary business practices.

Revenue is measured at the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods or services to the customers, excluding amounts collected on behalf of third parties such as sales taxes or services taxes. If the amount of consideration varies due to discounts, rebates, refunds, credits, incentives, penalties or other similar items, the Company estimates the amount of consideration to which it will be entitled based on the expected value or the most likely outcome. If the contract with customer contains more than one performance obligation, the amount of consideration is allocated to each performance obligation based on the relative stand-alone selling prices of the goods or services promised in the contract. Revenue is recognised to the extent that it is highly probable that a

significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The control of the promised goods or services may be transferred over time or at a point in time. The control over the goods or services is transferred over time and revenue is recognised over time if:

- i. the customer simultaneously receives and consumes the benefits provided by the Company's performance as the Company performs;
- ii. the Company's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or
- iii. the Company's performance does not create an asset with an alternative use and the Company has an enforceable right to payment for performance completed to date.

Revenue for performance obligation that is not satisfied over time is recognised at the point in time at which the customer obtains control of the promised goods or services.

Sales of service

Revenue from rendering of service is recognised upon the delivery of service to the customers.

Interest Income

Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that assets' net carrying amount on initial recognition.

AASB 9 - Financial Instruments

AASB 9 Financial instruments replaces AASB 139 Financial Instruments: Recognition and Measurement, bringing together all three aspects of accounting for financial instruments: classification and measurement, impairment and hedge accounting. The hedge accounting changes are not applicable to the Company.

Classification and measurement

Under AASB 9, the Company initially measures a financial asset as its fair value plus, in the case of financial asset not at fair value through profit or loss, transaction costs. Financial assets are then subsequently measured at fair value through profit or loss ('FVTPL'), amortised cost, or fair value through other comprehensive income ('FVOCI').

On adoption of AASB 9, the Company has reclassified its financial assets as subsequently measured at amortised cost or fair value depending on the business model for those assets and contractual cash flow characteristic. There was no change in the classification or measurement of financial liabilities. Under AASB 9 the Company's financial assets of cash and cash equivalents and trade and other receivables are classified as 'financial assets at amortised cost'.

The Standard is applicable retrospectively (subject to the comment on hedge accounting below) and includes revised requirements for the classification and measurement of financial instruments, revised recognition and derecognition requirements for financial instruments and simplified requirements for hedge accounting.

AASB: 16 Leases

As at 30 June 2019, the Company has operating lease commitments of \$919,727. The leases will be recognised as a finance lease and the interest and amortisation expense will increase and rental expense will decrease.

Financial Assets

Initial recognition and measurement

Financial assets are classified at initial recognition and subsequently measured at amortised cost, fair value through other comprehensive income (OCI), and fair value through profit or loss. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient, the Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient are measured at the transaction price determined under AASB 15.

Subsequent measurement

The Company's financial assets at amortised cost includes trade receivables.

Impairment of financial assets

For trade receivables, the Company applies a simplified approach in calculating expected credit losses ('ECLs'). Therefore, the Company does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date.

Financial Liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables or as derivatives designated as hedging instruments in an effective hedge, as appropriate. All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Company's financial liabilities include trade and other payables and convertible notes.

Subsequent measurement

Loans and borrowings

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost using the effective interest rate method. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process. Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included as finance costs in the statement of profit or loss. This category generally applies to interest-bearing loans and borrowings.

Derecognition

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognised in the statement of profit or loss.

There were no financial instruments which the Company has designated at fair value through profit or loss under AASB 139 that were subject to reclassification. The Board assessed the Company's financial assets and determined the application of AASB 9 does not result in a change in the classification of the Company's financial instruments. In relation to the reclassification and measurement of financial assets and liabilities, there was no impact on the

Statement of Profit or Loss and Other Comprehensive Income; Statement of Financial Position; or Statement of Changes in Equity on adoption of AASB 9.

Compound Instruments

The component parts of compound instruments (convertible bonds) 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. Conversion options 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 similar non-convertible instruments. This amount is recognised 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 share capital. Where the conversion option remains unexercised at the maturity date of the convertible note, the balance recognised in equity will be transferred to retained earnings. No gain or loss is recognised in profit or loss and other comprehensive income upon conversion or expiration of the conversion option. Transaction costs that relate to the issue of the convertible 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 notes using the effective interest method.

e) New, revised or amending Accounting Standards and Interpretations not adopted

Accounting Standards issued by the AASB that are not yet mandatorily applicable to the Company, together with an assessment of the potential impact of such pronouncements on the Company when adopted in future periods, are discussed below:

AASB 16: Leases (applicable to annual reporting periods commencing on or after 1 January 2019).

When effective, this Standard will replace the current accounting requirements applicable to leases in AASB 117: Leases and related interpretations. AASB 16 introduces a single lessee accounting model that eliminates the requirement for leases to be classified as either operating leases or finance leases. Lessor accounting remains similar to current practice.

The main changes introduced by the new Standard are as follows:

- recognition of the right-to-use asset and liability for all leases (excluding short term leases with less than 12 months of tenure and leases relating to low value assets);
- depreciating the right-to-use assets in line with AASB 116: Property, Plant and Equipment in profit or loss and unwinding of the liability in principal and interest components;

- inclusion of variable lease payments that depend on an index or a rate in the initial measurement of the lease liability using the index or rate at the commencement date;
- application of a practical expedient to permit a lessee to elect not to separate non-lease components and instead account for all components as a lease; and
- additional disclosure requirements.

The transitional provisions of AASB 16 allow a lease to either retrospectively apply the Standard to comparatives in line with AASB 108 or recognise the cumulative effect of retrospective application as an adjustment to opening equity at the date of initial application. Although the directors anticipate that the adoption of AASB 16 may have an impact on the Company's financial statements, it might be expected that EBITDA will improve as lease expenses will decrease while its interest and depreciation expense will increase. The current liabilities may also increase which could reduce the net working capital of the Company.

f) Income Tax

The income tax expense or revenue for the year is the tax payable on the current year's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses. Deferred income tax is provided on all temporary differences at the balance sheet date between the tax bases of the assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognised for all taxable temporary differences except where the deferred income tax arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred income tax assets are recognised for all deductible temporary differences, carry forward of unused tax assets and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax assets and unused tax losses can be utilised except where the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

The carrying amount of deferred income tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the when the asset is realised or the liability is settled, based on tax rates of (and tax laws) that have been enacted or substantially enacted at the balance sheet date. Income taxes relating to items recognised directly in equity are recognised in equity and not in the statement of comprehensive income.

g) Cash and Cash Equivalents

Cash and cash equivalents includes cash at bank and in hand, deposits held at call with financial institutions, other short-term highly liquid deposits with an original maturity 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, and bank overdrafts.

h) Revenue Recognition

Revenues are recognised at fair value of the consideration received net of the amount of GST.

Interest

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

i) Provisions

General

Provisions are recognised when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Company expects some or all of a provision to be reimbursed the reimbursement is recognised as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in the Statement of Profit or Loss and Other Comprehensive Income net of any reimbursement.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date. The discount rate used to determine the present value reflects current market assessments of the time value of money and the risks specific to the liability.

The increase in the provision resulting from the passage of time is recognised in finance costs.

j) Trade and Other Payables

Trade and other payables represent the liability outstanding at reporting date for goods and services received by the Company during the reporting year, which remain unpaid. The balance is recognised as a current liability with the amounts normally paid within 30 days of recognition of the liability.

k) Borrowings

Borrowings are initially recognised at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortised cost. Any difference between proceeds (net of transaction costs) and the redemption amount is recognised in the statement of financial performance over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the statement of financial position date.

l) Goods and Services Tax (GST)

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

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

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

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

m) Impairment of assets

At each reporting date, the Company reviews the carrying values of its tangible and intangible assets to determine whether there is any indication that those assets have been impaired. If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the income statement.

Financial Assets

A financial asset is considered to be impaired if objective evidence indicates that one or more events have had a negative effect on the estimated future cash flows of that asset.

Non-Financial Assets

The carrying amounts of the non-financial assets are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists then the asset's recoverable amount is estimated. For goodwill and intangible assets that have indefinite lives or that are not yet available for use, recoverable amount is estimated at each reporting date.

An impairment loss is recognised if the carrying amount of an asset or its cash-generating unit exceeds its recoverable amount. A cash-generating unit is the smallest identifiable asset group that generates cash flows that largely are independent from other assets and groups. Impairment losses are recognised in the statement of financial performance. Impairment losses recognised in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the units and then to reduce the carrying amount of any goodwill allocated to the units and then to reduce the carrying amount of the other assets in the unit (group of units) on a pro rata basis.

n) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. The cost of self-constructed assets includes the cost of materials and direct labour, any other costs directly attributable to bringing the assets to a working condition for their intended use, the costs of dismantling and removing the items and restoring the site on which they are located and capitalised borrowing costs.

Purchased software that is integral to the functionality of the related equipment is capitalised as part of that equipment. When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognised net within other income in profit or loss. When revalued assets are sold, the amounts included in the revaluation reserve are transferred to retained earnings.

(ii) Subsequent costs

The cost of replacing a part of an item of property, plant and equipment is recognised in the carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Company, and its cost can be measured reliably. The carrying amount

of the replaced part is derecognised. The costs of the day-to-day servicing of property, plant and equipment are recognised in profit or loss as incurred.

(iii) Depreciation

Depreciation is calculated over the depreciable amount, which is the cost of an asset, or other amount substituted for cost, less its residual value. Depreciation is recognised in the profit or loss on a straight-line basis over the estimated useful lives of each part of an item of property, plant and equipment, since this most closely reflects the expected pattern of consumption of the future economic benefits embodied in the asset. Leased assets are depreciated over the shorter of the lease term or their useful lives unless it is reasonably certain that the Company will obtain ownership by the end of the lease term.

The depreciation rates used for each class of asset are:

- fixtures and fittings 22.5% - 40%
- leasehold improvements 20%
- computer equipment and software 22.5% - 40%

Depreciation methods, useful lives and residual values are reviewed at each financial year-end and adjusted if appropriate.

o) Contributed Equity

Ordinary shares are classified as equity.

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

p) Employee Benefits

Wages and Salaries, Annual Leave and Sick Leave

Liabilities for wages and salaries, including non-monetary benefits, annual leave and accumulating sick leave expected to be settled within 12 months of the statement of financial position date are recognised in respect of employees' services rendered up to statement of financial position date and measured at amounts expected to be paid when the liabilities are settled.

Liabilities for non-accumulating sick leave are recognised when leave is taken and measured at the actual rates paid or payable. Liabilities for wages and salaries are included as part of Other Payables and liabilities for annual and sick leave are included as part of Employee Benefit Provisions.

Long Service Leave

Liabilities for long service leave are recognised as part of the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees to the statement of financial position date using the projected unit credit method. Consideration is given to expect future salaries and wages levels, experience of employee departures and periods of service. Expected future payments are discounted using national government bond rates at the statement of financial position date with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

Share-based payments transactions

The Company provides benefits to employees (including directors) of the Company in the form of share options. The fair value of options granted is recognised as an employee expense with a corresponding increase in equity. The fair value is measured at grant date and spread over the period during which the employee becomes unconditionally entitled to the options. The fair value of the options granted is measured using Black-Scholes valuation model, taking into account the terms and conditions upon which the options were granted.

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, on a straight line basis over the period from grant date to the date on which the relevant employees become fully entitled to the award (**‘Vesting date’**). The amount recognised as an expense is adjusted to reflect the actual number that vest.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

q) Accounting estimates and judgements

In the process of applying the accounting policies, management has made certain judgements or estimations which have an effect on the amounts recognised in the financial information.

The carrying amounts of certain assets and liabilities are often determined based on estimates and assumptions of future events. The key estimates and assumptions that have a significant risk causing a material adjustment to the carrying amounts of certain assets and liabilities within the next annual reporting period are:

Valuation of share based payment transactions

The valuation of share-based payment transactions is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using the Black Scholes model taking into account the terms and conditions upon which the instruments were granted.

Options

The fair value of options issued is determined using the Black-Scholes model, taking into account the terms and conditions upon which the options were granted.

Taxation

The Company is subject to income taxes in Australia. Significant judgement is required when determining the Company’s provision for income taxes. The Company estimates its tax liabilities based on the Company’s understanding of the tax law.

	Audited as at 30-Jun-19	Pro-forma after Offer Min	Pro-forma after Offer Max
NOTE 2. CASH AND CASH EQUIVALENTS	\$	\$	\$
Cash and cash equivalents	2,658,814	8,885,592	10,763,592
Audited balance of Emerald at 30 June 2019		2,658,814	2,658,814
<i>Subsequent events:</i>			
Proceeds from pre-IPO Raise		500,000	500,000
R&D refund received		409,078	409,078
		909,078	909,078
<i>Pro-forma adjustments:</i>			
Proceeds from shares issued under this Prospectus		6,000,000	8,000,000
Capital raising costs		(682,300)	(804,300)
		5,317,700	7,195,700
Pro-forma Balance		8,885,592	10,763,592

	Audited as at 30-Jun-19	Pro-forma after Offer
NOTE 3. CONVERTIBLE NOTES	\$	\$
Convertible notes	2,752,621	-
Audited balance of Emerald at 30 June 2019		2,752,621
<i>Pro-forma adjustments:</i>		
Conversion of convertible notes at \$0.16 per share		(2,752,621)
		(2,752,621)
Pro-forma Balance		-

		Audited as at 30-Jun-19	Pro-forma after Offer Min	Pro-forma after Offer Max
NOTE 4. CONTRIBUTED EQUITY		\$	\$	\$
Contributed equity		2,872,738	13,004,088	14,883,088
	Number of Shares (min)	Number of Shares (max)	\$	\$
Audited balance of Emerald at 30 June 2019	130,500,000	130,500,000	2,872,738	2,872,738
	130,500,000	130,500,000	2,872,738	2,872,738
<i>Subsequent events:</i>				
Issue of shares for pre-IPO raise	2,777,778	2,777,778	500,000	500,000
	2,777,778	2,777,778	500,000	500,000
<i>Pro-forma adjustments:</i>				
Conversion of Convertible Notes	20,625,000	20,625,000	4,125,000	4,125,000
Proceeds from shares issued under this Prospectus	30,000,000	40,000,000	6,000,000	8,000,000
Costs of the Offer	-	-	(493,650)	(614,650)
	50,625,000	60,625,000	9,631,350	11,510,350
Pro-forma Balance	183,902,778	193,902,778	13,004,088	14,883,088

	Audited as at 30-Jun-19	Pro-forma after Offer
NOTE 5. RESERVES	\$	\$
Reserves	374,069	156,050
Audited balance of Emerald at 30 June 2019		374,069
<i>Subsequent events:</i>		
Grant of options to employees and consultants		46,800
		46,800
<i>Pro-forma adjustments:</i>		
Transfer of Convertible Notes to issued capital on conversion		(369,334)
Additional expense on revaluation of Existing Options		104,515
		(264,819)
Pro-forma Balance		156,050

The following Options were issued subsequent to 30 June 2019:

- 3,500,000 employee Options were issued to the Managing Director on 10 July 2019 at an exercise price of \$0.45 per share with an expiry of 13 June 2023. The vesting conditions are:
 - One third vest immediately on issue;
 - One third vest one year from date of issue subject to continued employment or service; and
 - One third vest two years from date of issue subject to continued employment or service.
- 600,000 Options were issued to Australian Medical Research as per the Heads of Agreement entered into with the Company. The Options were issued on 26 September 2019 at an exercise price of \$0.45 per share with an expiry 26 September 2023. The vesting conditions are:
 - One third vest immediately on issue;
 - One third vest twelve months from date of issue as per the heads of agreement between the Company and Australian Medical Research (**Heads of Agreement**); and
 - One third vest eighteen months from date of issue as per the Heads of Agreement.
- 1,000,000 Options were issued to a medical consultant on 24 October 2019 at an exercise price of \$0.45 per share with an expiry of 13 June 2023. The vesting conditions are:

- One third vest immediately on issue;
 - One third vest one year from date of issue subject to continued employment or service; and
 - One third vest two years from date of issue subject to continued employment or service.
- 1,000,000 employee Options were issued to the Chief Financial Officer on 12 November 2019 at an exercise price of \$0.45 per share with an expiry of 13 June 2023. The vesting conditions are:
 - One third vest immediately on issue;
 - One third vest one year from date of issue subject to continued employment or service; and
 - One third vest two years from date of issue subject to continued employment or service.

The fair value of the options has been calculated using the Black-Scholes option pricing model. The terms of the options issued and the inputs used in valuing the options is set out below:

Existing Options

Item	Existing Options (Vested)	Existing Options	Consultants Options
Value of the underlying security	\$0.10	\$0.10	\$0.10
Exercise price	\$0.45	\$0.45	\$0.45
Valuation date	13-Jun-19	13-Jun-19	19-Jun-19
Expiration date	13-Jun-23	13-Jun-23	13-Jun-23
Life of the options (years)	4.00	4.00	3.99
Volatility	70%	70%	70%
Dividend yield	Nil	Nil	Nil
Risk-free rate	0.99%	0.99%	0.97%
Number of Options	1,500,000	9,750,000	1,000,000
Valuation per Option	\$0.019	\$0.019	\$0.019
Valuation per Tranche	\$28,500	\$185,250	\$19,000
Value that vests immediately	\$28,500 ¹	\$61,750 ²	\$19,000 ¹

¹ Options vest immediately

² Given that one third of the Options vest immediately on issue, the pro-forma balance sheet has been adjusted to reflect one third of the value of the Options.

The share based payments expense that has been included in the audited financial statements for the year ended 30 June 2019 is \$4,735. Based on the above valuations, the expense for the year ended 30 June 2019 is \$109,250. Therefore, the pro-forma balance sheet has been adjusted to reflect an additional expense of \$104,515.

Options Issued subsequent to 30 June 2019

Item	Managing Director Options	Australian Medical Research Options	Medical Consultant Options	Chief Financial Officer Options
Value of the underlying security	\$0.10	\$0.10	\$0.10	\$0.18
Exercise price	\$0.45	\$0.45	\$0.45	\$0.45
Valuation date	10-Jul-19	26-Sep-19	24-Oct-19	11-Nov-19
Expiration date	13-Jun-23	26-Sep-23	13-Jun-23	13-Jun-23
Life of the options (years)	3.93	4.00	3.64	3.59
Volatility	70%	70%	70%	70%
Dividend yield	Nil	Nil	Nil	Nil
Risk-free rate	0.97%	0.70%	0.74%	0.84%
Number of Options	3,500,000	600,000	1,000,000	1,000,000
Valuation per Option	\$0.018	\$0.019	\$0.016	\$0.050
Valuation per Tranche	\$63,000	\$11,400	\$16,000	\$50,000
Value that vests immediately	\$21,000	\$3,800	\$5,333	\$16,667

¹ Options vest immediately

² Given that one third of the Options vest immediately on issue, the pro-forma balance sheet has been adjusted to reflect one third of the value of the Options. The remaining value of the Options will be expensed over the vesting period, therefore as at the pro-forma date, there is no adjustment required. Therefore, the total adjustment to the pro-forma balance sheet is \$46,800.

	Audited as at 30-Jun-19	Pro-forma after Offer Min	Pro-forma after Offer Max
NOTE 6. ACCUMULATED LOSSES	\$	\$	\$
Accumulated losses	(2,747,268)	(3,681,200)	(3,682,200)
Audited balance of Emerald at 30 June 2019		(2,747,268)	(2,747,268)
<i>Subsequent events:</i>			
Share based payments expense for Employee options		(46,800)	(46,800)
R&D refund received		409,078	409,078
		362,278	362,278
<i>Pro-forma adjustments:</i>			
Financing charge associated with Convertible Notes		(1,003,045)	(1,003,045)
Costs of the Offer not directly attributable to the capital raising		(188,650)	(189,650)
Additional expense on revaluation of Existing Options		(104,515)	(104,515)
		(1,296,210)	(1,297,210)
Pro-forma Balance		(3,681,200)	(3,682,200)

NOTE 7: RELATED PARTY DISCLOSURES

Transactions with Related Parties and Directors Interests are disclosed in the Prospectus.

NOTE 8: COMMITMENTS AND CONTINGENCIES

At the date of the report no material commitments or contingent liabilities exist that we are aware of, other than those disclosed in the Prospectus.

APPENDIX 5

FINANCIAL SERVICES GUIDE

BDO Corporate Finance (WA) Pty Ltd ABN 27 124 031 045 ('we' or 'us' or 'ours' as appropriate) has been engaged by Emerald Clinics Limited ('the Company') to provide an Independent Limited Assurance Report ('ILAR' or 'our Report') for inclusion in this Prospectus.

Financial Services Guide

In the above circumstances we are required to issue to you, as a retail client, a Financial Services Guide ('FSG'). This FSG is designed to help retail clients make a decision as to their use of the general financial product advice and to ensure that we comply with our obligations as financial services licensee.

This 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. 316158;
- remuneration that we and/or our staff and any associates receive in connection with the general financial product advice;
- any relevant associations or relationships we have; and
- our internal and external complaints handling procedures and how you may access them.

Information about us

BDO Corporate Finance (WA) Pty Ltd 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 financial product advice in our Report is provided by BDO Corporate Finance (WA) Pty Ltd 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.

Financial services we are licensed to provide

We hold an Australian Financial Services Licence that authorises us to provide general financial product advice for securities to retail and wholesale clients.

When we provide the authorised financial services we are engaged to provide an ILAR in connection with the financial product of another entity. Our Report indicates who has engaged us and the nature of the report we have been engaged to provide. When we provide the authorised services we are not acting for you.

General Financial Product Advice

We only provide general financial product advice, not personal financial product advice. Our Report does not take into account your personal objectives, financial situation or needs. You should consider the appropriateness of this general advice having regard to your own objectives, financial situation and needs before you act on the advice.

Fees, commissions and other benefits that we may receive

We charge fees for providing reports, including this Report. These fees are negotiated and agreed with the person who engages us to provide the report. Fees are agreed on an hourly basis or as a fixed amount depending on the terms of the agreement. The fee payable to BDO Corporate Finance (WA) Pty Ltd for this engagement is approximately \$15,000 (exclusive of GST).

Except for the fees referred to above, neither BDO, 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 the Report.

Remuneration or other benefits received by our employees

All our employees receive a salary. Our employees are eligible for bonuses based on overall productivity but not directly in connection with any engagement for the provision of a report. We have received a fee from Emerald for our professional services in providing this Report. That fee is not linked in any way with our opinion as expressed in this 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.

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. All complaints must be in writing addressed to The Complaints Officer, BDO Corporate Finance (WA) Pty Ltd, 38 Station Street, Subiaco, Perth WA 6008.

When we receive a written 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

A complainant 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 was established on 1 November 2018 to allow for the amalgamation of all Financial Ombudsman Service schemes into one. AFCA will deal with complaints from consumers in the financial system by providing free, fair and independent financial services complaint resolution. If an issue has not been resolved to your satisfaction you can lodge a complaint with AFCA at any time.

Our AFCA Membership Number is 12561. Further details about AFCA are available on its website www.afca.org.au or by contacting it directly via the details set out below:

Australian Financial Complaints Authority
GPO Box 3
Melbourne VIC 3001
Toll free: 1300 931 678
Website: www.afca.org.au

Contact details

You may contact us using the details set out on page 2 of our Report.

Annexure B Legal Opinion

5 December 2019

Legal opinion for Emerald Clinics Limited

To: Adam James
Commercial Director
Emerald Clinics Limited

Opinion on medicinal cannabis prescribing and health data use by Emerald Clinics Limited

Part A Introduction

1. Request for an opinion

You have asked us to provide an opinion in relation to Emerald Clinics Limited's (**Emerald**) prescribing of cannabinoid medicines and commercialisation of patient health data for the purpose of research.

It is intended that this Opinion be publicised in association with Emerald's initial public offering (**Capital Raising**) and may be included in its accompanying prospectus.

This Opinion addresses the following questions, in the following parts:

- Part B: Can Emerald's medical practitioners (**Emerald Medical Practitioners**) lawfully prescribe medicinal cannabis products?
- Part C: Can Emerald lawfully conduct clinical trials using medicinal cannabis products?
- Part D: Can Emerald advertise its business without breaching prohibitions relating to advertising medicinal cannabis products and other relevant advertising prohibitions?
- Part E: Can Emerald lawfully commercialise the identifiable information it collects about its patients?

2. Summary and conclusions

2.1 Prescribing medicinal cannabis products

We are not aware of any legal barriers to Emerald Medical Practitioners prescribing registered or unapproved medicinal cannabis products if they have the appropriate Commonwealth and state approvals or permits to do so.

We have reviewed relevant representative documentation evidencing that Emerald Medical Practitioners have previously received Commonwealth approvals to prescribe unregistered medicinal cannabis products either through the Special Access Scheme (Category B) or the Authorised Prescriber Scheme. We are not aware of any reason why the Emerald Medical Practitioners would be unable to obtain such approvals in the future.

We have reviewed relevant representative documentation evidencing that Emerald Medical Practitioners have previously received state approvals or permits to prescribe medicinal cannabis products as required by the particular state. We are not aware of any reason why the Emerald Medical Practitioners would be unable to obtain such approvals or permits in the future.

2.2 Clinical trials

We are not aware of any reason why Emerald may not lawfully conduct or otherwise be involved in clinical trials of registered or unapproved medicinal cannabis products through the Clinical Trial Notification (CTN) Scheme or the Clinical Trial Exemption (CTX) Scheme, as appropriate.

2.3 Advertising of medicinal cannabis products

In Australia, the advertising of therapeutic goods, and especially Schedule 4 and Schedule 8 substances, such as medicinal cannabis products, is tightly regulated. It is an offence for a person to advertise a Schedule 4 or Schedule 8 substance. It is also an offence to advertise an unapproved therapeutic good the subject of an Authorised Prescriber or Special Access Scheme approval.

We have reviewed what can be expected to be Emerald's main form of advertising, its website, and we consider that there are no instances of breach of laws relating to the advertising of therapeutic goods, including medicinal cannabis products.

2.4 Commercialisation of patient identifiable information

Emerald intends to commercialise patient identifiable information in the form of real world evidence (**RWE**) to support innovation across the cannabinoid medicine industry. Emerald is subject to the *Privacy Act 1988* (Cth) and other privacy laws in its handling of patient identifiable information.

We have reviewed the key elements of applicable privacy laws—collection, use and disclosure, deidentification and non-reidentification, security, and privacy by design—as they apply to Emerald's intentions to commercialise patient identifiable information. We are not aware of any compliance barriers to Emerald pursuing this aspect of its business.

3. Our expertise

Geoff Bloom specialises in providing commercial and regulatory advice to health, life sciences and aged care and disability industries, as well as privacy advice. He has practiced in these areas for over 20 years, 10 years of which he has been a partner at HWL Ebsworth.

Geoff's clients include:

- (a) *Health services providers*: operators of public and private hospitals, medical centres, medical imaging providers, IVF providers, abortion providers, pharmacy businesses, and providers of medical services in relation to medicinal cannabis products;
- (b) *Life sciences industry*: universities and medical research organisations, medical device manufacturers and pharmaceutical companies, including sponsors of medicinal cannabis products;
- (c) *Government agencies*: Commonwealth Department of Human Services, the National Health and Medical Research Council, the Australian Health Ministers Advisory Council, NSW Health, the Tasmanian Health and Human Services; and
- (d) *Aged care and disability industry*: For profit and not for profit providers of residential and home care services for the aged, and for profit and not for profit disability services providers.

Geoff is:

- (a) co-author of CCH's *Australian Privacy Law Reporter*;
- (b) a member of the Editorial Board of LexisNexis' *Privacy Law Bulletin*; and
- (c) a member of the Privacy Law Committee, Law Council of Australia.

Over several years including the current year, Geoff has been named in Best Lawyers as one of Australia's best lawyers in the fields of Health & Aged Care, Life Sciences Practice, and Privacy and Data Protection, as well as in in Doyle's Guide to the Australian Legal Profession as a Leading Lawyer in Health & Aged Care.

He was formerly a Principal Legal Officer at NSW Health, Adjunct Lecturer in Health Law at the UNSW Faculty of Law, and Policy Advisor at the AIDS Council of NSW.

HWL Ebsworth is a leading Australian law firm, with offices in all capital cities in Australia, and is the largest law firm in Australia by partner numbers.

Part B Prescribing of medicinal cannabis

4. Background to Emerald's prescribing of medicinal cannabis

4.1 Background documents

In preparing this Opinion we have relied on the following documents provided by you:

- (a) eight notices from the Therapeutic Goods Administration (**TGA**) relating to Special Access Scheme (Category B) approvals of the Emerald Medical Practitioners (**SAS-B Approvals**). The SAS-B Approvals ranged in date from 30 May 2019 to 12 November 2019;
- (b) seven letters from the TGA to Dr Finch approving Dr Finch as an authorised prescriber in relation to seven medicinal cannabis products (**Dr Finch's AP Approvals**). Dr Finch's AP Approvals ranged in date from 8 April 2019 to 22 August 2019;
- (c) fourteen letters from the Therapeutic Goods Administration to Dr Gunn approving Dr Gunn as an authorised prescriber in relation to 14 separate medicinal cannabis products (**Dr Gunn's AP Approvals**). Dr Gunn's AP Approvals are all dated 11 November 2019;
- (d) a letter from the National Institute of Integrative Medicine to Associate Professor Alistair Vickery dated 4 October 2019 stating that the Institute's Human Research Ethics Committee had approved Associate Professor Vickery's authorised prescriber application (**A/Prof Vickery's HREC Approval**).
- (e) a letter from the National Institute of Integrative Medicine to Dr Stephen Chalk dated 4 October 2019 stating that the Institute's Human Research Ethics Committee had approved Dr Chalk's authorised prescriber application (**Dr Chalk's HREC Approval**);
- (f) five notices from the Western Australian Department of Health authorising the Emerald Medical Practitioners in that state to prescribe a schedule 8 medicine (**WA-S8 Notices**). The notices ranged in date from 30 May 2019 to 7 November 2019;
- (g) a letter from the Western Australian Department of Health dated 10 June 2019 approving Dr Finch to prescribe four schedule 8 cannabis based products (**Dr Finch's WA-S8 Approval**);
- (h) a permit dated 1 November 2019 from the Victorian Department of Health and Human Services authorising Dr Francis Olopade to prescribe a specific cannabinoid medicine to a specific patient (**Dr Olopade's Permit**);
- (i) a six page document entitled 'Medicinal Cannabis - Informed Consent' which discusses the possible benefits, possible risks, risk management plan, avoiding

pregnancy, driving or operating machinery, roadside drug testing, employment matters and a list of sixteen conditions the patient agrees to abide by in order to receive ongoing treatment at medical clinics operated by Emerald (**Medicinal Cannabis Consent Form** and **Emerald Clinics**, respectively); and

- (j) Emerald's website available via: <https://www.emeraldclinics.com.au/> [accessed 28 November 2019].

4.2 Background facts

Based on our discussions with you, we understand that the three questions relating to Emerald's prescribing of medicinal cannabis (see paragraph 1 above) arise out of the following facts:

- (a) Emerald's strategic goal is to become the leading, independent operator of data-driven, patient-centric, specialist cannabinoid management clinics across Australia and the world;
- (b) where appropriate, Emerald provides patients with access to a range of imported and domestically-produced medicinal cannabis products;
- (c) Emerald currently operates clinics in Subiaco in Western Australia, Woolloomooloo and Tintenbar in New South Wales, and Richmond in Victoria;
- (d) Emerald intends to open additional clinics in 2020 and extend into South Australia and Queensland;
- (e) currently, Emerald contracts seven general practitioners and one pain specialist who prescribe medicinal cannabis products to patients (**Emerald Medical Practitioners**);
- (f) the following Emerald Medical Practitioners are located in the following states:
 - (i) *Western Australia*: Associate Professor Vickery, Dr Stephen Chalk, Dr Ben Addison, Dr Jenny Tai, and Dr Philip Finch;
 - (ii) *Victoria*: Dr Francis Olapade;
 - (iii) *New South Wales*: Dr David Gunn and Dr Nelson Lau;
- (g) Emerald Medical Practitioners typically prescribe medicinal cannabis products that are not registered on the Australian Register of Therapeutic Goods;
- (h) two Emerald Medical Practitioners are Authorised Prescribers (see paragraph 6.3 below for the definition of an Authorised Prescriber), with the remaining eight Emerald Medical Practitioners prescribing medicinal cannabis products via the Special Access Scheme (Category B) pathway;
- (i) although the Emerald Medical Practitioners prescribe medicinal cannabis products to patients, Emerald does not cultivate, manufacture, import, export, or administer cannabis or cannabis products; and

- (j) Emerald has no affiliation with any pharmacists, or financial interest in any pharmacies, that dispense medicinal cannabis products to patients.

5. Overview of medicinal cannabis laws in Australia

5.1 Therapeutic Goods Act

Medicinal cannabis is regulated at both a federal, and state and territory, level in Australia by multiple pieces of legislation. At a federal level the two main acts are the *Narcotic Drugs Act 1967* (Cth), which regulates the cultivation and manufacture of medicinal cannabis, and the *Therapeutic Goods Act 1989* (Cth) (**TG Act**), which regulates the supply, import, export, manufacturing and advertising of medicinal cannabis.¹

At a state and territory level, a variety of medicines and poisons acts regulate access to medicinal cannabis. Each state or territory's respective medicines and poisons legislation does this by reference to the national *Standard for the Uniform Scheduling of Medicines and Poisons* (**Poisons Standard**). The Poisons Standard provides a risk based framework for categorising medicines and poisons, including medicinal cannabis products (see paragraph 5.2 below).

As Emerald does not cultivate, manufacture, import, export or administer medicinal cannabis, the legislation governing these activities, such as the *Narcotic Drugs Act 1967* (Cth) or the *Customs Act 1901* (Cth), does not directly apply to Emerald. Instead the prescribing of medicinal cannabis products by Emerald Medical Practitioners is governed chiefly by the TG Act and the applicable state or territory poisons and medicines legislation.

5.2 Poisons Standard

The Poisons Standard is incorporated by reference into the TG Act, and maintained by the Therapeutic Goods Administration (**TGA**). The Poisons Standard sits at the centre of a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into schedules in the Poisons Standard according to the risk they pose to public health and safety. The decision to include a medicine in a particular schedule takes into consideration toxicity, the purpose of use, potential for abuse, safety in use, and the need for the substance.

The Poisons Standard categorises "poisons" in ten schedules according to the degree of control recommended to be exercised over their availability to the public. Poisons for therapeutic use (medicines) are mostly included in Schedules 2, 3, 4 and 8 with progression through these schedules signifying increasingly restrictive regulatory controls. Schedule 9 sets out prohibited substances.

Schedules 2 and 3 of the Poisons Standard set out medicines that are pharmacy medicines available without prescription. Schedules 2 and 3 do not include any cannabis products or extracts. Schedule 4 sets out medicines that are only available via prescription and includes a cannabis extract known as cannabidiol (**CBD**). A medicine

¹ The *Customs Act 1901* (Cth) also regulates the import and export of medicinal cannabis.

comprised of CBD is only considered a Schedule 4 medicine where the CBD comprises 98% or more of the total cannabinoid content of the preparation. If other cannabinoids comprise more than 2% of the CBD extract, the medicine will be considered a Schedule 8 substance (see below).

Schedule 8 of the Poisons Standard sets out controlled drugs. Controlled drugs are prescription-only medicines that are subject to controls additional to those applying to Schedule 4 medicines. Controlled drugs are substances which are available for therapeutic use but require further restrictions to reduce abuse, misuse and physical or psychological dependence. Cannabis is a Schedule 8 medicine when prepared appropriately for human therapeutic use. Other cannabis extracts or derivatives, such as nabiximols, dronabinol (delta-9-tetrahydrocannabinol) and tetrahydrocannabinols (**THC**), are also Schedule 8 medicines when prepared appropriately for human therapeutic use.

Schedule 9 of the Poisons Standard contains prohibited substances which may be abused or misused and are only available for medical or scientific research, or for analytical, teaching or training purposes with the approval of Commonwealth and state or territory health authorities. Schedule 9 includes substances like heroin. It also includes cannabis unless the specific form of cannabis is provided for elsewhere in the schedules or is classified as hemp. Hemp is a strain of cannabis with low THC content. Schedule 9 also includes THC, when not prepared appropriately, and synthetic cannabinomimetics, which are substances that mimic cannabinoids.

6. Prescribing medicinal cannabis products in accordance with the TG Act

Prescription of medicinal cannabis products is regulated at a federal level by the TG Act and the *Therapeutic Goods Regulation 1990* (Cth) (**TG Regulations**). The TGA is a division of the Australian Department of Health and is the regulatory body responsible for administering the TG Act. It regulates the supply, import, export, manufacturing and advertising of therapeutic goods.

Therapeutic goods are products that are intended to be used for human health and include medicines, biologicals and medical devices.² The TGA's approach to regulation of therapeutic goods depends on the level of risk to public health or safety posed by the product. Therapeutic goods that pose a higher risk of adverse effects are more tightly regulated and monitored than those that pose a lower risk.

One of the main ways the TGA regulates therapeutic goods is by maintaining the Australian Register of Therapeutic Goods (**ARTG**). A person cannot supply therapeutic goods in Australia unless they are listed or registered on the ARTG or subject to certain exemptions. Therapeutic goods must either be listed, if they are low risk, or registered, if they are higher risk. Prescription medicines (Schedule 4 or 8 substances) require registration.³

² See *Therapeutic Goods Act 1989* (Cth) s 3.

³ See *Therapeutic Goods Act 1989* (Cth) ss 26A(2)(ca) and 26BB(1)(a); *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2019* (Cth) Sch 1.

The entries of medicines registered on the ARTG state the indication (purpose) for which the medicine is to be used. In order for a sponsor (such as a manufacturer or importer) to have their medicine registered on the ARTG they must produce sufficient evidence, which may include clinical trial data, to demonstrate to the TGA the safety and efficacy of the medicine.

All cannabis medicines, such as CBD and THC, are prescription medicines (see paragraph 5.2 above) and therefore require registration on the ARTG. Although several cannabis medicines are listed for export only, there is currently only one cannabis medicine registered for supply in Australia. That is Sativex Oromucosal Spray (an aerosol of nabiximols 80 mg/mL) that is indicated for the improvement of spasticity in multiple sclerosis (MS) patients.

It is an offence for a person to import, export, manufacture or supply an unregistered or unlisted therapeutic good.⁴ There are two main exceptions to this requirement and that is if the therapeutic good is exempt under the TG Regulations or the subject of a limited approval by the Secretary of the Department of Health.⁵ These two exceptions provide the legal basis for what are known as the Special Access Scheme, the Authorised Prescriber Scheme and the Clinical Trials Scheme. Under these different schemes patients may be able to access unapproved therapeutic goods with medicinal cannabis as an active pharmaceutical ingredient.

6.1 The Special Access Scheme, Category B

Section 19(1)(a) of the TG Act states that the Secretary may grant an approval to a health practitioner to import, export, or supply an unregistered therapeutic good for use in the treatment of another person. An approval under section 19(1)(a) may be given subject to such conditions as are specified in the notice of approval. This provision provides the legal basis for what is known as the Special Access Scheme.

There are three further sub-pathways within the Special Access Scheme, described as Category A, Category B (**SAS-B**), and Category C. The Category A and C pathways are notification pathways that are typically not suitable for prescribing medicinal cannabis. The SAS-B is an application pathway that allows for health practitioners to apply to the TGA for approval to supply a specified medicinal cannabis product to a specified patient. Generally, applications are made by medical practitioners, but other health practitioners, such as dentists, nurses, and psychologists, may also apply depending on the product.

When lodging an application for an SAS-B approval the applicant medical practitioner may only propose treating the patient with a medicinal cannabis product that conforms with the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 (TGO 93)*. TGO 93 is an order made by the Minister setting out a standard designed to ensure the quality of medicinal cannabis products supplied in Australia.

When deciding whether to approve an SAS-B application for medicinal cannabis the Secretary must review the evidence of efficacy and safety relating to the specific medicinal cannabis product, the seriousness of the patient's condition, and the

⁴ See *Therapeutic Goods Act 1989* (Cth) s 19B.

⁵ See *Therapeutic Goods Act 1989* (Cth) ss 18 and 19.

qualifications or expertise of the applicant medical practitioner.⁶ If the Secretary is satisfied that the evidence is sufficient they may approve the application. If the Secretary decides not to grant the approval they must provide reasons for their decision.⁷ The Secretary may grant an SAS-B approval subject to such conditions as are specified in the notice of approval.⁸

The TGA's website indicates the number of SAS-B approvals for unregistered medicinal cannabis products has increased more than ten-fold over the past year. In October 2018 the Secretary approved 331 SAS-B applications, while in October 2019 the Secretary approved 3,594 applications.⁹ To date, the TGA has approved SAS-B applications for, among other things, the following indications:

- (a) chemotherapy-induced nausea and vomiting;
- (b) refractory paediatric epilepsy;
- (c) palliative care indications;
- (d) cancer pain;
- (e) neuropathic pain;
- (f) spasticity from neurological conditions; and
- (g) anorexia and wasting associated with chronic illness (such as cancer).¹⁰

6.2 SAS-B approvals of Emerald Medical Practitioners

We requested Emerald provide us with samples of SAS-B approvals relating to the Emerald Medical Practitioners. Emerald selected, and provided us with, the SAS-B Approvals (see paragraph 4.1(a) above) which we have reviewed.

Each SAS-B Approval corresponds to an SAS-B approval for a different Emerald Medical Practitioner. Each approval relates to only one medicinal cannabis product for one patient. Emerald redacted each patient's personal information on the SAS-B Approvals, but it has informed us that each notice corresponds to a different patient.

The SAS-B Approvals refer to four different medicinal cannabis products comprising solutions or oils consisting of THC or CBD or both as the active pharmaceutical ingredient. The four different products vary in the ratio of THC to CBD, or the concentrations of THC and CBD, or both. The approvals range from 6 to 12 months.

⁶ See *Special Access Scheme Guidance for health practitioners and sponsors V1.1 September 2017* p 15. <https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf> [accessed at 29 November 2019].

⁷ See *Therapeutic Goods Act 1989* (Cth) s 19(4).

⁸ See *Therapeutic Goods Act 1989* (Cth) s 19(1).

⁹ <https://www.tga.gov.au/access-medicinal-cannabis-products-1> [accessed at 29 November 2019].

¹⁰ <https://www.tga.gov.au/access-medicinal-cannabis-products-1> [accessed at 29 November 2019].

Each SAS-B Approval sets out conditions imposed by the Secretary. The conditions of each notice require the Emerald Medical Practitioner to do the following:

- (a) only supply the treatment to the patient in accordance with the manner set out in the application;
- (b) accept responsibility (along with the patient) for the outcome of the use of the specified medicine;
- (c) obtain informed consent in writing from the patient in relation to the proposed use of the specified medicine; and
- (d) report adverse events or defects associated with the use of the specified medicine to the TGA within 15 calendar days of the practitioner becoming aware of the adverse event or defect.

In addition to reviewing the SAS-B Approvals, we reviewed Emerald's most recent Medicinal Cannabis Consent Form. We are satisfied the consent form includes the information required under the SAS-B approval conditions.

In summary, for each Emerald Medical Practitioner we have sighted an SAS-B approval that permits the respective Emerald Medical Practitioner to prescribe a specified medicinal cannabis product to a specified patient for a period of 6 or 12 months. On the assumption that the documents that we have reviewed are relevantly typical, we have no reason to believe that Emerald Medical Practitioners will not be able to continue utilising the SAS-B pathway when seeking to prescribe medicinal cannabis to their patients.

As an SAS-B approval is a Commonwealth government approval to prescribe an unregistered medicinal cannabis product, the Emerald Medical Practitioner may also require an approval from the state government of their jurisdiction in order to lawfully prescribe the product to their patient (see paragraphs 7 to 12 below for an analysis of state legislation applying to Emerald's prescribing).

6.3 The Authorised Prescriber Scheme

Section 19(5) of the TG Act states the Secretary may authorise a specified medical practitioner to supply specified unregistered therapeutic goods, or a class of goods, to a specified class of recipients. This provides the legal basis for what is known as the **Authorised Prescriber Scheme**.

The Authorised Prescriber Scheme differs from the SAS-B scheme in that it allows for a medical practitioner to be authorised by the Secretary to provide a medicinal cannabis product, or multiple products, for a particular condition or conditions, rather than to a specific person. It therefore entails a lower degree of ongoing regulatory oversight.

In order to become an Authorised Prescriber a medical practitioner must first receive approval from a Human Research Ethics Committee (**HREC**)¹¹ with respect to the product

¹¹ A reference to a Human Research Ethics Committee (HREC) in this opinion is a reference to an ethics committee constituted and operating in accordance with the *National Health and Medical Research Council Act 1992* (Cth).

or class of products they want to prescribe for a particular condition or conditions.¹² If the medical practitioner does not have access to an HREC they may instead seek approval from a 'specialist college with established expertise relevant to the use of the medicines'.¹³

As the Secretary may approve an Authorised Prescriber application subject to any conditions¹⁴ or may impose further conditions after granting approval,¹⁵ the TGA has set out guidance on what conditions are usually imposed by the Secretary.¹⁶ The TGA guidance states that medical practitioners who become Authorised Prescribers must:

- *remain informed about changes to the benefits and risks of the good as they arise;*
- *consider the potential benefits and risks the unapproved good may offer each patient it is prescribed for;*
- *obtain written informed consent from each patient before prescribing;*
- *arrange supply of the goods directly through a sponsor or pharmacy;*
- *monitor the patient during and after use of the unapproved good;*
- *provide the TGA with a supply report every six months for the periods ending 30 June and 31 December;*
- *inform the TGA of adverse events associated with use of the good;*
- *meet any conditions the TGA, HREC or specialist college applies to the approval or endorsement; and*
- *comply with relevant state or territory legislation governing the supply of therapeutic goods.¹⁷*

6.4 Authorised Prescriber approvals of Emerald Medical Practitioners

We have reviewed Dr Finch's AP Approvals (see 4.1(b) above) and Dr Gunn's AP Approvals (see 4.1(c) above). Each approval relates to a single specified medicinal cannabis product and sets out the indications for which the Emerald Medical Practitioner can prescribe the product. Like the SAS-B Approvals, the products referred to in the Authorised Prescriber Approvals vary in form (oil, capsule and solution), concentration of THC and CBD, and ratio of THC to CBD.

¹² See *Therapeutic Goods Act 1989* (Cth) s 19(6)(aa).

¹³ See *Therapeutic Goods Regulations 1990* (Cth) reg 12B(1A)(b).

¹⁴ See *Therapeutic Goods Act 1989* (Cth) s 19(5A).

¹⁵ See *Therapeutic Goods Act 1989* (Cth) s 19(5B).

¹⁶ TGA, Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors, <https://www.tga.gov.au/authorised-prescriber-scheme>, accessed 30 November 2019.

¹⁷ TGA, Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors, <https://www.tga.gov.au/authorised-prescriber-scheme>, accessed 30 November 2019.

All of the approvals state that the applications were supported by HREC approvals from the National Institute of Integrative Medicine (NIIM) HREC. The indications for each product are the same, and are as follows:

Cancer pain and or palliation

Inclusive of cancer pain, chemotherapy or cancer associated nausea and vomiting, anorexia, insomnia, cachexia related to cancer treatment when standard treatments have failed to adequately control symptoms and/or if the patient suffers intolerable adverse reactions or side-effects to standard care therapies or medications.

Chronic non-cancer pain (CNCP)

When all other standard therapies have proven inadequate to control symptoms and/or if the patient suffers intolerable adverse reactions or side-effects to standard care treatment or medications.

Chronic pain to include, but not limited to conditions below:

- *Neuropathic pain when all other standard therapies have proven inadequate to control symptoms and/or if the patient suffers intolerable adverse reactions or side-effects to standard care treatment or medications.*
- *Musculo-skeletal pain when all other standard care therapies have proven inadequate to control symptoms and/or if the patient suffers intolerable adverse reactions or side-effects to standard care treatment or medications.*
- *Fibromyalgia associated generalised pain and muscle stiffness severe enough to interfere with daily activities of living where standard therapies have failed to adequately control clinical symptoms and/or if the patient suffers intolerable adverse reactions or side-effects to standard care treatment or medications.*

Any other non-nociceptive chronic pain where:

- *the medical practitioner believes that standard therapies have been inadequate in controlling clinical symptoms and/or*
- *if the patient suffers intolerable adverse reactions or side-effects to standard care treatment or medications and/or*
- *the medical practitioner believes that medical cannabis may be beneficial to the patient.*

All of Dr Gunn's AP Approvals and Dr Finch's AP Approvals are valid for a year. Dr Gunn's approvals expire on 11 November 2020, whereas Dr Finch's approvals expire on varying dates ranging from 8 April 2020 to 22 August 2020.

The conditions of approval for each product are nearly identical, although Dr Gunn's approvals all include a further two conditions not included in Dr Finch's approvals. These additional approvals likely reflect the fact that Dr Gunn's AP Approvals were granted

some months after the last of Dr Finch's approvals were granted, at a time when the Secretary may have changed the standard conditions for these kinds of approval.

In addition to the conditions referred to in paragraph 6.3 above, the approvals require each medical practitioner to do the following:

- (a) inform their patients that the product is not on the Australian register and has not been evaluated for quality, safety and efficacy in the Australian context;
- (b) notify the TGA if the NIIM HREC withdraws its approval; and
- (c) instruct the patient to return any unused part of the goods to the authorised prescriber or to a pharmacy for destruction.

Dr Gunn's AP Approvals also require Dr Gunn do the following:

- (a) provide on-going monitoring and prescribing in consultation with any specialists involved in treating the patient's condition; and
- (b) include in the required six monthly reports to the TGA details of the medical conditions for which each product was prescribed and the number of each condition.

Emerald's Medicinal Cannabis Consent Form includes the information required by paragraphs (a) and (c) above. Emerald has instructed us that Dr Finch and Dr Gunn have not had their approvals withdrawn or modified by the NIIM HREC. Emerald has also instructed us that Dr Finch and Dr Gunn have been complying with their reporting obligations to the TGA and otherwise complying with the conditions of their Authorised Prescriber Approvals.

In addition to reviewing Dr Gunn and Dr Finch's Authorised Prescriber Approvals we reviewed A/Prof Vickery's HREC Approval and Dr Chalk's HREC Approval. The approvals are identical in terms. They approve Associate Professor Vickery and Dr Chalk to each use 17 specified medicinal cannabis products for the same indications as in Dr Gunn and Dr Finch's Authorised Prescriber Approvals (see above). Associate Professor Vickery and Dr Chalk may apply to the TGA for approvals as authorised prescribers for each of the 17 products in accordance with the terms of the HREC approvals. We are not aware of any reason why Associate Professor Vickery or Dr Chalk would be rejected by the TGA given that they have already received HREC approval.

In summary, we have sighted Dr Gunn's AP Approvals and Dr Finch's AP Approvals that allow Dr Gunn and Dr Finch to prescribe specified medicinal cannabis products for cancer pain, palliation or chronic non-cancer pain. We are instructed by Emerald that Dr Gunn and Dr Finch are complying with the conditions associated with their approvals. Accordingly, we have no reason to believe that Dr Gunn and Dr Finch will not be able to continue to use their authorised prescriber status when seeking to prescribe medicinal cannabis to their patients. We further note that Associate Professor Vickery and Dr Chalk have received similar HREC approvals, which are a prerequisite to TGA authorised prescriber approvals.

As an approval by the TGA under the Authorised Prescriber scheme in this context is only a Commonwealth approval to prescribe an unregistered medicinal cannabis product, Dr Gunn and Dr Finch may also require an approval from the state in which they are based in order to be legally allowed to prescribe the product to their patient (see paragraphs 7 to 12 below for an analysis of state legislation applying to Emerald's prescribing).

7. Regulation of medicinal cannabis by relevant states

At a state and territory level, a variety of medicines and poisons legislation regulates how medicinal cannabis is administered, dispensed, sold, prescribed, stored, transported and disposed. Each state or territory's respective medicines and poisons legislation does this by reference to the Poisons Standard (see paragraph 5.2 above).

Emerald currently operates clinics in Western Australia, New South Wales and Victoria. We are instructed by Emerald that it intends to use some of the funds from the Capital Raising to open clinics in Queensland and South Australia. We have, therefore, reviewed the legality of Emerald's current, and proposed, prescribing in relation to these five states.

8. Prescription of medicinal cannabis in Western Australia

8.1 Medicines and Poisons Act 2014 (WA)

Patient access to medicinal cannabis products in Western Australia is primarily regulated by the *Medicines and Poisons Act 2014* (WA) (**WA Act**) and its subordinate legislation. The Health Department of Western Australia is principally responsible for the administration of the WA Act.

The WA Act makes it an offence for a person to possess a Schedule 4 or Schedule 8 substance unless various circumstances apply, such as that the person was lawfully prescribed the substance.¹⁸ A medical practitioner may administer, possess, prescribe or supply a Schedule 4 or Schedule 8 substance only in accordance with the WA Act and the *Medicines and Poisons Regulations 2016* (WA) (**WA Regulations**).¹⁹

Regulation 51 of the WA Regulations states that a medical practitioner 'acting in their lawful practice of their profession' may prescribe Schedule 4 substances. Medical practitioners may also prescribe Schedule 8 substances in accordance with Part 11 of the WA Regulations.²⁰ Part 11 of the WA Regulations imposes general requirements (Division 2) and specific requirements (Divisions 3 to 5) on the prescription of Schedule 8 substances that are in addition to the requirements imposed in respect of the prescription of Schedule 4 substances.

Under the general requirements (Division 2), the CEO of the Health Department may authorise a medical practitioner to prescribe a specified Schedule 8 medicine to a

¹⁸ See, *Medicines and Poisons Act 2014* (WA), ss 14(3) and 14(4)(d).

¹⁹ See, *Medicines and Poisons Act 2014* (WA), s 25.

²⁰ See, *Medicines and Poisons Regulations 2016* (WA) regs 50-1.

specified patient.²¹ This approval mechanism is similar in nature to the SAS-B pathway at a Commonwealth level (see 6.1 above).

Under the specific requirements, Division 3 sets out regulations relating to the prescription of cannabis-based products.²² In accordance with these regulations, the CEO of the Health Department may designate a medical practitioner as a "**Cannabis-Based Product Prescriber**". This designation operates in a similar manner to the Authorised Prescriber pathway at a Commonwealth level (see 6.3 above). A Cannabis-Based Product Prescriber may only prescribe cannabis-based products in accordance with the *Schedule 8 medicines prescribing code (Prescribing Code)*.

The CEO may add any conditions to an approval, in relation to the prescribing or dispensing of a Cannabis-Based Product, believed to be necessary to protect the safety of the patient, in respect of a Schedule 8 substance.²³

8.2 Prescribing cannabis-based products under the Prescribing Code

Medical practitioners practicing in Western Australia, who are not otherwise restricted from prescribing Schedule 8 medicines, may be approved as Cannabis-Based Product Prescribers if they fall into any of the following categories:

- (a) a medical practitioner currently authorised by the TGA as an Authorised Prescriber for a Cannabis-Based Product, in relation to the specific class of patients or medical condition specified in the Authorised Prescriber approval;
- (b) a medical practitioner prescribing a Cannabis-Based Product for a patient enrolled to participate in a clinical trial that is approved by a recognised HREC, and in the case that the product is an unapproved therapeutic good, where the clinical trial is notified or registered with the TGA under the respective CTN or CTX Schemes; or
- (c) a relevant specialist, or other medical practitioner, as determined by the CEO, for the prescribing of a Cannabis-Based Product, which is on the ARTG, for the purposes of treating the registered indication.²⁴

Cannabis-Based Product Prescribers must notify the Department when they commence treating any patient with Cannabis-Based Products. This includes when a patient transfers to a new approved Cannabis-Based Product Prescriber, even if the patient is already being treated with Cannabis-Based Products.²⁵

Cannabis Based Product Prescribers are unable to prescribe to patients in a range of circumstances without further prior authorisation from the CEO. These further restrictions include where:

- (a) the patient is under 18 years of age;²⁶

²¹ See, *Medicines and Poisons Regulations 2016* (WA) reg 118.

²² See, *Medicines and Poisons Regulations 2016* (WA) reg 114.

²³ See, *Schedule 8 medicines prescribing code* (WA) s 5.5.4.

²⁴ See, *Schedule 8 medicines prescribing code* (WA) s 5.6.1.

²⁵ See, *Schedule 8 medicines prescribing code* (WA) s 5.7.1.

²⁶ See, *Schedule 8 medicines prescribing code* (WA) s 5.8.4.

- (b) the patient has a history of psychosis or bipolar disorder, substance abuse, diversion or misuse of drugs of addiction or Schedule 9 poisons within the previous five years, or a record of Oversupply or Drug Dependence;²⁷ and
- (c) the product is a Schedule 8 substance that is unregistered, does not comply with TGO 93, and is not being used in a clinical trial setting.²⁸

Where an SAS-B approval is required from the TGA, an application to the CEO, for authorisation under the Prescribing Code, must be made through the TGA. Where a medical practitioner is seeking to prescribe a Schedule 8 Cannabis-Based Product that is listed on the ARTG the medical practitioner must apply to the Western Australian Department of Health directly.

It is a general condition of any authorisation granted, that the patient will provide the prescriber with informed consent to treatment with a Schedule 8 substance, and, where relevant, the use of an unregistered therapeutic good. This consent must address issues related to legality and safety of driving a vehicle while taking a Cannabis-Based Product.²⁹

8.3 Approvals of Emerald Medical Practitioners to prescribe cannabis-based products in Western Australia

We have reviewed the WA-S8 Notices (see paragraph 4.1(f) above). Each notice relates to one of the five Western Australian based Emerald Medical Practitioners (see paragraph 4.2(f)(i) above) and details a specific approval for that Emerald Medical Practitioner to prescribe a specified medicinal cannabis product to a specified patient. The approvals range from six months to 12 months.

We also reviewed Dr Finch's WA-S8 Approval, which detailed Dr Finch's approval to prescribe four medicinal cannabis products following his approval as an Authorised Prescriber under the Commonwealth legislation (see paragraph 6.4 above). The WA-S8 Approval designates Dr Finch a Cannabis-Based Product Prescriber with respect to those four products. The WA-S8 Approval requires Dr Finch comply with the Prescribing Code and the notification requirements under the code.

In addition to reviewing the WA-S8 Notices and Dr Finch's WA-S8 Approval, we reviewed Emerald's most recent Medicinal Cannabis Consent Form. We are satisfied the consent form includes the information required under the Prescribing Code, including appropriate information relating to the legality and safety of driving a vehicle while taking a Cannabis-Based Product.

In summary, for each Emerald Medical Practitioner operating in Western Australia we have sighted a CEO approval that allows the respective Emerald Medical Practitioner to prescribe a specified medicinal cannabis product to a specified patient in Western Australia for a period of 6 or 12 months. We have also sighted a Cannabis-Based Product Prescriber approval in relation to Dr Finch. Given the information before us, we have no

²⁷ See, *Schedule 8 medicines prescribing code* (WA) s 5.8.2. Further, s 5.8.6 states: a urine drug screen (in accordance with Australian/New Zealand Standard 4308) should be undertaken by all patients 18 years and older before treatment with a Cannabis-Based Product is commenced. Further testing is recommended annually, and as indicated.

²⁸ See, *Schedule 8 medicines prescribing code* (WA) s 5.8.1.

²⁹ See, *Schedule 8 medicines prescribing code* (WA) s 5.5.4.

reason to believe that Emerald Medical Practitioners will not be able to continue utilising the two pathways provided under the WA Regulations when seeking to prescribe medicinal cannabis to their patients in Western Australia.

9. Prescription of medicinal cannabis in New South Wales

Patient access to medicinal cannabis products in New South Wales is primarily regulated by the *Poisons and Therapeutic Goods Act 1966* (NSW) (**NSW Act**) and its subordinate legislation. The New South Wales Ministry of Health is principally responsible for the administration of the NSW Act.

The NSW Act makes it an offence for a person to supply a Schedule 4 substance unless otherwise exempted or authorised to do so.³⁰ Medical practitioners may supply Schedule 4 substances 'in the lawful practice of [their] profession'.³¹

Schedule 8 substances are regarded by the NSW Act as 'drugs of addiction'. Drugs of addiction are classified into three categories (type A, B and C). The different types of drugs of addiction are set out in the *Poisons and Therapeutic Goods Regulation 2008* (NSW) (**NSW Regulations**). Type A consists of amphetamine and amphetamine-like drugs.³² Type B consists of benzodiazepines and opioid-like drugs.³³ Type C are defined as all other drugs of addiction and include cannabis.³⁴

A medical practitioner may prescribe a type C drug of addiction in the lawful practice of their profession subject to the restrictions set out in the NSW Regulations.³⁵ The restrictions imposed by the NSW Regulations are limited when compared with the WA Act and WA Regulations.

Medical practitioners only need an authority from the Ministry of Health to prescribe Schedule 8 medicinal cannabis products in the following circumstances:

- (a) if the patient is a drug dependent person;³⁶
- (b) if the patient is a child under the age of 16 years;³⁷ or
- (c) if the medicinal cannabis product is unregistered and to be used for the purposes of a clinical trial.³⁸

We are instructed by Emerald that neither of its New South Wales based Emerald Medical Practitioners (Dr David Gunn and Dr Nelson Lau) have sought to prescribe

³⁰ *Poisons and Therapeutic Goods Act 1966* (NSW) ss 9-10.

³¹ *Poisons and Therapeutic Goods Act 1966* (NSW) ss 10(4)(a).

³² *Poisons and Therapeutic Goods Regulation 2008* (NSW) reg 122.

³³ *Poisons and Therapeutic Goods Regulation 2008* (NSW) reg 123.

³⁴ *Poisons and Therapeutic Goods Act 1966* (NSW) s 28(6).

³⁵ *Poisons and Therapeutic Goods Act 1966* (NSW) s 24(2); *Poisons and Therapeutic Goods Regulation 2008* (NSW) reg 101.

³⁶ *Poisons and Therapeutic Goods Act 1966* (NSW) s 28(3).

³⁷ *Children and Young Persons (Care and Protection) Act 1998* (NSW) ss 175(2)(d) and 175(5)(c1).

³⁸ *Poisons and Therapeutic Goods Regulation 2008* (NSW) reg 84A. On 30 September 2019 the *Poisons and Therapeutic Goods Amendment (Cannabis Medicines) Regulation 2019* (NSW) came into force, amending the NSW Regs to require medical practitioners to seek State authority to use unregistered medicinal cannabis products in clinical trials.

medicinal cannabis to a drug dependant person or child or sought to prescribe medicinal cannabis for the purposes of a clinical trial. Accordingly, Emerald has provided us with no approvals for us to sight since its New South Wales based practitioners have not required, to date, State approvals to prescribe either registered or unregistered medicinal cannabis.

10. Prescription of medicinal cannabis in Victoria

Patient access to medicinal cannabis products in Victoria is primarily regulated by the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) (**Victorian Act**) and its subordinate legislation. The Victorian Department of Health and Human Services is principally responsible for the administration of the Victorian Act.

Under section 13 of the Victorian Act, a medical practitioner is authorised to supply a controlled substance or drug of dependence in the lawful practice of their profession subject to the *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) (**Victorian Regulations**).³⁹ Controlled substances include Schedule 4 and Schedule 8 medicines.⁴⁰

The Victorian Regulations further regulate what is defined as 'special Schedule 8 poisons' which includes nabiximols, Schedule 8 cannabis and Schedule 8 THC.⁴¹ It is an offence for a medical practitioner to issue a prescription for a special Schedule 8 poison without a special Schedule 8 permit, except in certain circumstances.⁴²

A medical practitioner may apply to the Secretary for a special Schedule 8 permit where the patient is not a drug dependent person and the proposed length of use of the special Schedule 8 poison does not exceed 8 weeks.⁴³ In the case of drug dependence or use exceeding 8 weeks, a medical practitioner must apply for a regular Schedule 8 permit.⁴⁴ With respect to the prescription of medicinal cannabis there appears to be little practical difference between the two permits.

The Victorian Act and Victorian Regulations do not provide for an authorised prescriber-type scheme like the WA Act. Accordingly, medical practitioners must obtain a Schedule 8 permit in relation to each patient. Both forms of Schedule 8 permits may specify conditions on the use of the Schedule 8 substance. These conditions ordinarily set out the patient, the active ingredient (Schedule 8 medicine), the specific product, the route of administration, the maximum dose, and the frequency of doses.

We requested Emerald provide us with a sample of a Schedule 8 permit granted to Dr Olopade. Emerald selected, and provided us with, Dr Olopade's Permit (see paragraph 4.1(h) above) which we have reviewed.

³⁹ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 13.

⁴⁰ The Act does not define "controlled substance" but Vic Health refers to "controlled substances" as anything controlled by the Act: <https://www2.health.vic.gov.au/alcohol-and-drugs/aod-policy-research-legislation/aod-legislation/drugs-and-poisons-act>

⁴¹ See, *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) reg 5.

⁴² See, *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) reg 17.

⁴³ See, *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) reg 17.

⁴⁴ See, *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) regs 34(1)-(2).

Dr Olopade's Permit authorises him to prescribe a specified medicinal cannabis product comprising CBD and THC to a specified patient. The permit is for a year. The only condition it states is that Dr Olopade should advise his patient not to drive while treated with medicinal cannabis. We note that Emerald's Medicinal Cannabis Consent Form contains such a warning. We are not aware of any reason why the Victorian Government may refuse to grant Dr Olopade future (special) Schedule 8 permits.

11. Prescription of medicinal cannabis in South Australia

Patient access to medicinal cannabis products in South Australia is primarily regulated by the *South Australian Controlled Substances Act 1984* (SA) (**SA Act**) and the *Controlled Substances (Poisons) Regulations 2011* (SA) (**SA Regulations**). The South Australian Department for Health and Wellbeing is principally responsible for the administration of the SA Act and SA Regulations.

The SA Act distinguishes between 'prescription drugs' and 'drugs of dependence'.⁴⁵ Both Schedule 4 and 8 substances are 'prescription drugs',⁴⁶ whereas only Schedule 8 substances are 'drugs of dependence'.⁴⁷

It is an offence for a person to possess a prescription drug unless they were lawfully prescribed the drug.⁴⁸ A medical practitioner may lawfully prescribe a prescription drug that is not a drug of dependency if they are acting in the 'ordinary course of their profession'.⁴⁹

A medical practitioner must not prescribe a drug of dependence to a person for a period exceeding two months.⁵⁰ Additionally, a medical practitioner must not prescribe a drug of dependence to a person the practitioner knows, or has reasonable cause to believe, is dependent on drugs.⁵¹ The Minister may, however, grant an authority allowing a medical practitioner to prescribe a drug of dependency contrary to these requirements.⁵² The SA Regulations also set out two relevant exemptions.

Under the SA Regulations a medical practitioner may prescribe a drug of dependency for longer than two months or to a drug dependent person if:

- (a) The patient is aged 70 years or older;⁵³ or
- (b) The patient's life expectancy is reasonably believed to be less than 12 months.⁵⁴

⁴⁵ *Controlled Substances Act 1984* (SA) ss 12(2)-(3).

⁴⁶ *Controlled Substances (Poisons) Regulations 2011* (SA) reg 6.

⁴⁷ *Controlled Substances (Poisons) Regulations 2011* (SA) reg 7.

⁴⁸ *Controlled Substances Act 1984* (SA) s 18(3)(a).

⁴⁹ *Controlled Substances Act 1984* (SA) s 18(1)(a)(i).

⁵⁰ *Controlled Substances Act 1984* (SA) s 18A(1)(a).

⁵¹ *Controlled Substances Act 1984* (SA) s 18A(1)(b).

⁵² *Controlled Substances Act 1984* (SA) s 18A(1).

⁵³ *Controlled Substances (Poisons) Regulations 2011* (SA) reg 22(2)(a).

⁵⁴ *Controlled Substances (Poisons) Regulations 2011* (SA) reg 22(2)(b).

In respect of the latter exemption (palliative prescribing), the medical practitioner must inform the Minister of the patient's personal details and the nature of their condition and ensure the prescription is endorsed "notified palliative care patient" or "NPCP".⁵⁵

In summary, Emerald Medical Practitioners may prescribe Schedule 4 medicinal cannabis in South Australia without the need for any approvals from the South Australian Department of Health and Wellbeing. Emerald Medical Practitioners may also prescribe Schedule 8 medicinal cannabis without the need for an approval as long as they only prescribe for less than two months, or prescribe to patients who are 70 years or older or who are being palliated. In all other circumstances, Emerald Medical Practitioners will require an approval from the Minister to prescribe Schedule 8 medicinal cannabis.

Emerald Medical Practitioners prescribing medicinal cannabis in South Australia are also required to comply with any applicable Commonwealth laws (see paragraph 6 above).

12. Prescription of medicinal cannabis in Queensland

12.1 Health Act 1937 (Qld)

Patient access to medicinal cannabis products in Queensland is primarily regulated by the *Health Act 1937 (Qld)* (**Queensland Act**) and its subordinate legislation, chiefly the *Health (Drugs and Poisons) Regulation 1996 (Qld)* (**Queensland Regulations**). The Queensland Department of Health is principally responsible for the administration of the Queensland Act and Queensland Regulations.

The Queensland Act states that a regulation may be made controlling the prescription of restricted drugs or controlled drugs.⁵⁶ The Queensland Regulations define restricted drugs as Schedule 4 substances while controlled drugs are defined as Schedule 8 Substances.⁵⁷

The Queensland Regulations prohibit a person from possessing a restricted drug unless they lawfully obtained the drug, such as via a prescription.⁵⁸ A person may only prescribe a restricted drug if they are endorsed to do so under the Queensland Regulations.⁵⁹ Doctors are authorised to prescribe restricted drugs to a person if they are reasonably satisfied the person 'needs a restricted drug for a therapeutic use as part of the person's medical treatment'.⁶⁰

The Queensland Regulations further restrict a doctor's ability to prescribe two subsets of restricted drugs known as 'regulated restricted drugs'⁶¹ and 'restricted drugs of dependency'.⁶² CBD is not considered a regulated restricted drug or a restricted drug of dependency.⁶³ Accordingly, Emerald Medical Practitioners may prescribe Schedule 4

⁵⁵ *Controlled Substances (Poisons) Regulations 2011 (SA)* reg 22(2)(b).

⁵⁶ *Health Act 1937 (Qld)* s 132(u).

⁵⁷ *Health Act 1937 (Qld)* s 5; *Health (Drugs and Poisons) Regulation 1996 (Qld)* app 9.

⁵⁸ *Health (Drugs and Poisons) Regulation 1996 (Qld)* reg 204.

⁵⁹ *Health (Drugs and Poisons) Regulation 1996 (Qld)* reg 146(3).

⁶⁰ *Health (Drugs and Poisons) Regulation 1996 (Qld)* reg 161.

⁶¹ See, eg, *Health (Drugs and Poisons) Regulation 1996 (Qld)* reg 161(2).

⁶² See, eg, *Health (Drugs and Poisons) Regulation 1996 (Qld)* regs 212-213.

⁶³ *Health (Drugs and Poisons) Regulation 1996 (Qld)* ch 3 pt 3; app 8.

cannabis medicines without any further authorisations, permits or approvals in Queensland as long as they comply with the ordinary requirements for prescribing a Schedule 4 substance.⁶⁴

The Queensland Regulations prohibit a person from possessing a controlled drug unless they lawfully have obtained the drug.⁶⁵ A person may only prescribe a controlled drug if they are endorsed to do so under the Queensland Regulations.⁶⁶ Doctors are authorised to prescribe restricted drugs to a person if they are reasonably satisfied the person 'needs a controlled drug for a therapeutic use as part of the person's medical treatment'.⁶⁷

The Queensland Regulations further restrict a doctor's ability to prescribe 'regulated controlled drugs'.⁶⁸ Schedule 8 medicinal cannabis is a regulated controlled drug regardless of whether it is registered on the ARTG.⁶⁹ A doctor must not prescribe Schedule 8 medicinal cannabis unless the doctor is a specialist medical practitioner or is granted an approval by the chief executive.⁷⁰ A specialist medical practitioner is any specialist in the medical profession registered under the *Health Practitioner Regulation National Law*, and includes a specialist general practitioner.⁷¹

In addition to the general restrictions imposed on a doctor prescribing Schedule 8 medicinal cannabis, a doctor must not prescribe a controlled drug to a drug dependent person without the approval of the chief executive.⁷²

In summary, Emerald Medical Practitioners may prescribe Schedule 4 medicinal cannabis in Queensland without the need for any approvals from the Queensland Department of Health. Emerald Medical Practitioners may also prescribe Schedule 8 medicinal cannabis without the need for an approval if they are registered specialists. If they are not registered specialists, or the patient is a drug dependent person, they will require an approval. Emerald Medical Practitioners prescribing medicinal cannabis in Queensland are also required to comply with any applicable Commonwealth laws (see paragraph 6 above).

12.2 Commencement of the Medicines and Poisons Act 2019 (Qld)

On 26 September 2019, the *Medicines and Poisons Act 2019* (Qld) (**New Act**) and the *Therapeutic Goods Act 2019* (Qld) became law in Queensland but they will not commence until a later date. On its commencement, the New Act will repeal, among other things, the Queensland Act and Queensland Regulations. It is expected that the new regulatory framework will commence in the second half of 2020.⁷³

The explanatory notes to the New Act state that the New Act will streamline the requirements for prescribing medicinal cannabis in Queensland by enabling non-

⁶⁴ See, eg, *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 190.

⁶⁵ *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 94.

⁶⁶ *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 51(3).

⁶⁷ *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 58.

⁶⁸ *Health (Drugs and Poisons) Regulation 1996* (Qld) ch 2 pt 3.

⁶⁹ *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 78A; app 9.

⁷⁰ *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 78A.

⁷¹ *Health (Drugs and Poisons) Regulation 1996* (Qld) app 9.

⁷² *Health (Drugs and Poisons) Regulation 1996* (Qld) reg 122.

⁷³ See, <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/medicines-poisons-act>

specialist medical practitioners to prescribe it without the need for approval from Queensland Health. The Explanatory Note to the New Act states:

Once the Health Act is repealed by the Medicines and Poisons Bill, the use of medicinal cannabis in Queensland will be authorised by the medicines and poisons framework in the Bill, provided the activity is authorised by the Therapeutic Goods Administration under the Commonwealth Therapeutic Goods Act.

The Medicines and Poisons Bill will further streamline the regulatory framework for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe it without the need for approval from Queensland Health. This will eliminate duplication of the Commonwealth approval process and remove the potential for Queensland Health and the Therapeutic Goods Administration to reach different conclusions about applications for access to eligible patients.⁷⁴

Based on the Explanatory Note to the New Act, we do not envisage Emerald's ability to prescribe medicinal cannabis in Queensland will be adversely impacted by the commencement of the New Act.

Part C Clinical trials

13. CTX and CTN Schemes

The TG Act provides two pathways to supply unregistered therapeutic goods for people participating in experimental trials. The two pathways are known as the Clinical Trial Notification (**CTN**) Scheme⁷⁵ and the Clinical Trial Exemption (**CTX**) Scheme.⁷⁶ Under both schemes clinical trials must be conducted in accordance with the *Guidelines for Good Clinical Practice (GCP Guidelines)*⁷⁷ and the ethical standards set out in the *National Statement on Ethical Conduct in Research Involving Humans (National Statement)*^{78, 79}.

Under the CTN Scheme, scientific and ethical review is provided by an HREC, and the TGA subsequently notified, if the HREC approves the clinical trial. Under the CTX Scheme, the TGA has a direct role in the review of trial scientific data and must approve the proposed trial program before it can proceed, although HREC review of the trial is still required under the CTX Scheme.

⁷⁴ Explanatory Note, *Medicines and Poisons Bill 2019* (Qld) 7.

⁷⁵ See *Therapeutic Goods Act 1989* (Cth) ss 12AD, 18(1) and 31A(1); *Therapeutic Goods Regulations 1990* (Cth) regs 12(2) and sch 5A item 3.

⁷⁶ *Therapeutic Goods Act 1989* (Cth) ss 19(1)(b), 19(4A), 31B(1)-(2); *Therapeutic Goods Regulations 1990* (Cth) regs 12AB and 12AD.

⁷⁷ See *Therapeutic Goods Regulations 1990* (Cth) reg 12AB(2)(a) and 12AD(a). The Practice Guidelines are published jointly by the International Conference on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use and the Committee for Medicinal Products.

⁷⁸ The National Statement is published by the National Health and Medical Research Council.

⁷⁹ See *Therapeutic Goods Regulations 1990* (Cth) reg 12AB(2)(a) and 12AD(c).

The CTN Scheme may be used for earlier phase studies if there is adequate pre-clinical information available, especially regarding safety. The CTX route is generally for high risk or novel treatments, such as gene therapy, where there is no or limited knowledge of safety.⁸⁰

Either notification under the CTN Scheme or application under the CTX Scheme is required for all clinical investigational use of a medicine, where that use involves:

- (a) any medicine not registered on the ARTG, including any new formulation of an existing medicine or any new route of administration; or
- (b) use of a registered medicine beyond the conditions of its existing ARTG approval, including new indications (extending the use of a medicine to a new population group) or changes to doses or duration of treatments outside the range for the approved indications.

The choice of which scheme to follow (CTN or CTX) lies firstly with the sponsor and then with the HREC that reviews the protocol. The determining factor for an HREC when deciding whether to approve a clinical trial is whether it has access to appropriate scientific and technical expertise in order to assess the safety of the product.

Emerald may conduct clinical trials of medicinal cannabis products where it has received HREC approval to do so and has either notified the TGA, in accordance with the CTN Scheme, or has received TGA approval, in accordance with the CTX Scheme.

Emerald Medical Practitioners may also require approval at a state or territory level if they are responsible for prescribing or supplying medicinal cannabis products to the participants in the clinical trial (see paragraphs 8 to 12).

In Emerald's prospectus to its Capital Raising, it indicated it does not intend to undertake any clinical trials in the near term that would require any Emerald Medical Practitioners to obtain Schedule 8 approvals but it may choose to partner with third parties that hold such licences.⁸¹ If this is the case, an Emerald Medical Practitioner may be involved in a clinical trial without the need for an approval, so long as the Emerald Medical Practitioner does not prescribe, administer or otherwise supply Schedule 8 medicinal cannabis products to clinical trial participants.

Part D Advertising of medicinal cannabis

14. Advertising of medicinal cannabis

In addition to regulating the supply of therapeutic goods, the TG Act and TG Regulations tightly regulate the advertising of therapeutic goods. It is an offence for a person to advertise a Schedule 4 or Schedule 8 substance.⁸² It is also an offence to advertise an

⁸⁰ <https://www.tga.gov.au/book-page/ctn-and-ctx-schemes>

⁸¹ See Emerald Clinics Limited Prospectus, Section 2.4 (Strategy of the Company).

⁸² *Therapeutic Goods Act 1989* (Cth) ss 42DL(1)-(3) and 42DL(10).

unapproved therapeutic good that is the subject of an Authorised Prescriber or Special Access Scheme approval.⁸³

The definition of 'advertise' is broad and covers any form of direct or indirect promotion.⁸⁴ In the context of advertising medicinal cannabis health services, a clinic cannot refer to medicinal cannabis, including making references through:

- (a) company, business or trading names (e.g. Can Clinic);
- (b) product names or trade names;
- (c) abbreviation or acronyms for the good;
- (d) colloquial names; and
- (e) any other reference, including images, that are likely to draw the consumer's attention to medicinal cannabis.⁸⁵

We have reviewed Emerald's website on 28 November 2019 (see 4.1(j) above). When reviewing Emerald's website we saw no direct or indirect references to cannabis, CBD, THC or other cannabis products. Accordingly, we are of the opinion that Emerald's website is compliant with the TG Act with respect to not advertising medicinal cannabis.

We are instructed that any advertising by Emerald other than through its website follows the approach taken in Emerald's website. Accordingly, we are of the opinion that Emerald's advertising is compliant with the TG Act with respect to not advertising medicinal cannabis.

Part D Commercialisation of patient identifiable information

15. Background

15.1 Documents reviewed

In providing advice in relation to Part C of this opinion, we have relied principally on the following documents:

- (a) Emerald's Data Governance Framework;
- (b) Emerald's Data Governance Policy;
- (c) Emerald's Privacy Policy;

⁸³ *Therapeutic Goods Act 1989* (Cth) s 42DL(1)-(3) and 42DL(12); *Therapeutic Goods Regulations 1990* (Cth) reg 7.

⁸⁴ *Therapeutic Goods Act 1989* (Cth) s 3.

⁸⁵ See, eg, <https://www.tga.gov.au/publication/advertising-guidance-businesses-involved-medicinal-cannabis-products>

- (d) Emerald's Health Information Collection, Use and Disclosure, Patient Consent Form (**Privacy Consent Form**); and
- (e) Emerald's Clinical Research Platform: Data Collection.

15.2 Operational background

Based on the draft Prospectus in the version existing about at the date of this Opinion, and our review of the documents listed in paragraph 15.1 above, we understand that privacy compliance issues for Emerald stem from the following aspects of Emerald's current or proposed operations:

- (a) Emerald captures comprehensive real world data (**RWD**) consisting of the identifiable health information of Emerald's patients (**Patient Identifiable Information**) providing consent under the Privacy Consent Form, that can be used as real world evidence (**RWE**) to support innovation across the cannabinoid medicine industry (**Emerald Data Platform**);
- (b) all Patient Identifiable Information is captured, encrypted and stored in either an electronic health record (**EHR**) or an FDA-compliant electronic data capture system (**EDC**);
- (c) the Emerald Data Platform adheres to strict security, data governance and quality management standards, as set out in Emerald's Data Governance Framework and Data Governance Policy, and all Patient Identifiable Information is captured, encrypted and stored in either an EHR or an EDC;
- (d) this helps ensure that the RWE generated from Emerald's RWD could be presented to major global regulators such as the Food and Drug Administration (**FDA**) in the US and the European Medicines Agency (**EMA**) in Europe;
- (e) Emerald follows an (at least) two-step process to de-identify Patient Identifiable Information before any analysis or data sharing takes place. Under page 9 of Emerald's Data Governance Framework and as stated in the draft Prospectus, the first step is that software within the EDC automatically seeks to de-identify all Patient Identifiable Information (**De-identified Data**).
- (f) The second step is for Emerald to submit that information to manual review against baseline questions that include, but are not limited to, the following:
 - (i) Does the De-identified Data contain names, address, phone number, unique government identifiers?
 - (ii) Does the De-identified Data contain any unique identification numbers that associate the identity of an individual in one system to another (for example, a medical reference number that can be used to associate a set of de-identified data in one database to a set of identifiable personal information in another database)?

- (iii) Can an individual be uniquely identified using the De-identified Data by any means including the combination of multiple data values (for example, the combination of a date of birth, postcode, and gender)?

(together, the **Baseline Questions**);

- (g) in the event that the answer to the any of the Baseline Questions indicates that the relevant data has not been sufficiently de-identified, the data is stripped of the information that can lead to re-identification and then re-tested;
- (h) Emerald contends that major international regulators are increasingly aware of the shortcomings of evidence produced by randomised clinical trials and that, because of this, are and may be increasingly interested in RWE of the kind that Emerald intends to collect; and
- (i) Emerald further contends that, due to regulator interest in RWE, drug developers are likely to value, and pay for, Emerald's RWE in order to use that RWE to de-risk or accelerate their clinical development programs.

16. Issue for Opinion

The concatenation of facts, circumstances and contentions set out above in paragraph 15.2 above gives rise to the question on which we have been asked to opine in Part C of this Opinion, namely: are there any compliance barriers or risks, in particular under Privacy Laws, to Emerald pursuing its purpose of commercialising the health information of its patients (**Commercialisation Purpose**)?

17. Applicable privacy laws

Privacy laws regulate the handling of personal information, defined in the *Privacy Act 1988* (Cth) (**Privacy Act**) as, basically, information about an identified or reasonably identifiable individual. Sensitive information is a sub-set of personal information and includes health information. Sensitive information attracts some greater protections than other personal information.

In its dealings with personal information, including health information, Emerald is subject to the following legislation:

- (a) Privacy Act;
- (b) *Health Records and Information Privacy Act 2002* (NSW) (**HRIP Act**); and
- (c) *Health Records Act 2001* (Vic) (**HR Act**) (collectively, **Privacy Laws**).

The three above acts are all relevantly similar. For the purposes of this advice, if Emerald complies with the Privacy Act, it will also comply with the HRIP Act and the HR Act. For this reason, we only consider the application of the Privacy Act.

If Emerald expands its operations in the future into the United Kingdom, it will be subject to the privacy law applicable in the United Kingdom. At the moment, by virtue of its membership of the European Union, the United Kingdom is subject to the General Data Protection Regulation (EU) 2016/679 (**GDPR**). If the United Kingdom ceases to be a member of the European Union, then it may not continue to be subject to the GDPR. Given that expansion to the United Kingdom is not imminent, we do not cover the GDPR further in this Opinion, except to note that we see nothing in Emerald's proposed operations which are likely to be in breach of the GDPR.

18. Collection of Patient Identifiable Information

18.1 Notifying patients of the collection of Patient Identifiable Information

The Privacy Consent Form is a seven page document that sets out, clearly and in expansive detail, information including the purposes for collection of the Patient Identifiable Information, the entities to which Emerald may disclose that information, the fact that the patient can consult Emerald's privacy policy, information about how a patient can seek access to, and correction of, their personal information held by Emerald, and how to make a complaint in relation to privacy.

In providing this information, Emerald is complying with its obligation under Australian Privacy Principle (**APP**) 5.1 (and equivalent obligations under other Privacy Laws) to notify an individual of these matters before Emerald collects their personal information.

18.2 Collection of Patient Identifiable Information

APP 3 of the Privacy Act deals with the collection of personal information. As revealed by our consideration of the relevant elements of APP 3 below, we do not see any likely breach of APP 3 (of equivalent obligations under other Privacy Laws) in Emerald's proposed collection of personal information of patients.

APP 3.3 provides that an organisation, such as Emerald, must not collect sensitive information unless the individual consents to the collection of the information and the information is reasonably necessary for the organisation's functions or activities.

The Privacy Consent Form provides sufficient information to allow a patient to provide satisfactory consent to the collection and subsequent use and disclosure, of their personal information. We commend Emerald for providing such a clear and informative consent form.

Under APP 3.5, an organisation must collect personal information only by lawful and fair means. We see no basis on which Emerald could be considered to be breaching this obligation.

Under APP 3.6, an organisation must collect personal information about an individual only from the individual unless it is unreasonable or impracticable to do so. Emerald collects personal information of patient from patients, but also, as stated in page 2 of the Privacy Consent Form, from third parties being other medical providers such as a patient's GP, diagnostic services such as radiology and pathology, and where relevant the Medicare

Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) which hold information about a patient's government funded medical care. We consider that it would be not just unreasonable or impractical, but usually impossible, for Emerald to collect, directly from the patient, the personal information that it proposes to collect from the identified third parties. Accordingly, these measures do not appear to breach APP 3.6.

19. Use and disclosure of Patient Identifiable Information

APP 6 deals with use and disclosure of personal information. APP 6.1 states that, "If an APP entity holds personal information about an individual that was collected for a particular purpose (**the primary purpose**), the entity must not use or disclose the information for another purpose (**the secondary purpose**)" unless certain circumstances obtain.

The Privacy Consent Form states on page 1 that Emerald intends to collect the Patient Identifiable Information for the purposes of "providing quality health care and for research to improve treatments for you and other patients similar to you". This statement transparently establishes that the purposes of providing quality health care, and the Commercialisation Purpose are the primary purposes for which Emerald is collecting the patient information.

The effect of the excerpt of APP 6.1, quoted above, is that, if Emerald uses or discloses the Patient Identifiable Information in accordance with the conditions stated in the Privacy Consent Form for the Commercialisation purpose, there will be no restrictions imposed by the Privacy Act on Emerald's use or disclosure of that information.

Significant conditions stated in the Privacy Consent Form include:

- (a) keeping any information confidential and securely stored;⁸⁶
- (b) not disclosing the Patient Identifiable Information without the patient's permission, except in compliance with the law;⁸⁷
- (c) not sharing Patient Identifiable Information with anyone outside Emerald;⁸⁸
- (d) transferring data based on Patient Identifiable Information to third parties such as research collaborators at universities or in industry only in summary form, coded to be "functionally anonymous", that is, so that it is "functionally impossible for a patient to be re-identified", including when the data is sent through the internet;⁸⁹ and
- (e) combining Patient Identifiable Information when reporting the results of studies or clinical trials in such a way that only grouped outcomes are published.⁹⁰

⁸⁶ Privacy Consent Form, page 2.

⁸⁷ Privacy Consent Form, page 2.

⁸⁸ Privacy Consent Form, page 3.

⁸⁹ Privacy Consent Form, pages 3 and 4.

⁹⁰ Privacy Consent Form, page 4.

We interpret the above to mean that Emerald will not breach APP 6 (or equivalent obligations under other Privacy Laws) if it uses and discloses the Patient Identifiable Information in order to construct RWE for the Commercialisation Purpose.

20. De-identification and non-re-identification of Patient Identifiable Information

20.1 The risk of re-identification

As presented in paragraph 15.2, de-identification of Patient Identifiable Information plays an important part of Emerald's privacy compliance measures. As noted in paragraph 15.2(e), Emerald's method for de-identification is manually to submit Patient Identifiable Information to review against the Baseline Questions.

In principle, the Baseline Questions seem eminently reasonable however, for the purpose of compliance with relevant Privacy Laws and the conditions in Emerald's Patient Privacy Consent, "mere" de-identification is not sufficient. In order to transform personal information, as defined in the Privacy Act, into information other than personal information, and thereby achieve the desired effect of avoiding the further application of Privacy Law, the transformed information must not just be de-identified, but rendered non-re-identifiable.

A simple example may suffice to illustrate the distinction. If information about an Emerald patient were published that had stripped out the patient's name and address and so on but which made it clear that the patient was female and had formerly been the Prime Minister of Australia, that information might not directly state the identity of the patient but, when combined with publicly available information, given there has only ever been one female Prime Minister, that information is re-identifiable.

So, when Emerald states that it will "de-identify" Patient Identifiable Information, then in order to achieve that in the way that counts under the Privacy Laws, it must be de-identification to the point of non-re-identifiability. In the age of Big Data, it can be surprisingly difficult to de-identify unit level data, that is, information about specific, albeit de-identified individuals, to the point of non-re-identifiability when that information is in the hands of people with relevant IT skills. See, for example, the case of researchers at Melbourne University who were able to re-identify numerous people whose de-identified information was published by Medicare as a resource for researchers, by combining that information with publically available data sets.⁹¹ Examples of this kind can be easily multiplied⁹² and suggest that it is extremely difficult to render Patient Identifiable

⁹¹ "The simple process of re-identifying patients in public health records" by Dr Vanessa Teague, Dr Chris Culnane and Dr Ben Rubinstein, University of Melbourne, <https://pursuit.unimelb.edu.au/articles/the-simple-process-of-re-identifying-patients-in-public-health-records>, accessed 28 November 2019.

⁹² See for example, "Reidentification of Individuals in Chicago's Homicide Database - A Technical and Legal Study" by Salvador Ochoa, Jamie Rasmussen, Christine Robson and Michael Salib, <http://web.mit.edu/sem083/www/assignments/reidentification.html> in which researchers analysed a deidentified unit level dataset of Chicago homicide victims over a span of three decades and, by comparing the records in the Chicago data set with records in the Social Security Death Index, they were able to associate names with, or reidentify, 35% of the victims.

Information as non-re-identifiable if it is published at "unit level", that is, as information about specific individuals rather than being aggregated.

20.2 The need for Emerald to provide unit level data to maximise the Commercialisation Purpose

We assume that Emerald will need to provide unit level information about its patients to third parties such as drug developers or researchers for the Commercialisation Purpose, because Emerald's dataset will be significantly more valuable in that form. These kinds of third parties are likely to have, or have access to, the skills necessary to re-identify unit level de-identified data. That is, it appears that it may be practically impossible to be certain of preventing a sufficiently skilled person from being able to re-identify unit level de-identified data. This poses a challenge to Emerald, in order to comply with the Privacy Laws and the conditions in its Patient Privacy Consent.

The Anonymisation Decision-Making Framework, by Mark Elliot et al, with a foreword by Elizabeth Denham, UK Information Commissioner (2016) is a United Kingdom publication which was adapted by the Office of the Australian Information Commissioner and the Commonwealth Scientific and Industrial Research Organisation's Data61 in the *De-identification Decision-Making Framework* (2017). These authoritative publications recognise both the significant difficulty of preventing re-identification, the considered measures that can assist, and the importance and legitimacy of continuing to make use of de-identified unit level data.

20.3 Measures to address the risk of re-identification

We consider that Emerald will be able satisfactorily to abide by the conditions in Emerald's Patient Privacy Consent, if Emerald provides unit level de-identified data to a recipient third party in compliance with its Data Governance Framework, which relevantly provides that Emerald must:

- (a) use well informed and considered methods to reduce the likelihood of re-identifiability of unit level de-identified data;
- (b) obtain binding undertakings from the recipient third party that that third party:
 - (i) will not seek to re-identify that data; and
 - (ii) will obtain Emerald's consent to disclosure by the recipient third party of the unit level de-identified data to any other third party, such consent to be withheld unless the other third party makes similar undertakings and can reasonably be expected to keep those undertakings; and
- (c) conduct sufficient due diligence to satisfy itself that the recipient third party is likely to keep those undertakings.

In our view, Emerald is entitled to rely on these measures to prevent re-identification of its unit level de-identified data as long as recipient third parties have enough to lose from attempting re-identification (in terms of loss of accreditations, reputation and compliance with their own legal obligations) that they are unlikely to do so.

If Emerald is able to achieve the result that it sets itself to achieve through this process, then it will indeed have transformed the Patient Identifiable Information from personal information, as defined in the Privacy Act, to information that is not personal information. If it achieves that, then the resulting information will not be subject to Privacy Laws, meaning that it will be impossible for Emerald to breach the Privacy Laws in handling the Patient Identifiable Information.

21. Security of Patient Identifiable Information

Under APP 11.1 of the Privacy Act, an organisation such as Emerald must take such steps as are reasonable to protect Patient Identifiable Information from misuse, interference and loss; and from unauthorised access, modification or disclosure.

Emerald instructs us it has engaged the services of Diamond Cyber and XCY to support development and maintenance of the security of Emerald's information infrastructure. We understand from Emerald that both service providers have an in-depth experience in cyber security.

Emerald also instructs us it has an ongoing program to support staff with Good Clinical Practice (GCP) training, SOP development and review related to trials activity and is developing standard policies and procedures in line with RACGP accreditation.

Having regard to the above, we have no reason to suspect that Emerald is in breach of APP 11.1 in relation to the Patient Identifiable Information.

22. Privacy by design

APP 1.2 requires an organisation such as Emerald to take such steps as are reasonable in the circumstances to implement practices, procedures and systems relating to the organisation's functions that will ensure that the organisation complies with the APPs. Often referred to as "privacy by design", APP 1.2 goes beyond prohibiting breaches of the Privacy Act, and requires the implementing of proactive privacy compliance measures. This obligation reflects a OECD-wide trend towards privacy by design.

The documents referenced in paragraph 15.1 above take Emerald a long way towards complying with APP 1.2. as does Emerald's engagement of Diamond Cyber and XCY for cyber security expertise. Emerald informs us that it engages with Diamond Cyber and XCY when considering changes to its systems and processes to ensure a privacy by design approach is undertaken with appropriately skilled resources.

We have not sought to do a more elaborate review of Emerald's information security systems than is stated above, nor have we engaged independent IT professionals to verify independently Emerald's claim that it has sourced and applied suitable IT expertise in relation to privacy and information protection, nor do we think that that additional due diligence is necessary in the circumstances.

From the inquiries and review that we have undertaken, we have no reason to suspect that Emerald has failed to comply with its obligation under APP 1.2 to ensure privacy by design.

23. Conclusion on handling Patient Identifiable Information for the Commercialisation Purpose

We have reviewed the key elements of the Privacy Laws, through a review of key elements of the Privacy Act, as they apply to Emerald's handling of Patient Identifiable Information for the Commercialisation Purpose. In particular, we have assessed collection (paragraph 18), use and disclosure (paragraph 19), de-identification and non-re-identification (paragraph 20), security (paragraph 21) and privacy by design (paragraph 22).

Based on Emerald's awareness of privacy issues as they apply to handling of Patient Identifiable Information for the Commercialisation Purpose, and its creation of practices, procedures and systems for privacy compliance, we see no reason why Emerald cannot use Patient Identifiable Information for the Commercialisation Purpose and comply with the Privacy Laws.

Part E Assumptions, benefit and reliance

24. Assumptions

For the purposes of giving this legal opinion we have relied upon the following assumptions and qualifications:

- (a) we have not certified the authenticity of any documents set out at paragraphs 4.1 and 15 above and have assumed they are genuine, true copies of the original documents and all certificates, licences, consents, approvals and permits:
 - (i) have been issued or granted to Emerald in compliance with all applicable laws; and
 - (ii) have not been revoked;
- (b) we have not conducted any searches in any official registry or with any public authorities in relation to any matter, including without limitation, any legal, governmental or regulatory proceedings pending in relation to Emerald and any certificates, licenses, consents, approvals and permits issued to Emerald;
- (c) employees, officers, directors and agents of Emerald have disclosed all material information about the operations of Emerald and all information is true and accurate in all material respects and contain no material omissions;

- (d) all factual matters (as distinct from matters of Australian law) stated in any document or response provided to us, or reviewed by us, for the purpose of this legal opinion are true and correct;
- (e) in respect of all factual matters material to the opinions, statements and assumptions expressed in this Opinion, we have relied on statements from the employees, officers, directors and agents of Emerald and have not taken any steps to verify those statements;
- (f) there has been no historical non-compliance by Emerald in respect of any certificate, license, consent, approval, permits or authorisation, nor has there been any breach by Emerald of any applicable law or regulation relating to its operations or proposed operations;
- (g) this Opinion relates to the laws of the Commonwealth of Australia and the states of Western Australia, New South Wales, Victoria, South Australia and Queensland in force at the date of this Opinion. We do not express or imply any opinion as to the laws of any other jurisdiction, nor have we investigated the laws of any other jurisdiction;
- (h) this Opinion is given as of the date of the opinion, and we express no opinion as to the effect of any change in the facts or law or policy (or interpretations of such laws or policy) on which such opinions are based subsequent to the date of this Opinion. We disclaim any obligation to update this Opinion for any change in the facts or law occurring after the date of this Opinion, which might affect this Opinion;
- (i) Emerald's management has reviewed this Opinion and confirmed its factual accuracy;
- (j) we provide this Opinion and have acted only in our capacity as an Australian legal advisor to Emerald;
- (k) this Opinion does not express an opinion on any matter requiring skill or expertise of a non-legal nature, including business, operational, commercial, financial, market-related, statistical or accounting matters;
- (l) the statements made and opinions in this Opinion are based on the knowledge (as to matters of fact not law) of those partners and solicitors of HWL Ebsworth Lawyers only who have acted for Emerald in relation to this Opinion. We have not made any inquiries of other partners or solicitors of the firm who may have knowledge acquired in the course of acting on other matters for Emerald or for other clients of the firm; and
- (m) the statements made and opinions in this Opinion are given only to the extent that a law firm, having the role described above, could reasonably be expected to have become aware of relevant facts and to have identified the implications of those facts.

25. Benefit and reliance

25.1 Benefit

This Opinion is given for the sole benefit of Emerald.

25.2 Reliance

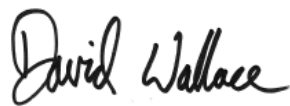
This Opinion shall be governed by and construed in accordance with the laws of Australia and is limited to the matters expressly stated. This Opinion is limited to matters of Australian law and practice as at the date of this Opinion and we have made no investigation and express no opinion with respect to the law or practice of any other jurisdiction.

Yours faithfully



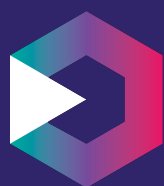
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