KOLIGO THERAPEUTICS LIMITED
ACN 627 117 677

REPLACEMENT PROSPECTUS

For an offer of 30,000,000 Shares at an issue price of $0.20 per Share to raise $6,000,000 (Public Offer). Oversubscriptions of up to a further 5,000,000 Shares at an issue price of $0.20 per Share to raise up to a further $1,000,000 may be accepted under the Public Offer, and for the offer of up to 5,500,000 Options to the Joint Lead Managers

IMPORTANT INFORMATION
This is an important document that should be read in its entirety. If you do not understand it you should consult your professional advisers without delay. The Securities offered by this Prospectus should be considered highly speculative.

Joint Lead Managers:
APP Securities Pty Ltd (AFSL No. 307706)
Novus Capital Ltd (AFSL No. 238168)

Corporate Advisor:
Brentridge Capital Pty Ltd, A Corporate Authorised Representative (CAR 1269419) of Pinnacle Securities Limited (AFSL No. 485760)
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
TABLE OF CONTENTS

1. COMPANY DIRECTORY ........................................................................................................... 2
2. IMPORTANT NOTICE................................................................................................................ 4
3. INVESTMENT OVERVIEW ......................................................................................................... 7
4. CHAIRMAN’S LETTER ............................................................................................................ 31
5. DETAILS OF THE OFFERS ...................................................................................................... 34
6. COMPANY OVERVIEW ......................................................................................................... 44
7. RISK FACTORS ....................................................................................................................... 67
8. INTELLECTUAL PROPERTY REPORT ................................................................................... 81
9. FINANCIAL INFORMATION AND INDEPENDENT LIMITED ASSURANCE REPORT .......... 100
10. LEGAL REPORT – FDA MATTERS ...................................................................................... 119
11. BOARD, MANAGEMENT AND CORPORATE GOVERNANCE .............................................. 131
12. MATERIAL CONTRACTS ...................................................................................................... 138
13. ADDITIONAL INFORMATION ............................................................................................ 148
14. DIRECTORS’ AUTHORISATION ........................................................................................... 159
15. GLOSSARY ........................................................................................................................... 160
1. COMPANY DIRECTORY

DIRECTORS
Peter James Non-Executive Chairman
Matthew Lehman Executive Director
Stuart Williams, PhD Executive Director
Jethro Marks Non-Executive Director
Robert Clisdell Non-Executive Director

MANAGEMENT
Matthew Lehman Chief Executive Officer
Stuart Williams, PhD Chief Technology Officer
Balamurugan Appakalai, PhD Chief of Manufacturing
Mike Hughes, MD Chief Medical Officer
David Blanford Chief Operating Officer
Ariel Sivikofsky, Chief Financial Officer

COMPANY SECRETARY
Andrew Bursill

PROPOSED ASX CODE
KOL – Ordinary Shares

SOLICITORS IN AUSTRALIA
Steinepreis Paganin
Level 4, The Read Buildings
16 Milligan Street
Perth WA 6000

SOLICITORS IN US
Moses & Singer LLP
405 Lexington Avenue
New York NY 10174-1299

INTELLECTUAL PROPERTY COUNSEL
K&L Gates LLP
70 W Madison St #3300
Chicago IL 60602

CORPORATE ADVISOR
Brentridge Capital Pty Ltd
A Corporate Authorised Representative (CAR 1269419) of Pinnacle Securities Limited (AFSL No. 485760)
Level 36, Governor Phillip Tower, 1 Farrer Place
Sydney NSW 2000

REGISTERED OFFICE
Level 5, 126 Phillip Street
Sydney NSW 2000
Telephone: +61 2 9299 9690
Facsimile: +61 2 9251 7455
Email: info@koligo.net
Website: www.koligo.net

SHARE REGISTRY*
Automic Group
Level 5, 126 Phillip Street
Sydney NSW 2000
Telephone: 1300 288 664

INVESTIGATING ACCOUNTANT
HLB Mann Judd Corporate (NSW) Pty Ltd
Level 19, 207 Kent Street
Sydney NSW 2000

AUDITOR OF KOLIGO THERAPEUTICS, INC.
CohnReznick LLP
4 Becker Farm Road
Roseland NJ 07068

SOLICITORS IN US – FDA MATTERS
Buchanan Ingersoll & Rooney PC
1700 K Street, N.W., Suite 300
Washington, DC 20006-3807

JOINT LEAD MANAGERS
APP Securities Pty Ltd
AFSL No 307706
Level 41, 259 George Street
Sydney NSW 2000
Novus Capital Ltd
AFSL No 238168
56 Pitt Street
Sydney NSW 2000

* This entity is included for information purposes only. It has not been involved in the preparation of this Prospectus.
Kyslecel™ being prepared for infusion

IMPORTANT NOTICE
2. IMPORTANT NOTICE

This is a replacement prospectus dated 25 February 2019 which replaces a prospectus dated 8 February 2019. This replacement prospectus was lodged with the ASIC on 25 February 2019. For the purpose of this document, this replacement prospectus will be referred to as “this Prospectus”.

The ASIC, the ASX and their respective officers take no responsibility for the contents of this Prospectus or the merits of the investment to which this Prospectus relates.

No Securities may be issued on the basis of this Prospectus later than 13 months after the date of this Prospectus.

No person is authorised to give information or to make any representation in connection with this Prospectus, which is not contained in the Prospectus. Any information or representation not so contained may not be relied on as having been authorised by the Company in connection with this Prospectus.

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

2.1 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 and, in those circumstances, any application that has been received may need to be dealt with in accordance with section 724 of the Corporations Act. Applications for Securities under this Prospectus will not be processed by the Company until after the expiry of the Exposure Period. No preference will be conferred on applications lodged prior to the expiry of the Exposure Period.

2.2 Currency conversions

Where an amount is expressed in this Prospectus in Australian Dollars and United States Dollars, the conversion is based on an indicative exchange rate (being $1.420455 = US$1.00) unless otherwise stated. The amount when expressed in Australian Dollars or United States Dollars may change as a result of fluctuations in the exchange rate between those currencies. Please refer to Section 9 of the Prospectus for all exchange rates applied to historical Financial Information.

2.3 Web Site – On-line Prospectus

A copy of this Prospectus can be downloaded from the website of the Company at www.koligo.net. If you are accessing the on-line version of this Prospectus, you must be a resident of Australia and must only access this Prospectus from within Australia, as the case may be. In particular, the on-line version of this Prospectus may not be accessed within any other jurisdiction, including the United States.

The Corporations Act prohibits any person passing onto another person an Application Form unless it is attached to a hard copy of this Prospectus or it accompanies the complete and unaltered version of this Prospectus. You may obtain a hard copy of this Prospectus free of charge by contacting the Company or contacting the Koligo Public Offer Information Line on 1300 288 684 if calling within Australia or +61 2 9698 5414 if calling from outside of Australia.

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 on-line Application Form, it was not provided together with the on-line Prospectus and any relevant supplementary or replacement prospectus or any of those documents were incomplete or altered.

2.4 Website

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

2.5 Forwarding-looking statements

This Prospectus contains forward-looking statements which are identified by words such as ‘may’, ‘could’, ‘believes’, ‘estimates’, ‘targets’, ‘expects’, or ‘intends’ 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.

The Company cannot and does not give any assurance that the results, performance or achievements expressed or implied by 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.
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.

These forward-looking statements are subject to various risk factors that could cause the Company’s actual results to differ materially from the results expressed or anticipated in these statements. These risk factors are set out in Sections 3.7 and 7 of this Prospectus.

2.6 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 the 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.

2.7 Replacement Prospectus

The differences between this Prospectus and the original prospectus dated 8 February 2019 are:

a. the inclusion of the Legal Report prepared by Buchanan Ingersoll & Rooney PC in relation to Koligo’s compliance with US FDA regulations for Kyslecel™ at Section 10 and additional references throughout the Prospectus to such Report;

b. the deletion of the estimated market sizes for Kyslecel™ in the U.S. and Kyslecel™ v2.0 worldwide, including the assumptions and calculations upon which these were based, throughout the Prospectus;

c. the inclusion of Buchanan Ingersoll & Rooney PC in the Corporate Directory and details of the fees they have been paid and the consent they have provided to be named in this Prospectus in Sections 13.8 and 13.9;

d. the amendment to the Indicative Timetable in Section 3.9; and

e. the amendment to the Expenses of the Offer table in Section 13.10 to include legal fees paid to Buchanan Ingersoll & Rooney PC.
INVESTMENT OVERVIEW

Koligo lab technician
3. INVESTMENT OVERVIEW

This section is a summary only and not intended to provide full information for investors intending to apply for Securities offered pursuant to this Prospectus. This Prospectus should be read and considered in its entirety.

3.1 The Company

Koligo Therapeutics Limited (the Company) was incorporated on 27 June 2018 for the primary purpose of acquiring Koligo Therapeutics, Inc. (a company incorporated in the Commonwealth of Kentucky in the United States) (Koligo).

Koligo is a U.S.-based biotechnology company focused on the development and commercialisation of a range of cell therapy, three-dimensional (3D) bioprinted tissue and other regenerative medicine products for serious unmet medical needs.

Koligo has successfully commercialised and has recently commenced selling its first cell therapy transplant product, Kyslecel™, in the United States. Kyslecel™ is used in the treatment of patients suffering from chronic or acute recurrent pancreatitis, a debilitating and painful condition with few effective treatment options. Koligo is currently developing Kyslecel™ v2.0, an improved formulation that is intended to extend its shelf life and thus expand the markets it serves.

Koligo also intends to develop a pipeline of regenerative medicine products that utilise 3D bioprinting, adipose-derived cells (regenerative cells derived from fat tissue) and other tissue processing techniques (referred to as Koligo’s 3D-V technology platform) for novel cell therapy and engineered tissue products. The products that Koligo intends to develop using its 3D-V technology platform are KT-CP-203 and KT-DM-103 (Stylecel-L), engineered tissue products containing pancreatic islets for the treatment of pancreatitis, type 1 diabetes, and other pancreatic diseases. Koligo has not yet commercialised the 3D-V technology platform, which is still subject to the completion of its development, clinical testing and regulatory approval. Further, KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development.

Longer term, the Company aims to be a leader in the development of novel cell therapy and engineered tissue products for liver failure, neurological diseases, metabolic disorders, and genetic disorders, using Koligo’s 3D-V technology platform, subject to its successful development.

Koligo’s proprietary cell therapy, 3D bioprinting, and tissue engineering technologies are protected by patents exclusively licensed by Koligo, a patent application filed by Koligo and non-patented proprietary databases, processes, and know-how owned by Koligo.

3.2 Exchange Agreement

On 22 November 2018, the Company entered into an exchange agreement (Exchange Agreement) with the current shareholders of Koligo to acquire 100% of the issued and outstanding shares of capital stock of Koligo in consideration for the issue of an aggregate of 75,000,000 Shares and 25,000,000 Performance Shares in the Company to the current shareholders of Koligo, such issue to be conditional upon, and to occur concurrently with the Company issuing the Shares under the Public Offer (the Exchange). The terms and conditions of the Performance Shares to be issued pursuant to the Exchange are set out in Section 13.5.
The effect of the Exchange Agreement is that, upon the Company obtaining the Listing Approval, raising the minimum subscription and issuing the Shares under the Offers, the current shareholders of Koligo will own approximately 71.4% of the Shares of the Company (or, in the event full oversubscriptions are raised under the Public Offer, the current shareholders of Koligo will own approximately 68.2% of the Shares of the Company) and Koligo will be a wholly owned subsidiary of the Company. Please refer to Section 12.1 for a summary of the key terms of the Exchange Agreement.

3.3 Exchange Consideration

The Board considers that the quantum of Shares and Performance Shares to be issued by the Company for the acquisition of Koligo reflects reasonable fair value of Koligo in view of the key investment highlights set out in Section 3.6 of the Prospectus and the Company having conducted arm’s length negotiations with the shareholders of Koligo to arrive at the commercial terms of the acquisition. In determining the quantum of Shares and Performance Shares to be issued for the Koligo acquisition, the Company also took into account the following considerations:

- the fact that Koligo has recently commenced sales of its first product Kyslecel™ to hospitals in the U.S., which Koligo has determined meets the criteria to be regulated under Section 361 of the U.S. Public Health Service Act and applicable U.S. Food and Drug Administration (FDA) regulations and therefore is qualified for sale in the United States without FDA premarket clearance or approval – refer to the Legal Report in Section 10 for further details in respect of Koligo’s compliance with FDA regulations;

- the fact that Koligo has generated revenues of approximately $1,600,000 from the sale of Kyslecel™ between November 2017 when it began offering the product to a select number of pancreatic centres and the date of this Prospectus;

- the fact that the Company believes Kyslecel™ has a substantial addressable market in the U.S. and that Koligo has opportunities for growth in the U.S. and internationally;

- the fact that no other business or enterprise is known by Koligo to be widely selling a product similar to Kyslecel™ as a commercial for-profit endeavour;

- the fact that Koligo has exclusively licensed intellectual property to protect its product pipeline, which potentially provides Koligo with a defensible position in relation to third party infringement;

- the Board’s assessment of the future prospects of Koligo based on the status of its know-how, technology and products, growth plans and interest from third parties; and

- valuations of comparable cell therapy, regenerative medicine and 3D bioprinting companies.

As with the acquisition of any relatively early stage growth company, there is not always an appropriate formal valuation methodology (e.g. discounted cash flow) available when determining the purchase price and the Company was required to take into account qualitative factors such as those set out above in coming to a decision on price.
3.4 Business Model

Koligo’s business model is to grow sales of its first commercially available cell therapy product Kysleccl™, while, at the same time, to develop and commercialise a range of 3D-bioprinted cell therapy and regenerative medicine products.

3.4.1 Kysleccl™ and Kysleccl™ v2.0

Kysleccl™ is Koligo’s first cell therapy product which it has recently commenced sales of. Kysleccl™ is used in the treatment of patients suffering from chronic or acute recurrent pancreatitis, a debilitating and painful condition with few effective treatment options. Kysleccl™ is manufactured using a patient’s own diseased pancreas – it contains a patient’s own pancreatic islets (the cells that produce insulin) that are reintroduced into a patient’s body to produce insulin needed to regulate blood sugar. Koligo has determined that Kysleccl™ meets the criteria to be regulated under Section 361 of the U.S. Public Health Service Act and applicable U.S. Food and Drug Administration (FDA) regulations and therefore is qualified for sale in the United States without FDA premarket clearance or approval. Refer to the Legal Report in Section 10 for further details in respect of Koligo’s compliance with FDA regulations.
Kyslecel™ is used after a patient has undergone a total pancreatectomy (complete removal of the pancreas) (TP) to relieve the pain and inflammation caused by pancreatitis. Historically, TP procedures have been performed at a very limited number of hospitals with islet-autotransplantation (IAT) capabilities to treat the side effects caused by TP (namely diabetes). Yet, at present, Koligo is not aware of any other business or enterprise that sells IAT products as a commercial for-profit endeavour. In fact, Koligo believes a large proportion of patients suffering from chronic or acute recurrent pancreatitis do not seek treatment using TP with IAT due to, among other things, a lack of access to IAT products.

Koligo commercialised Kyslecel™ in order to meet this pressing clinical need for IAT products. Koligo believes Kyslecel™ can significantly expand access to treatments for chronic and acute recurrent pancreatitis by being available for sale at local qualified hospitals in the U.S.

In order to further expand patient access, Koligo is currently developing Kyslecel™ v2.0, an improved formulation of Kyslecel™ that is intended to extend its shelf life. Koligo intends to launch Kyslecel™ v2.0 in the second half of 2019, subject to completion of its development – refer to Section 6.2 for further details.
Since commencement of sales of Kyslecel™ in November 2017 until the date of this Prospectus, Koligo has sold Kyslecel™ for use in the treatment of 22 patients who undertook TP procedures in the U.S., with revenues of approximately $1,600,000 generated from these sales. Prior to founding Koligo, Dr. Balamurugan Appakalai (Koligo’s Chief of Manufacturing) performed over 800 similar human islet isolation procedures at various academic institutions for research and clinical purposes.

Koligo believes the market for Kyslecel™ in the U.S. is significant. An estimated 16,000 to 39,000 people in the U.S. are diagnosed with chronic or acute recurrent pancreatitis each year. Further, Koligo believes the market for Kyslecel™ v2.0 worldwide could be larger, given that it is expected to be available to more patient groups and expected to be shipped over longer distances, including to international markets (subject to meeting foreign regulatory requirements - see Section 6.2 for further information). Since it currently has limited competition, Koligo believes it can capture a substantial part of these markets. However, it is not possible to reliably quantify the size of the markets of Kyslecel™ and Kyslecel™ v2.0 in terms of potential revenue.

In order to increase its sales of Kyslecel™ (and subsequently Kyslecel™ v2.0), Koligo intends to focus on the following growth strategies:

- expanding Koligo’s sales force and investing in the marketing of Kyslecel™;
- increasing the number of insurers that reimburse for Kyslecel™;
- expanding the network of hospitals and doctors who offer Kyslecel™; and
- evaluating international opportunities for Kyslecel™ v2.0 through potential licensing and collaboration agreements for specific countries and regions.

3.4.2 Product Development Pipeline

Koligo intends to develop and commercialise a range of cell therapy, 3D bioprinted tissue and other regenerative medicine products based on the 3D-V technology platform which Koligo is developing. It is intended that the products will utilise 3D bioprinting of adipose-derived cells (regenerative cells derived from fat tissue), and other tissue processing techniques to engineer tissue to replace damaged or diseased tissue or organs. Investors should note that Koligo has not yet commercialised its 3D-V technology platform.

The 3D-V technology platform is principally based on research and development conducted by Stuart Williams, PhD (now Koligo’s Chief Technology Officer and a Director of the Company) while a faculty researcher at the University of Arizona and later the University of Louisville.

Koligo intends to use its 3D-V technology platform in the development of KT-CP-203 and KT-DM-103 (Stylecel-L), novel pancreatic islet engineered tissue products for the treatment of pancreatitis, type 1 diabetes, and other pancreatic diseases. KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development.

- KT-CP-203 is an engineered tissue product containing 3D bioprinted autologous (patient derived) pancreatic islets which aims to provide a treatment for chronic and acute recurrent pancreatitis.
- Stylecel-L is an engineered tissue product containing 3D bioprinted allogeneic (donor derived) pancreatic islets which aims to provide a treatment for type 1 diabetes with hypoglycaemic unawareness and other pancreatic diseases.
Koligo intends to develop and commercialise KT-CP-203 and Stylecel-L by:

- seeking orphan designation for Stylecel-L in the U.S.;
- completing pre-clinical safety studies of 3D bio-printed islets to begin human clinical trials for KT-CP-203 and Stylecel-L;
- developing cryo-preservation system to maintain an inventory of Stylecel-L that is available to meet patient demand; and
- identifying licensees or strategic commercial partners to commercialise KT-CP-203 and Stylecel-L.

Longer term, Koligo intends to leverage its 3D-V technology platform to develop products that treat diseases or disorders using cell or tissue transplant therapies with proven pre-clinical or clinical results, including neurodegenerative diseases (e.g., Parkinson’s, Lou Gehrig’s and Huntington’s diseases), Chondral lesions (e.g., knees, hips and other joints), DiGeorge syndrome and Acute liver failure (liver based metabolic disorders). The Company believes that the development of products for the treatment of these diseases or disorders would present significant growth opportunities for the Company.
3.5 The Objectives

The Company’s main objectives on completion of the Offers are to:

• expand Koligo’s sales force,
• invest in marketing and public relations activities for Kyslecel™,
• expand Koligo’s manufacturing capabilities, and
• conduct research and development to facilitate the development and commercialisation of other regenerative medicine products.

Each of these areas is important to the Company’s ability to execute its strategy.

3.6 Key Investment Highlights

The Directors consider the key highlights of an investment in the Company include:

• Koligo has the potential to become a successful regenerative medicine platform for the development and commercialisation of scalable bioengineered tissue transplant products.
• Koligo has commenced sales of its first cell therapy product Kyslecel™ for the treatment of chronic or acute recurrent pancreatitis.
• Koligo believes there is a serious unmet medical need for Kyslecel™, as the current treatments for chronic or acute recurrent pancreatitis seldom provide meaningful long-term relief to patients.
• No other business or enterprise is known by Koligo to be widely selling a product similar to Kyslecel™ as a commercial for-profit endeavour.
• Koligo believes that Kyslecel™ has a substantial addressable market in the U.S., that Koligo has opportunities to significantly broaden its U.S. addressable market and that it is well positioned for growth in international markets, subject to the receipt of all relevant regulatory approvals.
• Koligo believes that the U.S. market size for Kyslecel™ is significant and that, subject to its development and launch, the worldwide market for Kyslecel™ v2.0 could be larger. However, it is not possible to reliably quantify the size of these markets in terms of potential revenue.
• Koligo has determined that Kyslecel™ meets the criteria to be regulated under section 361 of the U.S. Public Health Service Act and applicable FDA regulations and therefore is qualified for sale in the United States without FDA premarket clearance or approval. Refer to the Legal Report in Section 10 for further details in respect of Koligo’s compliance with FDA regulations;
• Koligo believes that its 3D-V technology platform can potentially support the development of a range of cell therapy, 3D bioprinted tissue and other regenerative medicine products with significant market potential in the treatment of serious unmet medical needs including pancreatitis, type 1 diabetes, liver failure, neurological diseases, metabolic disorders, and genetic disorders.
• Koligo has exclusively licensed know-how, patents and other intellectual property associated with Kyslecel™ and its 3D-V technology platform, which potentially provides Koligo with a defensible position in relation to third party infringement.
• The Company and Koligo are backed by a U.S. institutional investor.
• Members of the Company’s Board and management are experienced in the regenerative medicine industry and in successful ASX small-caps. The calibre, ability and relevant experience of the Board are highlighted by the following:
  • the Executive Director and Chief Executive Officer Matthew Lehman has over 18 years’ executive experience at numerous biotechnology and pharmaceutical companies;
  • the Non-Executive Chairman Peter James has over 30 years’ public company experience as Chair, Non-Executive Director and Chief Executive Officer across a range of publicly listed and private companies;
  • the Executive Director and Chief Technology Officer Stuart Williams, PhD is an internationally recognised expert in regenerative medicine and is the Endowed Chair of Cardiovascular Innovation and Director of the Bioficial Organs Program at the University of Louisville; and
  • the Non-Executive Director Jethro Marks has over 18 years’ experience in marketing and is the co-founder and Chief Executive Officer of The Nile, an established Australian online retailer.
3.7 Key Risks

The business, assets and operations of the Company are subject to certain risk factors that have the potential to influence the operating and financial performance of the Company in the future. These risks can impact the value of an investment in the securities of the Company.

The Board aims to manage these risks by carefully planning its activities and implementing risk control measures. Some of the risks are, however, unpredictable and the extent to which the Company can effectively manage them is limited.

Set out below are specific risks that the Company is exposed to. Further risks associated with an investment in the Company are outlined in Section 7.

a. Limited History

The Company was only recently incorporated and has limited operating history and limited historical financial performance. Further, Koligo has a limited operating history and has operated at a loss since its inception in March 2016. In the financial years ending 31 December 2017 and 31 December 2018, Koligo had net losses of $127,321 and $2,967,804, respectively. Please refer to the financial information in Section 9 for further details.

Although members of Koligo’s management team have experience with islet production, transplantation, biotechnology product development, and other aspects of Koligo’s business, much of this experience was gained as employees of other entities. There is no guarantee that the past individual experiences of the Company’s management team will translate into success for the Company.

No assurance can be given that the Company will achieve commercial viability through the sale of Kyslecel™ with total pancreatectomy, the development of the products in Koligo’s pipeline, or otherwise. Koligo has sold a limited number of units of Kyslecel™ since it commenced sales in November 2017. Unless widespread adoption of Kyslecel™ as a treatment for chronic or acute recurrent pancreatitis is achieved, the Company is likely to incur ongoing operating losses.

Refer to Section 7.2(a) for further details in respect of this risk factor.

b. Regulatory risks for Kyslecel™

Kyslecel™ is regulated by the U.S. Food and Drug Administration (FDA). As described below, Koligo has determined that Kyslecel™ meets the criteria specified in Title 21 of the U.S. Code of Federal Regulations (CFR) Part 1271.10(a) to be regulated solely under Section 361 of the U.S. Public Health Service Act and 21 CFR Part 1271 as a human cell, tissue and cellular- and tissue-based product (HCT/P) – refer to the Legal Report in Section 10 for further details.

FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called 361 HCT/Ps) are not subject to any premarketing clearance or approval requirements but are subject to a variety of other regulatory requirements. Failure to meet these criteria may result in Kyslecel™ being adulterated and/or misbranded and therefore prevent the sale of Kyslecel™ in the U.S., which would materially and adversely affect the Company’s business prospects and financial performance.

If Kyslecel™ or Kyslecel™ v2.0 does not, in FDA’s view, meet the criteria for regulation as a 361 HCT/P, Koligo would need FDA approval to lawfully market Kyslecel™ or Kyslecel™ v2.0 in the United States as a biological product. Further, the development of Kyslecel™ v2.0 may result in it no longer qualifying as a 361 HCT/P. In addition, FDA’s regulation of minimally-manipulated autologous HCT/Ps is subject to change, which may result in Kyslecel™ or Kyslecel™ v2.0 not satisfying the criteria to be regulated as a 361 HCT/P.

Refer to Section 7.2(b) for further details in respect of this risk factor.

c. Market adoption and ongoing acceptance of Kyslecel™

The Company is heavily dependent on the success of Kyslecel™. The Company’s commercialisation strategy for Kyslecel™ relies on medical specialists, medical facilities and patients adopting TP with Kyslecel™ as an accepted treatment. At the date of this Prospectus, Kyslecel™ has been used in operations at two hospitals and medical facilities in the U.S. and Koligo is currently negotiating with several other facilities for the provision of Kyslecel™.

There is no guarantee that patient acceptance of TP with Kyslecel™ will be substantial. Further, there is no guarantee that Koligo will be able to achieve patient acceptance or obtain enough customers (clinical providers) to meet its sales objectives. If the Company does not meet its sales objectives, the Company’s business prospects and financial performance will be materially and adversely affected.

Refer to Section 7.2(c) for further details in respect of this risk factor.
d. Intellectual property protection for Kyslecel™ and the 3D-V technology platform

Koligo has exclusively licensed non-patented intellectual property related to Kyslecel™ from the University of Louisville Research Foundation, Inc. (the Foundation), until 20 November 2019, after which Koligo’s license to the intellectual property will become royalty-free and non-exclusive. Koligo has also entered into agreements with the University of Arizona and the Foundation to exclusively license patented intellectual property associated with its 3D-V technology platform. The periods during which Koligo has exclusively licensed these intellectual property rights are finite. Refer to Section 12.4 to 12.7 and the Intellectual Property Report in Section 8 for further details.

There is no guarantee that either the agreements under which Koligo has licensed intellectual property or the intellectual property licensed thereunder will not be challenged, or that the licensors under these agreements will comply with their respective obligations (including their obligation not to license the intellectual property to third parties). Further, the Company cannot guarantee that Koligo will be able to comply with the terms of these agreements, including terms that require Koligo to achieve certain research and development or commercial milestones. The loss of any of Koligo’s rights under these agreements due to a successful legal challenge, non-compliance, termination or otherwise would adversely affect the Company’s business and revenue.

The defence and prosecution of intellectual property rights are costly and time-consuming and their outcome is uncertain. There can be no assurance that the measures Koligo has implemented to protect its interests as the licensee of at least some of its intellectual property have been or will be sufficient.

Refer to Section 7.2(d) for further details in respect of this risk factor.

e. Product development for the Company’s product pipeline

KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development and have yet to be tested in humans. The Company expects that these products will not be 361 HCT/Ps, and will instead require FDA pre-approval of a marketing application. The success of these products will depend on, among other things, the Company’s ability to develop and commercialise these products, and obtain the necessary marketing approvals from the FDA and other regulatory authorities. There are many risks inherent in the development of new cell and tissue-based products, particularly where the products are in the early stages of development.

Refer to Section 7.2(e) for further details in respect of this risk factor.

f. Manufacturing risk

Production of Kyslecel™ is expensive, time-consuming, difficult to implement, and involves an uncertain outcome. Because Kyslecel™ is made for each patient individually from that patient’s pancreas, and because human tissue is inherently variable in biological function, the Company cannot guarantee that it will be able produce a safe and effective product for each patient. Further, the remote processing of a patient’s pancreas and the manufacturing and transportation of Kyslecel™ introduces risks of delay, contamination, temperature fluctuations, and transport conditions that may adversely impact the quality of the product. If Koligo is unable to implement effective logistics management systems, the Company’s business and revenues may be adversely affected.

Refer to Section 7.2(g) for further details in respect of this risk factor.

g. Facilities risk

Kyslecel™ is required to be produced and distributed in accordance with FDA’s current Good Tissue Practice (cGTP) requirements, and otherwise comply with all applicable U.S. federal and state regulations. Failure to meet these standards could result in FDA or other regulatory authorities ordering the Company to cease the production of Kyslecel™ (or other products) or to make improvements to the Company’s practices or facilities that are costly.

Refer to Section 7.2(i) for further details in respect of this risk factor.

h. Product liability risk

The sale of Koligo’s products involves the risk of product liability claims being brought against the Company or Koligo, including in the event of death, injury or damage to property being caused due to the sale, marketing, use or manufacture of Koligo’s products. Koligo seeks to limit its liability for such claims in its agreements with its customers (medical facilities and hospitals) and is also entitled to be indemnified by its customers in various circumstances. However, limitations of liability are not necessarily effective at law, and indemnification may not always be available.

Refer to Section 7.2(j) for further details in respect of this risk factor.

i. Customer risk

Koligo currently derives, and expects to continue to derive, a significant portion of its revenues from a limited
number of customers, including the Jewish Hospital located in Louisville, Kentucky, USA. The loss of, or a significant decrease in, business from any significant customer could seriously harm the Company’s business and revenues.

Refer to Section 7.2(k) for further details in respect of this risk factor.

j. Key personnel risk

The Company’s success will substantially depend on the continued employment or retention of senior executives, scientific and technical staff and other key personnel by Koligo, including Matthew Lehman, Stuart Williams, PhD, Mike Hughes, MD, and Balamurugan Appakalai, PhD.

Refer to Section 7.2(p) for further details in respect of this risk factor.

k. Concentration of ownership and dilution risk

The Company currently has 1 Share on issue and will issue 75,000,000 Shares and 25,000,000 Performance Shares in the Exchange, meaning that the maximum number of Shares issued under the Public Offer will represent up to approximately 31.82% of the issued Share capital of the Company on completion of the Offers (assuming the full oversubscription is raised). Further, assuming only the minimum subscription is raised under the Public Offer, the number of Shares issued will represent approximately only 28.57% of the issued Share capital of the Company on completion of the Offers.

Refer to Section 7.2(u) for further details in respect of this risk factor.

l. Liquidity

As noted above, 75,000,000 Shares and 25,000,000 Performance Shares in the Company will be issued to the existing owners of Koligo in the Exchange. All of these Shares and Performance Shares are likely to be classified by the ASX as restricted securities and be placed into escrow. Please refer to Section 3.14 for further details. Some investors may consider that there is an increased liquidity risk as a large portion of issued capital may not be able to be traded freely for a period of time.

Refer to Section 7.2(v) for further details in respect of this risk factor.

The above list of risk factors should not to be taken as exhaustive of the risks faced by the Company and you should refer to the additional risk factors in Section 7 of this Prospectus before deciding whether to apply for Securities pursuant to this Prospectus.

3.8 The Offers

Under the Public Offer, the Company invites applications for 30,000,000 Shares at an issue price of $0.20 per Share to raise $6,000,000. Oversubscriptions of up to a further 5,000,000 Shares at an issue price of $0.20 per Share to raise up to a further $1,000,000 may be accepted. As such, the maximum amount that can be raised under the Public Offer is $7,000,000.

The Prospectus also includes an offer of 75,000,000 Shares and 25,000,000 Performance Shares in consideration for the acquisition of Koligo. Only the Koligo shareholders may accept the Consideration Offer.

Further, the Joint Lead Managers (or their respective nominees) may subscribe for a total of 5,500,000 Options subject to the terms of the Joint Lead Manager Mandates summarised in Section 12.2. The Options offered under the Joint Lead Manager Offer will be issued on the terms and conditions set out in Section 13.4 of this Prospectus.

The key information relating to the Offers and references to further details are set out below.

3.9 Indicative timetable*

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lodgement of Prospectus with the ASIC</td>
<td>25 February 2019</td>
</tr>
<tr>
<td>Opening Date of the Offers</td>
<td>25 February 2019</td>
</tr>
<tr>
<td>Closing Date of the Offers</td>
<td>22 March 2019</td>
</tr>
<tr>
<td>Despatch of holding statements</td>
<td>29 March 2019</td>
</tr>
<tr>
<td>Expected date for quotation on ASX</td>
<td>05 April 2019</td>
</tr>
</tbody>
</table>

* The above dates are indicative only and may change without notice. The Company reserves the right to extend the Closing Date or close the Offers early without notice.

3.10 Purpose of the Public Offer

The purpose of the Public Offer is to facilitate an application by the Company for admission to the Official List of ASX and position the Company to seek to achieve the objectives set out above in Section 3.5.

3.11 Use of Funds

The Company intends to apply funds raised from the Public Offer, together with existing cash reserves, over the first two years following admission of the Company to the official list of ASX as follows:
INVESTMENT OVERVIEW

<table>
<thead>
<tr>
<th>FUNDS AVAILABLE</th>
<th>MINIMUM SUBSCRIPTION ($) ($6,000,000)</th>
<th>PERCENTAGE OF FUNDS (%)</th>
<th>FULL OVERSUBSCRIPTIONS ($) ($7,000,000)</th>
<th>PERCENTAGE OF FUNDS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Public Offer cash balance¹</td>
<td>$10,253</td>
<td>0.16%</td>
<td>$10,253</td>
<td>0.14%</td>
</tr>
<tr>
<td>Drawdown from Loan Facilities</td>
<td>$275,034</td>
<td>4.38%</td>
<td>$275,034</td>
<td>3.78%</td>
</tr>
<tr>
<td>Funds raised from the Public Offer</td>
<td>$6,000,000</td>
<td>95.46%</td>
<td>$7,000,000</td>
<td>96.08%</td>
</tr>
<tr>
<td>Total allocation of funds</td>
<td>$6,285,287</td>
<td>100.0%</td>
<td>$7,285,287</td>
<td>100%</td>
</tr>
<tr>
<td>Expansion of sales staff, and marketing and advertising expenditure</td>
<td>$1,192,500</td>
<td>18.97%</td>
<td>$1,286,250</td>
<td>17.66%</td>
</tr>
<tr>
<td>Expansion of manufacturing facilities and other capital expenditures</td>
<td>$800,000</td>
<td>12.73%</td>
<td>$1,100,000</td>
<td>15.10%</td>
</tr>
<tr>
<td>Research and development</td>
<td>$1,050,000</td>
<td>16.71%</td>
<td>$1,150,000</td>
<td>15.79%</td>
</tr>
<tr>
<td>Expansion of operational staff</td>
<td>$144,000</td>
<td>2.29%</td>
<td>$144,000</td>
<td>1.98%</td>
</tr>
<tr>
<td>Executive, head office and overhead</td>
<td>$998,800</td>
<td>15.89%</td>
<td>$1,150,050</td>
<td>15.79%</td>
</tr>
<tr>
<td>Administration and overheads²</td>
<td>$482,000</td>
<td>7.67%</td>
<td>$482,000</td>
<td>6.62%</td>
</tr>
<tr>
<td>Expenses of the Offers³</td>
<td>$1,194,536</td>
<td>19.01%</td>
<td>$1,255,909</td>
<td>17.24%</td>
</tr>
<tr>
<td>Repayment of Loans</td>
<td>$371,023</td>
<td>5.90%</td>
<td>$371,023</td>
<td>5.09%</td>
</tr>
<tr>
<td>Working capital</td>
<td>$52,428</td>
<td>0.83%</td>
<td>$346,055</td>
<td>4.75%</td>
</tr>
<tr>
<td>Total</td>
<td>$6,285,287</td>
<td>100%</td>
<td>$7,285,287</td>
<td>100%</td>
</tr>
</tbody>
</table>

¹ Refer to the Financial Information and Independent Limited Assurance Report set out in Section 9 of this Prospectus for further details regarding the cash and cash equivalents as at 31 December 2018.

² Including but not limited to share registry, company secretary, ASX, audit, legal, IP protection, insurance and investor relations costs.

³ Refer to Section 13.10 of this Prospectus for further details.

As noted above, the Company intends to use approximately $1,192,500 of the capital raised under the Public Offer (assuming minimum subscription), or approximately $1,286,250 (assuming full oversubscription) and its pre-Public Offer cash balance, to expand the Company's sales force and increase the marketing and advertising expenditure for Kyslecel™. These funds will predominantly be used to grow the sales of the Company's first commercially available product Kyslecel™ and to achieve profitability.

The Company intends to use approximately $998,800 of the capital raised under the Public Offer (assuming minimum subscription), or approximately $1,150,050 (assuming full oversubscription) and its pre-Public Offer cash balance, to hire additional head office staff, pay contractually agreed-upon salaries and bonuses to retain the Company's executives and to pay other overhead costs that will be borne by the Company in connection with the execution of its growth strategy.

Further, the Company intends to use approximately $1,050,000 of the capital raised under the Public Offer (assuming minimum subscription), or approximately $1,150,000 (assuming full oversubscription) and its pre-Public Offer cash balance, to fund research and development for the pre-clinical and clinical development of products in the Company's pipeline, including clinical development and validation of Kyslecel™ v2.0 and formulation development of KT-CP-203.

The Company also intends to use approximately $800,000 of the capital raised under the Public Offer (assuming minimum subscription), or approximately $1,100,000 (assuming full oversubscription) and its pre-Public Offer cash balance, to expand Koligo's manufacturing facilities in relation to Kyslecel™ and Kyslecel™ v2.0. Specifically, the funds are expected to be used to make improvements to
Koligo’s future leased facilities and to purchase or lease additional capital equipment (including air handlers and laboratory equipment) to fit out two production lines.

It is anticipated that the funds raised under the Public Offer will enable 2 years of full operations (if the minimum subscription is raised).

It should be noted that the Company may not be fully self-funding through its own operational cash flow at the end of this period. Accordingly, the Company may require additional capital beyond this point, which will likely involve the use of additional debt or equity funding. Future capital needs may also depend on development opportunities on new applications that may arise from the Company’s technologies as they are developed over time and which may have significant value if further developed for the market.

In the event the Company raises more than the minimum subscription of $6,000,000, and after payment of the increased expenses of the Offers, the additional funds raised will be first applied towards expansion of the Company’s sales staff, and marketing and advertising expenditure, and then towards commencing pre-clinical research and development for the Company’s product pipeline and then toward expansion of the Company’s manufacturing facilities and other capital expenditures and then towards executive, head office, overheads and general working capital. On completion of the Public Offer, the Board believes the Company will have sufficient working capital to achieve these objectives.

The above table is a statement of current intentions as of the date of this Prospectus. As with any budget, intervening events and new circumstances (including the need to adapt to a changing competitive environment, and the level of demand for the Company’s products) have the potential to affect the manner in which the funds are ultimately applied. The Board reserves the right to alter the way funds are applied on this basis.

The use of further debt or equity funding will be considered by the Board where it is appropriate to expand sales, research and development and operations efforts, accelerate product development or capitalise on further opportunities.

3.12 Capital Structure

The capital structure of the Company following completion of the Offers (assuming minimum subscription and full oversubscriptions under the Public Offer) is summarised below:

<table>
<thead>
<tr>
<th>SHAREs²</th>
<th>MINIMUM SUBSCRIPTION NUMBER</th>
<th>FULL OVER-SUBSCRIPTION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares currently on issue³</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Shares to be issued pursuant to the Exchange Agreement⁴</td>
<td>75,000,000</td>
<td>75,000,000</td>
</tr>
<tr>
<td>Shares to be issued pursuant to the Public Offer</td>
<td>30,000,000</td>
<td>35,000,000</td>
</tr>
<tr>
<td>Total Shares on completion of the Offers⁵</td>
<td>105,000,001</td>
<td>110,000,001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPTIONS</th>
<th>MINIMUM SUBSCRIPTION NUMBER</th>
<th>FULL OVER-SUBSCRIPTION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Options currently on issue</td>
<td>nil</td>
<td>nil</td>
</tr>
<tr>
<td>Options to be issued to Directors and management⁶</td>
<td>11,000,000</td>
<td>11,000,000</td>
</tr>
<tr>
<td>Options to be issued to the Joint Lead Managers (or their nominees)⁷</td>
<td>5,250,000</td>
<td>5,500,000</td>
</tr>
<tr>
<td>Options to be issued to medical advisory consultant of Koligo⁸</td>
<td>71,023</td>
<td>71,023</td>
</tr>
<tr>
<td>Total Options on completion of the Offers</td>
<td>16,321,023</td>
<td>16,571,023</td>
</tr>
</tbody>
</table>
INVESTMENT OVERVIEW

PERFORMANCE SHARES

<table>
<thead>
<tr>
<th></th>
<th>MINIMUM SUBSCRIPTION NUMBER</th>
<th>FULL OVER-SUBSCRIPTION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Shares currently on issue</td>
<td>nil</td>
<td>nil</td>
</tr>
<tr>
<td>Performance Shares to be issued under the Public Offer</td>
<td>nil</td>
<td>nil</td>
</tr>
<tr>
<td>Performance Shares to be issued pursuant to the Exchange Agreement</td>
<td>25,000,000</td>
<td>25,000,000</td>
</tr>
<tr>
<td>Total Performance Shares on completion of the Offers</td>
<td>25,000,000</td>
<td>25,000,000</td>
</tr>
</tbody>
</table>

1. Refer to the Independent Limited Assurance Report set out in Section 9 of this Prospectus for further details.

2. The rights attaching to the Shares are summarised in Section 13.2 of this Prospectus.

3. The Share currently on issue was issued on the date of incorporation of the Company to Long Hill Capital V, LLC.

4. Refer to Section 12.1 for a summary of the terms of the Exchange Agreement pursuant to which these Shares are to be issued.

5. As consideration for the license to the intellectual property granted under the Knowledge Licence Agreement summarised in Section 12.4 of the Prospectus, the Company has undertaken to issue to the University of Louisville Research Foundation, Inc. (the Foundation) on the second anniversary of the date the Company is admitted to the Official List (Listing Date) up to 1,041,903 Shares.

6. Each Option will be unquoted and is exercisable at $0.30 on or before the third anniversary of the date of its vesting. Refer to Section 3.20 for details of the vesting conditions attached to such Options and to Section 13.3 for the full terms and conditions of these Options.

7. Each Option will be unquoted and is exercisable at $0.30 on or before the third anniversary of the date of its issue. Refer to Section 13.4 for the full terms and conditions of these Options and to Section 12.2 for a summary of the Joint Lead Manager Mandates.

8. Each Option will be unquoted and is exercisable at $0.30 on or before the third anniversary of the date of its vesting. The Options will vest as follows: 17,756 Options on the Listing Date, 17,756 Options 12 months after the Listing Date, 17,756 Options 24 months after the Listing Date, 17,756 Options 36 months after the Listing Date.

9. Consisting of 12,500,000 Class A Performance Shares and 12,500,000 Class B Performance Shares. Each Performance Share is convertible into one Share in the Company on the achievement of certain milestones. Refer to Section 13.5 for the full terms and conditions of these Performance Shares.
### 3.13 Substantial Shareholders

Those Shareholders holding 5% or more of the Shares on issue as at the date of this Prospectus assuming completion under the Exchange Agreement has occurred and on completion of the Public Offer (assuming minimum subscription) are set out in the respective tables below.

<table>
<thead>
<tr>
<th>SHAREHOLDER</th>
<th>SHARES</th>
<th>OPTIONS</th>
<th>% (UNDILUTED)</th>
<th>% (FULLY DILUTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Hill Capital V, LLC</td>
<td>1</td>
<td>-</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**As at the date of the Prospectus**

<table>
<thead>
<tr>
<th>SHAREHOLDER</th>
<th>SHARES</th>
<th>OPTIONS</th>
<th>% (UNDILUTED)</th>
<th>% (FULLY DILUTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Hill Capital V, LLC</td>
<td>33,024,941</td>
<td>-</td>
<td>44.03</td>
<td>44.03</td>
</tr>
<tr>
<td>Matthew Lehman</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Balamurugan Appakalai</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Stuart Williams</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>David Blanford</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Michael Hughes</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
</tbody>
</table>

**As at the date of the Prospectus and assuming the Shares under the Exchange Agreement are issued to the Koligo shareholders**

<table>
<thead>
<tr>
<th>SHAREHOLDER</th>
<th>SHARES</th>
<th>OPTIONS</th>
<th>% (UNDILUTED)</th>
<th>% (FULLY DILUTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Hill Capital V, LLC</td>
<td>33,024,941</td>
<td>-</td>
<td>44.03</td>
<td>44.03</td>
</tr>
<tr>
<td>Matthew Lehman</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Balamurugan Appakalai</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Stuart Williams</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>David Blanford</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Michael Hughes</td>
<td>8,326,691</td>
<td>-</td>
<td>11.1</td>
<td>11.1</td>
</tr>
</tbody>
</table>

**On completion of the Offers (assuming no existing substantial Shareholder subscribes and receives additional Shares pursuant to the Public Offer and no subscriber in the Public Offer becomes a substantial Shareholder as a result of their subscription)**

<table>
<thead>
<tr>
<th>SHAREHOLDER</th>
<th>A SHARES</th>
<th>B OPTIONS</th>
<th>C TOTAL SHARES</th>
<th>D TOTAL OPTIONS</th>
<th>E+C=D DILUTED SHARES</th>
<th>F=A/C % UNDILUTED</th>
<th>G=A/E % DILUTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Hill Capital V, LLC</td>
<td>33,024,941</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>31.45</td>
<td>27.22</td>
</tr>
<tr>
<td>Matthew Lehman</td>
<td>8,326,691</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>7.93</td>
<td>6.86</td>
</tr>
<tr>
<td>Balamurugan Appakalai</td>
<td>8,326,691</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>7.93</td>
<td>6.86</td>
</tr>
<tr>
<td>Stuart Williams</td>
<td>8,326,691</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>7.93</td>
<td>6.86</td>
</tr>
<tr>
<td>David Blanford</td>
<td>8,326,691</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>7.93</td>
<td>6.86</td>
</tr>
<tr>
<td>Michael Hughes</td>
<td>8,326,691</td>
<td>-</td>
<td>105,000,001</td>
<td>16,321,023</td>
<td>121,321,024</td>
<td>7.93</td>
<td>6.86</td>
</tr>
</tbody>
</table>

1. Long Hill Capital V, LLC and/or its related parties may participate in the Public Offer.
On completion of the Offers (assuming no existing substantial Shareholder subscribes and receives additional Shares pursuant to the Public Offer, no subscriber in the Public Offer becomes a substantial Shareholder as a result of their subscription, all of the Performance Shares convert into Shares and no other Shares are issued in the Company)

<table>
<thead>
<tr>
<th>SHAREHOLDER</th>
<th>A SHARES</th>
<th>A1 PERFORMANCE SHARES</th>
<th>B OPTIONS</th>
<th>C TOTAL SHARES</th>
<th>D TOTAL OPTIONS</th>
<th>E=C+D DILUTED SHARES</th>
<th>F=(A+A1)/C % UNDILUTED</th>
<th>G=(A+A1)/E % DILUTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Hill Capital V, LLC</td>
<td>33,024,941</td>
<td>11,008,312</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>33.87%</td>
<td>30.09%</td>
</tr>
<tr>
<td>Matthew Lehman</td>
<td>8,326,691</td>
<td>2,775,562</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>8.54%</td>
<td>7.59%</td>
</tr>
<tr>
<td>Balamurugan Appakalai</td>
<td>8,326,691</td>
<td>2,775,562</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>8.54%</td>
<td>7.59%</td>
</tr>
<tr>
<td>Stuart Williams</td>
<td>8,326,691</td>
<td>2,775,564</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>8.54%</td>
<td>7.59%</td>
</tr>
<tr>
<td>David Blanford</td>
<td>8,326,691</td>
<td>2,775,564</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>8.54%</td>
<td>7.59%</td>
</tr>
<tr>
<td>Michael Hughes</td>
<td>8,326,691</td>
<td>2,775,564</td>
<td>-</td>
<td>130,000,001</td>
<td>16,321,023</td>
<td>146,321,024</td>
<td>8.54%</td>
<td>7.59%</td>
</tr>
</tbody>
</table>

1. Long Hill Capital V, LLC and/or its related parties may participate in the Public Offer.

The Company will announce to the ASX details of its top 20 Shareholders (following completion of the Offers) prior to the Shares commencing trading on ASX.

3.14 Restricted Securities

Subject to the Company being admitted to the Official List, certain Shares, Performance Shares and Options will be classified by ASX as restricted securities and will be required to be held in escrow for up to 24 months from the date of Official Quotation. 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 his or her Shares in a timely manner.

It is estimated that 75,000,001 Shares, 25,000,000 Performance Shares and 16,571,023 Options will be subject to escrow as follows:

a. 1 Share issued on the incorporation of the Company for 24 months from the date of Official Quotation (held by Long Hill Capital V, LLC, the sole shareholder of the Company at the date of this Prospectus);

b. 75,000,000 Shares and 25,000,000 Performance Shares for 24 months from the date of official quotation (to be issued under the Exchange Agreement and held by the shareholders of Koligo);

c. 11,071,023 Options for 24 months from the date of official quotation (held by Directors, management and medical advisory consultant); and

d. up to 5,500,000 Options for 24 months from the date of official quotation (to be issued to the Joint Lead Managers).

The Company will announce to the ASX full details (quantity and duration) of the Shares, Performance Shares and Options required to be held in escrow prior to the Shares commencing trading on ASX.

3.15 Financial Information

The Company was only recently incorporated (27 June 2018) and has no historic operating activities and limited historical financial performance information.

Contained in the financial information in Section 9 is the pro forma historical statement of financial position as at 31 December 2018 and related notes to provide investors with a summary of the Company’s historical financial information assuming Koligo had been owned by the Company at that date.

This Prospectus is taken to include information contained in the audited annual financial statements of Koligo for the period from inception (7 March 2016) to 31 December 2016 and for the 12 months ended 31 December 2017 and 31 December 2018 (together, the Included Documents).

The Included Documents were lodged with ASIC on the date of this Prospectus. The Company will give a copy of the Included Documents free of charge to any investor
who asks for a copy before the Closing Date. Any such request should be made by contacting the Company at its registered office during normal business hours. The Company will also announce the Included Documents to the ASX prior to the Shares commencing trading on ASX.

Koligo has operated at a loss for the previous financial years. In the financial years ending 31 December 2017 and 31 December 2018, Koligo had net losses of $127,321 and $2,967,804, respectively. Please refer to the financial information in Section 9 of this Prospectus for further details.

3.16 Taxation

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

Due to the circumstances of the Company’s organisation, its acquisition of Koligo and the continuation of Koligo shareholders as shareholders of the Company, the Company will be treated as a U.S. domestic corporation for U.S. tax purposes, and will therefore be subject to U.S., as well as Australian, tax laws. Please refer to Section 5.8 for further details.

The information contained in this Section 3.16 is not a complete summary of potential taxation consequences facing investors based on the applicable taxation law as at the date of this Prospectus. To the maximum extent permitted by law, the Company, its officers and each of their respective advisors accept no liability or responsibility with respect to the taxation consequences of subscribing for Securities under this Prospectus or the reliance of any Shareholder on any part of the summary contained in this Section 3.16 or Section 5.8.

3.17 Dividend Policy

The Company anticipates that significant expenditure will be incurred in the furtherance of the Company’s development. These activities are expected to dominate the two-year period following the date of this Prospectus. Accordingly, the Company does not expect to declare any dividends during that period.

Any future determination as to the payment of dividends by the Company will be at the discretion of the Directors and will depend on the availability of distributable earnings and operating results and financial condition of the Company, future capital requirements and general business and other factors considered relevant by the Directors. No assurance in relation to the payment of dividends or franking credits attaching to dividends can be given by the Company.
3.18 Directors and Key Personnel

Set out below are short descriptions of the Directors and key personnel of the Company. Please refer to Section 11.1 for the full biographies of the Directors and key personnel.

Mr. Lehman is currently Koligo’s Chief Executive Officer, which he has served as since its inception. Mr. Lehman previously served as interim Chief Executive Officer of M Pharmaceutical, Inc. (now Callitas Health Inc.). Prior to that, he was the CEO (and prior to that COO) of Prima Biomed Ltd, a dual-listed public company (ASX:PRR (now IMM)) and NASDAQ:PBMD (now IMMP) developing cellular immunotherapies for cancer. Earlier in his career, he was Chief Operating Officer of SPRI Clinical Trials, a global contract research organisation.

Mr. James has over 30 years’ experience in industries with emerging technologies, and has extensive experience as Chair, Non-Executive Director and Chief Executive Officer across a range of publicly listed and private companies. He is currently Chair of ASX-listed companies Macquarie Telecom Ltd, nearmap Ltd, Dreamscape Networks Ltd, DroneShield Limited and UUV Aquabotix Limited. Mr. James recently completed 12 years as a Non-Executive Director of ASX-listed iiNet, Australia’s second largest DSL Internet Services Provider, prior to it being acquired by TPG Telecom for $1.56 billion. Mr. James is a director of the New Zealand based public company, Snakk Media Limited which is listed on NXT, New Zealand’s secondary securities market. On 7 February 2019, Snakk Media Limited was placed into voluntary administration by its Board. The other Directors have considered the circumstances surrounding Mr. James’s involvement in Snakk Media Limited and are of the view that Mr. James’s involvement in no way impacts on his appointment and contribution as a Director of the Company.
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).

**INVESTMENT OVERVIEW**

**DR. STUART WILLIAMS**
Executive Director and Vice President, Chief Technology Officer (Koligo Therapeutics, Inc.)

Dr. Williams is an internationally recognised expert in regenerative medicine. He is a Professor in the Department of Physiology & Biophysics at the University of Louisville. He has held faculty appointments at Jefferson Medical College where he was Director of Research in the Department of Surgery, and the University of Arizona where he founded the University of Arizona Biomedical Engineering Program. Most recently he established the Bioficial Organs Program at the University of Louisville. He is a Fellow of the American Heart Association and Fellow of the American Institute of Medical and Biological Engineering.

**JETHRO MARKS**
Non-Executive Director

Mr. Marks has over 18 years’ experience in marketing. He is the co-founder and Chief Executive Officer of The Nile, an established Australian online retailer, and Mercury Retail, a leading Australian eCommerce service provider.

**ROBERT CLISDELL**
Non-Executive Director

Mr. Clisdell is a non-executive director of Keytone Dairy Corporation Limited (ASX:KTD), DroneShield Limited (ASX:DRO) and UUV Aquabotix Limited (ASX:UUV), and is the Managing Director of Brentridge Capital Pty Ltd, the Corporate Adviser to the Public Offer.

**DR. BALAMURUGAN APPAKALAI, PHD**
Vice President, Chief of Manufacturing (Koligo Therapeutics, Inc.)

Dr. Appakalai is an international pioneer in islet cell isolation and transplantation for the treatment of diabetes and chronic pancreatitis. Previously, Dr. Appakalai directed the clinical islet cGMP facility at the University of Louisville and Jewish Hospital Cardiovascular Innovation Institute.
INVESTMENT OVERVIEW

DR. MICHAEL HUGHES, MD
Vice President, Chief Medical Officer
(Koligo Therapeutics, Inc.)

Dr. Hughes is a transplant surgeon who started the clinical islet transplant program at Jewish Hospital in Louisville, Kentucky. He was awarded National Pancreas Foundation Center status for Chronic Pancreatitis on behalf of the Jewish Hospital. He is currently Director of the Pancreatic Disease Center at Jewish Hospital and Director of Pancreas and Islet Transplantation at the University of Louisville.

DAVID BLANFORD, CPA
Chief Operating Officer
(Koligo Therapeutics, Inc.)

Mr. Blanford has over 25 years of finance, accounting and operational experience. Prior to founding Koligo, Mr. Blanford previously served as Chief Financial Officer of The Geneva Foundation, a non-profit organisation that supports and advances innovative medical research and excellence in education within the U.S. military. He previously served as Chief Financial Officer of Logan’s Linens Holdings, Tacoma Electric Supply, and Connecticut Electric & Switch Mfg. Co. Mr. Blanford is a licensed Certified Public Accountant (CPA).

ARIEL SIVIKOFSKY, FCA
Chief Financial Officer

Mr. Sivikofsky has over 20 years’ industry experience in the biotech industry, financial services and accounting both in Australia and Europe. Mr. Sivikofsky is a seasoned finance executive, having been the Chief Financial Officer at Luoda Pharma and Bova UK, private biotech companies based in London, and Investor First Limited (now HUB24 Limited), an ASX-listed financial services company (ASX:INQ (now HUB)).

ANDREW BURSILL
Company Secretary

Mr. Bursill is a Chartered Accountant with more than 20 years of accounting experience. He is a Principal at Franks & Associates Pty Ltd, where he has assisted publicly listed and unlisted companies since 1998 with capital raising activities, financial management, investor relations and company secretarial services and compliance. Mr. Bursill is a Company Secretary of numerous publicly listed entities and several unlisted public and private companies.
3.19 Corporate Governance

To the extent applicable, in light of the Company’s size and nature, the Company has adopted The Corporate Governance Principles and Recommendations (3rd Edition) as published by ASX Corporate Governance Council (Recommendations).

The Company’s main corporate governance policies and practices as at the date of this Prospectus are outlined in Section 11.2 of this Prospectus and the Company’s departures from the Recommendations are set out in Section 11.3 of this Prospectus.

In addition, the Company’s full Corporate Governance Plan is available from the Company’s website www.koligo.net.

3.20 Disclosure of Interests

The Company has not paid any remuneration to its Board since incorporation to the date of this Prospectus. However, remuneration has accrued since incorporation to the date of this Prospectus as follows: Peter James, $59,726; Jethro Marks, $29,863; and Robert Clisdell $29,863; and will be paid to the Board as soon as practicable after the Company is admitted to the Official List of ASX. Further, in the same period, Koligo has paid Matthew Lehman and Stuart Williams remuneration of approximately US$77,291 (approximately $110,000) and US$20,000 (approximately $28,000), respectively.

For each of the Directors of the Company, the proposed annual remuneration for the financial year following the Company being admitted to the Official List together with the relevant interest of each of the Directors in the securities of the Company as at the date of this Prospectus is set out in the table below.

<table>
<thead>
<tr>
<th>DIRECTOR</th>
<th>REMUNERATION</th>
<th>SHARES</th>
<th>OPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matthew Lehman</td>
<td>$426,137</td>
<td>8,326,691</td>
<td>-</td>
</tr>
<tr>
<td>Peter James</td>
<td>$100,000</td>
<td>-</td>
<td>6,000,000</td>
</tr>
<tr>
<td>Stuart Williams, PhD</td>
<td>$85,227</td>
<td>8,326,691</td>
<td>-</td>
</tr>
<tr>
<td>Jethro Marks</td>
<td>$50,000</td>
<td>-</td>
<td>2,500,000</td>
</tr>
<tr>
<td>Robert Clisdell</td>
<td>$50,000</td>
<td>-</td>
<td>500,000</td>
</tr>
</tbody>
</table>

1 Exclusive of superannuation.
2 The Directors of the Company may participate in the Public Offer.
3 Each Option will be unquoted and exercisable at $0.30 each on the third anniversary of the date of its vesting.
4 From the date the Company is admitted to the Official List (Listing Date), Mr. Lehman will be paid US$300,000 per annum (being approximately $426,137 per annum) to act as Chief Executive Officer and President of Koligo and to act as Chief Executive Officer of the Company. Mr. Lehman is also entitled to incentive bonuses described in Section 12.10.
5 Each of Mr. Lehman and Mr. Williams own approximately 11.1% of the issued share capital of Koligo prior to the Exchange. Pursuant to the Exchange, each of Mr. Lehman and Mr. Williams will be issued 8,326,691 Shares and 2,775,562 Performance Shares in the Company on the acquisitio of their respective shareholdings in Koligo.
6 The Options to be granted to Mr. Lehman will vest as follows: 3,000,000 Options 12 months after the Listing Date and 3,000,000 Options 24 months after the Listing Date. The Options to be granted to Mr. Williams will vest as follows: 1,000,000 Options 12 months after the Listing Date, 750,000 Options 24 months after the Listing Date and 750,000 Options 36 months after the Listing Date. The Options to be issued to Mr. Clisdell will vest on the Listing Date.
7 Koligo has agreed to pay Dr. Williams US$60,000 per annum (being approximately $85,227 per annum) to act as Vice President and Chief Technology Officer of Koligo and is entitled to the cash bonuses upon achievement of certain milestones described in Section 12.11.
8 Pursuant to the University of Louisville’s Intellectual Property Policy (UofL IP Policy), Dr. Williams may be entitled to receive a portion of the payments made to the Foundation under the license agreements between the Foundation and Koligo, as a result of Dr. Williams being one of the creators of the intellectual property the subject of such license agreements. See Section 3.21 for further information regarding the UofL IP Policy.
9 Pursuant to the UofL IP Policy, Dr. Williams may also be entitled to receive a portion of any Shares received by the Foundation as consideration for the license granted by the Foundation to Koligo under the Knowledge License Agreement summarised in Section 12.4, again as a result of Dr. Williams being one of the creators of the intellectual property the subject of such license agreement. See Section 3.21 for further information regarding the UofL IP Policy.
3.21 Agreements with Directors or Related Parties

The Company’s policy in respect of related party arrangements is:

a. a Director with a material personal interest in a matter is required to give notice to the other Directors before such a matter is considered by the Board; and

b. for the Board to consider such a matter, the Director who has a material personal interest is, unless otherwise agreed by the Board (excluding the relevant Director), not present while the matter is being considered at the meeting and does not vote on the matter.

Executive Employment Agreement

MATTHEW LEHMAN

Matthew Lehman has entered into a contract of employment with Koligo and the Company to act in the capacity of President and Chief Executive Officer of Koligo and the Chief Executive Officer of the Company. Mr. Lehman has also entered into an appointment letter with the Company to act as an Executive Director of the Company. Mr. Lehman is currently receiving an annual salary of US$265,000 (approximately $376,000) from Koligo. Commencing on the date the Company is admitted to the Official List, Mr. Lehman will receive an annual salary of US$300,000 per annum (being approximately $426,000 per annum) and be entitled to certain incentive bonuses from Koligo (which will be the Company’s wholly-owned subsidiary from the Listing Date) and the Company. Please refer to Section 12.10 for further details.

Consulting Agreement

DR. STUART WILLIAMS

Dr. Stuart Williams has entered into a consulting agreement with Koligo to act in the capacity of its Vice President and Chief Technology Officer. Dr. Williams has also entered into an appointment letter with the Company to act as an Executive Director of the Company. Dr. Williams is currently receiving an annual consulting fee of US$60,000 (being approximately $85,000 per annum) from Koligo. In addition, Dr. Williams is entitled to a quarterly cash bonus of US$15,000 (approximately $21,000) for each calendar quarter in which Koligo meets both the sales goals and quality goals specified in the consulting agreement. Please refer to Section 12.11 for further details.

Deeds of indemnity, insurance and access

The Company has entered into a deed of indemnity, insurance and access with each of its Directors. Under these deeds, the Company agrees to indemnify each officer to the extent permitted by the Corporations Act against any liability arising as a result of the officer acting as an officer of the Company. The Company is also required to maintain insurance policies for the benefit of the relevant officer and must also allow the officers to inspect board papers in certain circumstances.

Exchange Agreement

– Koligo Therapeutics Inc.

As set out above, the Company is party to the Exchange Agreement with the current shareholders of Koligo to acquire 100% of the issued share capital of Koligo. Matthew Lehman and Dr. Stuart Williams, each of whom are directors of the Company, in the aggregate currently own approximately 22.2% of the issued share capital of Koligo. Pursuant to the Exchange, Mr. Lehman and Mr. Williams will each be issued 8,326,691 Shares and 2,775,562 Performance Shares in the Company, in consideration for the Company’s acquisition of their respective shareholdings in Koligo.

As such, the Exchange Agreement is a related party arrangement. The sole shareholder of the Company, Long Hill Capital V, LLC (who is unrelated to Mr. Lehman and Dr. Williams) approved the entry by the Company into the Exchange Agreement (which is deemed under the Corporations Act to be the giving of a financial benefit to Mr. Lehman and Dr. Williams). The Board (other than Mr. Lehman and Dr. Williams) also note that the Exchange Agreement is on arm’s length terms given the issues of Shares and Performance Shares to Mr. Lehman and Dr. Williams are on the same terms as the Shares and Performance Shares to be issued to all of Koligo’s shareholders. Full details of the material terms and conditions of the Exchange Agreement are set out at Section 12.1 of this Prospectus.

Appointment Letters

PETER JAMES, JETHRO MARKS AND ROBERT CLISDELL

Peter James, Jethro Marks and Robert Clisdell have entered into appointment letters with the Company to act in the capacity of Non-Executive Chairman and Non-Executive Directors respectively. These Directors will receive the remuneration set out in Section 3.20 above upon the Company being admitted to the Official List.
Corporate Advisory Mandate
– Brentridge Capital Pty Ltd

The Company has signed a corporate advisory mandate with Brentridge Capital Pty Ltd (Brentridge) to act as corporate adviser of the Company in respect of the Public Offer. Brentridge is a related party of Long Hill, the Company's sole shareholder at the date of this Prospectus. The Company has agreed to pay Brentridge the fees described in Section 12.3.

Loan Agreement – Long Hill Capital V, LLC

The Company is party to a Loan Agreement with Long Hill Capital V, LLC (the sole Shareholder of the Company at the date of this Prospectus) pursuant to which it can borrow a maximum of $300,000. Details of the material terms and conditions of the Loan Agreement are set out at Section 12.13 of this Prospectus.

Line of Credit Agreement
– Dr. Stuart Williams and Koligo

Koligo is party to a Line of Credit Agreement with Stuart Williams (a Director) pursuant to which Koligo can borrow a maximum of US$50,000 (being approximately $71,000). Details of the material terms and conditions of the Line of Credit Agreement are set out at Section 12.14 of this Prospectus.

University of Louisville Intellectual Property Policy

At the time of the invention of the intellectual property licensed by Koligo under the Knowledge License Agreement and Exclusive License Agreement between Koligo and the University of Louisville Research Foundation, Inc., (Foundation) (refer to Sections 12.4 and 12.6 respectively for summaries of these agreements) the inventors of such intellectual property (Drs. Stuart Williams, Balamurugan Appakalai, and/or Michael Hughes) were faculty members of the University of Louisville. Pursuant to the University of Louisville’s intellectual property policy, the inventors of any intellectual property rights held by the University of Louisville are entitled to a portion of any royalties, equity and other consideration received in connection with the licensing of such intellectual property. In general, under this policy, the inventors would be entitled to share in 50% any royalties, equity and other consideration received by the University in connection with the licensing of such intellectual property. As such, Drs. Stuart Williams, Balamurugan Appakalai, and/or Michael Hughes may be entitled to share in 50% of any cash paid by Koligo or the Company or Securities issued by the Company to the Foundation under the Knowledge License Agreement and Exclusive License Agreement between Koligo and the Foundation.
Surgeon performing TP-IAT in Louisville, Kentucky

CHAIRMAN’S LETTER
Dear Investor,

On behalf of the directors of Koligo Therapeutics Limited (Company), I am delighted to invite you to become a shareholder of the Company.

The Company is seeking to raise a minimum $6,000,000 through an issue of 30,000,000 Shares at a price of $0.20 per Share (Public Offer). Oversubscriptions of up to a further 5,000,000 Shares at an issue price of $0.20 per Share to raise up to a further $1,000,000 may be accepted under the Public Offer. The maximum amount which can be raised under the Public Offer is therefore $7,000,000.

The Company was formed on 27 June 2018 for the primary purpose of acquiring Koligo Therapeutics, Inc. (Koligo), a U.S.-based biotechnology company focused on the development and commercialisation of a range of cell therapy, three-dimensional (3D) bioprinted tissue and other regenerative medicine products for serious unmet medical needs.

Koligo has successfully commercialised and has recently commenced selling its first cell therapy transplant product, Kyslecel™, in the United States. Kyslecel™ is used in the treatment of patients suffering from chronic or acute recurrent pancreatitis, a debilitating and painful condition with few effective treatment options. Kyslecel™ is regulated by the United States Food and Drug Administration (FDA). Koligo has determined that Kyslecel™ meets the criteria to be regulated in the U.S. under Section 361 of the U.S. Public Health Service Act and applicable FDA regulations and therefore is qualified for sale in the United States without FDA pre-market clearance or approval. Refer to the Legal Report in Section 10 for further details.

Kyslecel™ was developed based on research conducted by Koligo’s scientific founders, Stuart Williams, PhD and Balamugaran Appakalai, PhD, into cell transplant technologies at the University of Louisville, a global leader in regenerative medicine, beginning in 2011. Koligo has exclusively (for a limited period of time) licensed the intellectual property related to the development and manufacturing of Kyslecel™ from University of Louisville’s research foundation. Dr. Williams and Dr. Appakalai now lead Koligo’s product development and manufacturing.

Kyslecel™ has to date been sold at two hospitals and medical centres with programs that specialise in conditions affecting the pancreas. These medical providers benefit from using Kyslecel™ because their patients have access to cellular transplantation procedures without the providers having to incur the risk, expense and uncertainty of establishing in-house capabilities to produce pancreatic islets used to treat those conditions.

Between November 2017 (when Koligo began selling Kyslecel™ to a select number of pancreatic centres) and the date of this Prospectus, Koligo generated approximately $1,600,000 in revenues from the sale of Kyslecel™.

Koligo believes the market for Kyslecel™ in the U.S. is significant. An estimated 16,000 to 39,000 people in the U.S. are diagnosed with chronic or acute recurrent pancreatitis each year. Koligo knows of no other business or enterprise in the U.S. that is widely selling a product similar to Kyslecel™ as a commercial for-profit endeavour. Since there is currently limited competition, Koligo believes it can capture a significant part of this market.

Koligo is currently developing Kyslecel™ v2.0, an improved formulation of Kyslecel™ that is intended to extend its shelf life, which is expected to be launched in the second half of 2019, subject to completion of its development. Koligo believes the worldwide market for Kyslecel™ v2.0 is larger than the market for Kyslecel™, given that Kyslecel™ v2.0 is expected to be available to more patient groups and is expected to be shipped over longer distances, including to international markets (subject to meeting foreign regulatory requirements).

However, it is not possible to reliably quantify the size of the markets of Kyslecel™ and Kyslecel™ v2.0 in terms of potential revenue.

Koligo also intends to develop a pipeline of regenerative medicine products that will utilise 3D bioprinting, adipose-derived cells (regenerative cells derived from fat tissue) and other tissue processing techniques (referred to as Koligo’s 3D-V technology platform) for novel cell therapy and engineered tissue products. The products that Koligo intends to develop using its 3D-V technology platform are KT-CP-203 and KT-DM-103 (Stylecel-L), engineered tissue products containing pancreatic islets for the treatment of pancreatitis, type 1 diabetes, and other pancreatic diseases.

Longer term, the Company aims to be a leader in the development of novel cell therapy and engineered tissue products for liver failure, neurological diseases, metabolic disorders, and genetic disorders, using Koligo’s 3D-V technology platform.

Koligo’s proprietary cell therapy, 3D bioprinting, and tissue engineering technologies are protected by patents exclusively licensed by Koligo, a patent application filed by Koligo and non-patented proprietary databases, processes, and know-how.

The Company seeks to support its commercialisation strategy and research and development work through applying the funds raised in the Public Offer to expand its sales and marketing capabilities, undertake pre-clinical and clinical studies, and invest in technology to support its product pipeline.

Before making your decision to invest, I ask that you carefully read this Prospectus, consider the extensive risks of investing in the Company (which include the risk factors set out in Sections 3.7 and 7) and seek professional advice if required.

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

Yours sincerely,

Peter James
Chairman
Preparation of Kyslecel™ infusion for a patient in Brooklyn, New York
5. DETAILS OF THE OFFERS

5.1 Public Offer

Pursuant to this Prospectus, the Company invites applications for 30,000,000 Shares at an issue price of $0.20 per Share to raise $6,000,000 under the Public Offer.

The Company may accept oversubscriptions of up to a further $1,000,000 through the issue of up to a further 5,000,000 Shares at an issue price of $0.20 each under the Public Offer. The maximum amount which may be raised under this Prospectus is therefore $7,000,000.

The Shares offered under the Public Offer will rank equally with the existing Shares on issue.

5.2 Consideration Offer and Joint Lead Manager Offer

This Prospectus includes an offer of 75,000,000 Shares and 25,000,000 Performance Shares to be issued to the Koligo shareholders pursuant to the Exchange Agreement in consideration for the acquisition by the Company of the entire issued capital of Koligo. The material terms and conditions of the Exchange Agreement are summarised at Section 11.1 of this Prospectus. Further, the Joint Lead Managers (or their respective nominees) may subscribe for up to 5,500,000 Options for nil cash consideration subject to the terms of the Joint Lead Manager Mandates summarised in Section 12.2.

The Shares offered under the Consideration Offer will rank equally with the existing Shares on issue. The terms of the Performance Shares are summarised in Section 13.5. The Options offered under the Joint Lead Manager Offer will be issued on the terms and conditions set out in Section 13.4.

Only the Koligo shareholders may accept the Consideration Offer and only the Joint Lead Managers (or their nominees) may accept the Joint Lead Manager Offer. A personalised Application Form in relation to the Consideration Offer and the Joint Lead Manager Offer will be issued to the Koligo shareholders and the Joint Lead Managers (or their nominees) respectively together with a copy of this Prospectus.

The Shares and Performance Shares issued under the Consideration Offer and the Options issued under the Joint Lead Manager Offer will be subject to escrow under the ASX Listing Rules. Please refer to Section 3.14 for a summary of the expected escrow position.

5.3 Minimum subscription

If the minimum subscription to the Public Offer of $6,000,000 has not been raised within four months after the date of this Prospectus, or such period as varied by the ASIC, the Company will not issue any Securities and will repay all application monies for the Shares within the time prescribed under the Corporations Act, without interest.

5.4 Applications

Applications for Shares under the Public Offer must be made using the Application Form or through electronic payment facility described on the Application Form. If you wish to make your payment electronically, please refer to the instructions on the Application Form.

Applications for Shares must be for a minimum of 10,000 Shares and thereafter in multiples of 500 Shares and payment for the Shares must be made in full at the issue price of $0.20 per Share.

Completed Application Forms and accompanying cheques, made payable to “Koligo Therapeutics Limited” and crossed “Not Negotiable”, must be mailed or delivered to the address set out on the Application Form by no later than the Closing Date.

Please refer to the Application form for instructions on how to apply for securities by electronic payment. The Company reserves the right to close the Offers early.

5.5 ASX listing

Application for Official Quotation by ASX of the Shares offered pursuant to this Prospectus will be made within 7 days after the date of this Prospectus. The Company will not apply for Official Quotation of the Performance Shares offered under this Prospectus or the Options offered under the Joint Lead Manager Offer.

If the Shares are not admitted to Official Quotation by ASX before the expiration of 3 months after the date of issue of this Prospectus, or such period as varied by the ASIC, the Company will not issue any Securities and will repay all application monies for the Shares within the time prescribed under the Corporations Act, without interest.

The fact that ASX may grant Official Quotation to the Shares is not to be taken in any way as an indication of the merits of the Company or the Securities now offered for subscription.
5.6 Issue

Subject to the minimum subscription to the Public Offer being reached (see Section 5.3 above) and ASX granting conditional approval for the Company to be admitted to the Official List, the issue of the Securities offered by this Prospectus will take place as soon as practicable after the Closing Date.

Pending the issue of the Securities or payment of refunds pursuant to this Prospectus, all application monies will be held by the Company in trust for the applicants in a separate bank account as required by the Corporations Act. The Company, however, will be entitled to retain all interest that accrues on the bank account and each applicant waives the right to claim interest.

To the extent application monies (or subscription proceeds in United States nomenclature) are raised through a concurrent Regulation D offering in the United States (see Section 5.7.1 below) or an equivalent concurrent offering in the United Kingdom (Section 5.7.2), Singapore (Section 5.7.3), Hong Kong (Section 5.7.4), Malaysia (Section 5.7.5 below), the People’s Republic of China (Section 5.7.6 below), or any offering in any other jurisdiction in which it is lawful to make such offering (see Section 5.7 below), any subscription proceeds furnished by investors in such a concurrent offering will be included for calculating whether the minimum subscription has been reached, and such proceeds will be held in trust for these investors along with those proceeds invested by applicants generally, pending the issue of the Securities or payment of any refunds as set out in Sections 5.3 and 5.5. For investors in the United States, such proceeds must be returned to such investors if the Closing Date does not occur by 4 months from the date of the Prospectus.

The Directors will determine the recipients of the issued Shares under the Public Offer in their sole discretion. The Directors reserve the right to reject any application or to allocate any applicant fewer Shares than the number applied for under the Public Offer. Where the number of Shares issued is less than the number applied for, or where no issue is made, surplus application monies will be refunded without any interest to the applicant as soon as practicable after the Closing Date. No Applicant under the Public Offer has any assurance of being allocated all or any Shares applied for. The allocation of Shares by Directors will be influenced by the following factors:

a. the number of Shares applied for;

b. the overall level of demand for the Public Offer;

c. the desire for a spread of investors, including institutional investors; and

d. the desire for an informed and active market for trading Shares following completion of the Public Offer.

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

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

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

If you are outside Australia it is your responsibility to obtain all necessary approvals for the issue of the Securities pursuant to this Prospectus. The return of a completed Application Form will be taken by the Company to constitute a representation and warranty by you that all relevant approvals have been obtained. The Company will be the sole judge of whether an investor possesses such qualifications as may be required to purchase Securities. Notwithstanding the delivery of this Prospectus or other materials, the Company does not intend to extend an offer to sell or to solicit an offer to buy its Securities until it determines that the investor is qualified and expressly communicates such determination to the investor by accepting that investor’s subscription.

5.7.1 United States securities law matters

The offering of Shares under this Prospectus is being effected outside the United States of America (“United States”) pursuant to Regulation S (Regulation S), a “safe harbor” from registration under the United States Securities Act of 1933, as amended (the Securities Act). The Shares offered by this Prospectus are being offered and sold outside the United States in an “offshore transaction” without “directed selling efforts” in the United States, as both these terms are used in Regulation S.

Each applicant purchasing Shares outside the United States will be taken to have represented, warranted and agreed as follows:

- the offer under this Prospectus was not made to the applicant while in the United States, and the applicant is not in the United States at the time of lodging its application;
- it will be purchasing the Shares in an “offshore transaction” meeting the requirements of Regulation S; and
- its purchase of Shares is not as a result of “directed selling efforts” in the United States.

The Shares have not been, and will not be, registered under the Securities Act or the securities laws of any state of the United States, and the Shares may not be offered or sold, directly or indirectly, in the United States, except in a transaction exempt from the registration requirements of the Shares Act and the qualification requirements of applicable state laws. The Company intends to conduct a private offering of the Shares in the United States, concurrent with the offer of Shares under this Prospectus, pursuant to Regulation D, a “safe harbour” exemption under the Securities Act.

5.7.2 United Kingdom

Neither the information in this Prospectus nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (FSMA) has been published or is intended to be published in respect of the Shares offered pursuant to this Prospectus. This document is issued on a confidential basis to “qualified investors” (within the meaning...
of section 86(7) of the FSMA) in the United Kingdom, and the Shares offered pursuant to this Prospectus may not be offered or sold in the United Kingdom by means of this Prospectus, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) of the FSMA. This Prospectus should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the Shares offered pursuant to this Prospectus has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this Prospectus is being distributed only to, and is directed at, persons:

a. who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (FPO);

b. who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO; or

c. to whom it may otherwise be lawfully communicated,

(together, relevant persons).

The investments to which this Prospectus relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

5.7.3 Singapore

This Prospectus and any other materials relating to the Shares do not constitute a prospectus as defined in the Securities and Futures Act, Chapter 289 of Singapore (SFA) and have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, statutory liability under the SFA in relation to the content of prospectuses would not apply. 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 other than to (i) an ‘institutional investor’ (as defined in section 4A(c) of the SFA); (ii) a ‘relevant person’ (as defined in section 275(2) of the SFA); (iii) pursuant to and in accordance with the exemptions in Subdivision (4) Division 1, Part XIII of the SFA; or (iv) otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

The following applies to persons in Singapore. 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 section 4A(c) of the SFA) or (iii) a “relevant person” (as defined in section 275(2) of 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 and you should note that any offer contained in this Prospectus is subject to the general resale restriction under section 257 of the SFA. You shall not be able to make any subsequent sale in Singapore, or any offer of such subsequent sale of the Shares in Singapore unless such sale or offer in Singapore is made pursuant to the exemptions under Part XIII Division (1) Subdivision (4) (other than section 280) of the SFA. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.
5.7.4 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) (the CWUMP) 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 by means of any document other than (a) to “professional investors” (as defined in the SFO) or (b) in other circumstances which do not result in the document being a “Prospectus” as defined in the CWUMP or which do not constitute an offer to the public within the meaning of the CWUMP.

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 (as defined in the SFO and any rules made under that ordinance). No person issued Shares may sell, or offer to sell, such securities in circumstances that amount to an “offer to the public” (within the meaning of the CWUMP) in Hong Kong following the date of issue of such Shares.

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 Public Offer. If you are in doubt about any contents of this Prospectus, you should obtain independent professional advice.

5.7.5 Malaysia

No approval, authorization or recognition from the Securities Commission of Malaysia (the SCM) has been applied for or will be obtained for the offer or sale, invitation for subscription or purchase of the Shares under the Malaysian Capital Markets and Services Act 2007 (CMSA). No prospectus or other offering material or document in connection with the offer or sale, invitation for subscription or purchase of the Shares has been or will be registered with the SCM as a prospectus or a disclosure document under the CMSA. By reason of the foregoing, whether or not you invest in the Shares, if you are in Malaysia, you may not distribute any information regarding the Shares. Any other reproduction or distribution of such information regarding the Shares in Malaysia, in whole or in part, or the disclosure of its contents in Malaysia, without the Company’s prior written consent, is prohibited.

5.7.6 People’s Republic of China

The information in this Prospectus does not constitute a public offer of Shares, whether by way of sale or subscription, in the People’s Republic of China (PRC) (excluding, for the purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The Shares may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to “qualified domestic institutional investors” authorised by the competent Chinese regulatory authorities.
5.8 Taxation

5.8.1 Certain Australian Tax Consequences to Holders of Shares

The following discussion summarises certain Australian tax consequences to investors who subscribe for Shares under this Prospectus. This discussion assumes that investors hold Shares as a capital asset (generally, property held for investment rather than for resale at a profit) and does not address all of the potential Australian tax consequences of the ownership of Shares. In particular, it does not address the positions of investors who acquire Shares in the course of a business of trading or investing in securities or who otherwise hold Shares on revenue account or as trading stock, nor does it address the position of investors who are subject to the provisions regarding the ‘taxation of financial arrangements’ in Division 230 of the Income Tax Assessment Act 1997.

a. Dividends

Australian resident investors will be required to include the amounts of any dividends paid by the Company in their assessable income. The Company does not expect to be subject to Australian income tax in respect of a potentially significant portion of its profit, being that portion derived in the form of dividends from its wholly-owned operating subsidiary, Koligo. Accordingly, the Company does not expect to be in a position to frank a material portion of any dividends which it may pay.

To the extent that a dividend paid by the Company is franked, an investor who is a resident of Australia and a qualified person in relation to that dividend will be required to include the amount of the franking credit attached to the dividend in its assessable income, but would also be entitled to a refundable tax offset in the same amount. In order to be a qualified person in relation to a dividend an investor must satisfy an at risk requirement for a particular holding period or qualify for a safe harbour for small investors. Potential investors should consult their own tax advisors regarding these requirements.

To the extent that dividends paid by the Company to non-Australian resident investors are neither franked nor declared to be conduit foreign income, that portion of any such dividend would be subject to the Australian dividend withholding tax, which is imposed at the rate of 30% of the gross amount of the dividend, unless that rate is reduced by an applicable double tax treaty between Australia and the country in which the non-Australian resident investor is a resident for tax purposes. If the non-Australian resident investor is entitled to the benefit of such a treaty, the rate of Australian dividend withholding tax is generally reduced from 30% to 15%.

b. Disposal of Shares

An Australian resident holder of Shares would be subject to the Australian capital gains tax rules in relation to any sale, other disposal or certain other dealings of or in relation to the Shares. Those rules generally include any gain in assessable income, but capital gain may be offset by capital losses incurred in the same or an earlier year of income. If the sale or other disposal by an Australian resident investor results in a capital loss, that loss would be available to offset other capital gains in that or a later year, but is not an allowable deduction.

Australian resident holders of Shares who are individuals or the trustees of complying superannuation entities or trusts may be entitled to reduce the amount of any capital gain made on the disposal of their Shares if they have held their Shares for at least 12 months since the acquisition date for capital gains tax purposes. This reduction is referred to as the ‘CGT discount’. The CGT discount, if it is available, is applied only after any available capital losses have been applied to reduce the capital gain. The discount rate is 50% for individuals and trusts, and 33.3% for complying superannuation entities. The rules relating to discount capital gains for trusts are complex and depend on a beneficiary’s entitlement to a discount. Trustees of trusts are encouraged to consult their tax advisors regarding these rules. The CGT discount is not available to a holder of Shares that is a company.

Non-Australian resident investors who do not hold their Shares in connection with a business carried on through a fixed place of business in Australia would generally only be subject to Australian capital gains tax on a sale, other disposal or other dealing of or in relation to Shares if they have held 10% or more of the total Shares in the Company and if more than half of the value of the Company’s assets is attributable to direct or indirectly held interests in Australian real property. The Company has no direct or indirectly held interests in Australian real property at the date of this Prospectus. A non-Australian resident holder of Shares would not be entitled to apply the CGT discount to a capital gain.
5.8.2 Certain U.S. Tax Consequences to Holders of Shares

a. Tax Residence of the Company

Due to the circumstances of the Company's formation, the Company is treated as a U.S. corporation for U.S. tax purposes, and is therefore subject to U.S. tax laws. U.S. tax law imposes U.S. federal income tax on the Company's worldwide income and withholding taxes on certain distributions with respect to, and on certain dispositions of, Shares in the Company, as further described below. However, under the Tax Cuts and Jobs Act of 2018, the Company will be entitled to a special deduction for any "foreign derived intangible income" it realizes. Each investor should consult its own tax advisor for more information regarding the potential effects of U.S. tax law (including under the Foreign Account Tax Compliance Act, described below) on holders of Shares.

Despite being treated as a U.S. corporation for U.S. tax purposes, the Company will still be treated as an Australian resident for Australian tax purposes and therefore subject to Australian income tax as well as United States income tax. As a dual resident, the Company will not be entitled to any of the benefits available under the Australia/United States Double Tax Agreement to U.S. corporations which are not residents of Australia or to Australian resident companies which are not U.S. corporations. Despite this, the Company understands that under current Australian tax law, the income from its conduct of business in the United States (or other countries outside Australia) through one or more fixed places of business in the United States (or that other country) would generally not be subject to Australian income tax. Australian income taxes payable on income from the Company's conduct of business in Australia may be creditable against the Company's U.S. income tax liabilities under the United States foreign tax credit regime. However, the rules governing utilization of United States foreign tax credits are complex, and the limitations imposed thereunder could prevent the Company from crediting some or all of its Australian income taxes against its U.S. tax liabilities.

The payment of Australian income tax would give rise to franking credits which, to that extent, would enable the company to frank, or partially frank, any dividends which it distributes to shareholders. The extent to which those franking credits arise would depend upon the extent to which the Company's income is subject to Australian, as opposed to US, income tax; the payment of U.S. income tax does not give rise to franking credits or any comparable benefits.

b. Certain U.S. Federal Income Tax Consequences to Non-U.S. Holders of Shares

The following discussion summarises certain U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of an investment in the Company. This discussion assumes that Non-U.S. Holders hold Shares as a capital asset (generally, property held for investment) and does not address all of the U.S. federal income tax considerations that may be relevant to Non-U.S. Holders in light of their particular circumstances or to Non-U.S. Holders subject to special treatment under U.S. federal income tax law.

As used in this discussion, the term "Non-U.S. Holder" means a beneficial owner of Shares that, for U.S. federal income tax purposes, is not (i) an individual who is a citizen or resident of the United States, (ii) an entity created or organized under the law of the United States, any state thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source, (iv) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has in effect a valid election under applicable Treasury Regulations to be treated as a United States person, or (v) an entity treated as a partnership.

i. Distributions with Respect to Shares

Subject to the discussion under the sub-section 5.8.2(b)(iii) below entitled "Foreign Account Tax Compliance Act", distributions made by the Company with respect to its Shares will be treated as U.S.-source dividends generally subject to U.S. federal withholding tax at a 30% rate to the extent of the Company’s current and accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent the amount of a distribution exceeds the Company’s current and accumulated earnings and profits, the distribution will be treated first as a non-taxable return of capital to the extent of a Non-U.S. Holder’s adjusted tax basis in the Shares and thereafter as gain from the sale of such Shares which is only subject to U.S. federal income tax as described under the sub-section 5.8.2(b)(ii) below entitled “Gain on Sale or Other Disposition of Shares”.

Australian residents may qualify for a reduced rate of U.S. dividend withholding tax, of 15%, under the income tax
A treaty between Australia and the United States. To obtain a reduced rate of U.S. federal withholding tax on dividends under an applicable income tax treaty, a Non-U.S. Holder will be required to certify its entitlement to benefits under the treaty (as well as its compliance with “FATCA” (discussed below) if applicable), generally on a properly completed IRS Form W-8BEN, W-8BEN-E, or other form, as appropriate.

Dividends that are effectively connected with a Non-U.S. Holder’s conduct of a trade or business within the United States and, where required by an income tax treaty, that are attributable to a permanent establishment or fixed base of the Non-U.S. Holder, are not subject to the withholding tax described in the previous paragraph, but instead are subject to U.S. federal net income tax at graduated rates, provided the Non-U.S. Holder complies with applicable certification and disclosure requirements, generally by providing a properly completed IRS Form W-8ECI. Non-U.S. Holders that are corporations conducting a trade or business in the United States may also be subject to an additional branch profits tax at a 30% rate, except as may be provided by an applicable income tax treaty.

In addition, certain information reporting requirements may apply to the Company with respect to any distributions paid to Non-U.S. Holders.

ii Gain on Sale or Other Disposition of Shares

Subject to the discussion under the sub-section 5.8.2(b)(iii) below entitled “Foreign Account Tax Compliance Act”, a Non-U.S. Holder will not be subject to U.S. federal income tax in respect of any gain on a sale or other disposition of Shares unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States and, where required by an income tax treaty, is attributable to a permanent establishment or fixed base of the Non-U.S. Holder;
- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale or other disposition and certain other conditions are met; or
- the Company is or has been a “U.S. real property holding corporation” during the shorter of the five-year period preceding the disposition and the Non-U.S. Holder’s holding period for the Shares.

Koligo technician preparing pancreas for Kyslecel™ production.
Non-U.S. Holders described in any of the bullet points above should consult their tax advisors regarding the U.S. federal income tax consequences to them of a sale or other disposition of the Shares. The Company does not expect to be a U.S. real property holding corporation at the completion of the Offers and intends to inform Shareholders, by posting a notice on its website, if it becomes aware that it is a U.S. real property holding corporation.

iii Foreign Account Tax Compliance Act

Pursuant to the Foreign Account Tax Compliance Act (FATCA), withholding taxes may apply to certain types of payments made to “foreign financial institutions” (as defined under those rules) and certain other non-U.S. entities. The failure to comply with additional certification, information reporting and other specified requirements could result in a withholding tax being imposed on payments of dividends and sales proceeds to foreign intermediaries and certain Non-U.S. Holders. A 30% withholding tax may be imposed on dividends on, or, commencing in 2019, gross proceeds from the sale or other disposition of, Shares in the Company paid to a foreign financial institution or to a non-financial foreign entity, unless (I) the foreign financial institution undertakes certain diligence and reporting obligations, (II) the non-financial foreign entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner, or (III) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (I) above, it generally must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States concerning FATCA may be subject to different rules.

Under the applicable United States Treasury regulations and administrative guidance, the FATCA provisions described above generally apply to payments of dividends on the Company’s Shares and will apply to payments of gross proceeds from a sale or other disposition of Shares on or after 1 January 2019. Prospective investors are encouraged to consult their tax advisors regarding the potential application of withholding under FATCA to an investment in Shares in the Company.

THE PRECEDING SUMMARY IS NOT A COMPLETE DESCRIPTION OF ALL TAX CONSEQUENCES RELATING TO THE OWNERSHIP AND DISPOSITION OF SHARES IN THE COMPANY AND IS NOT TAX ADVICE. PROSPECTIVE HOLDERS OF SHARES IN THE COMPANY SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM OF THE OWNERSHIP AND DISPOSITION OF SHARES.

5.9 Not Underwritten

The Public Offer is not underwritten.

5.10 Joint Lead Managers and Corporate Adviser

APP Securities Pty Limited and Novus Capital Limited have been appointed by the Company to jointly lead manage the Public Offer and Brentridge Capital Pty Ltd has been appointed by the Company as corporate adviser in respect of the Public Offer. In consideration for their roles, the Joint Lead Managers and Brentridge Capital Pty Ltd will be entitled to equally share a transaction success fee of $200,000 and a management fee equal to 1% of the amount raised under the Public Offer. Further each Joint Lead Manager will be entitled to a selling fee of 5% of the amount directly raised by such Joint Lead Manager and each will be issued such number of Options which equals 2.5% of the total number of Shares on issue upon the Company’s admission to the Official List on the terms and conditions set out in Section 13.3. Further, the Company has agreed to pay Brentridge Capital Pty Ltd a selling fee equal to 5% of the amount raised by the Company under the Public Offer less the selling fees paid to the Joint Lead Managers.

For further details relating to the appointment of the Joint Lead Managers and Brentridge Capital Pty Ltd, please refer to Sections 12.2 and 12.3. Any broker fees payable to other brokers or intermediaries (including those overseas) will be paid from the sales commission payable to the Joint Lead Managers and Brentridge Capital Pty Ltd.

5.11 Enquiries

Any questions concerning the Company or the Public Offer should be directed to the Koligo Public Offer Information Line on 1300 288 664 if calling within Australia or +61 2 9698 5414 if calling from outside of Australia.
Koligo team documenting Kyslecel™ production steps
6. COMPANY OVERVIEW

6.1 Background

6.1.1 Introduction

Koligo Therapeutics Limited (the Company) was incorporated on 27 June 2018 for the primary purpose of acquiring Koligo Therapeutics, Inc. (a company incorporated in the Commonwealth of Kentucky, United States) (Koligo).

Koligo is a U.S.-based biotechnology company focused on the development and commercialisation of a range of cell therapy, three-dimensional (3D) bioprinted tissue and other regenerative medicine products for serious unmet medical needs.

Koligo has successfully commercialised and has recently commenced selling its first cell therapy transplant product, Kyslecel™, in the United States. Kyslecel™ is used in the treatment of patients suffering from chronic or acute recurrent pancreatitis, a debilitating and painful condition with few effective treatment options.

Kyslecel™ is used after a patient has undergone a total pancreatectomy (complete removal of the pancreas) (TP) to relieve the pain and inflammation caused by chronic or acute recurrent pancreatitis. Kyslecel™ is an islet-autotransplantation (IAT) product, i.e., a product made from a patient’s own diseased pancreatic islets (the cells that produce insulin) that are reintroduced into a patient’s body to produce insulin needed to regulate blood sugar.

TP results in immediate diabetes for the patient, and Kyslecel™ can reduce the risk of diabetes from TP by preserving the patient’s insulin-producing cells (pancreatic islets) that regulate blood sugar.

Without access to TP with Kyslecel™, patients generally have limited treatment options (such as therapeutic endoscopy, partial pancreatic resections, and pain management with powerful opioids) that provide limited relief. Undergoing a TP with Kyslecel™ therefore offers a potential treatment option for sufferers of chronic or acute recurrent pancreatitis. Importantly, TP can significantly reduce or eliminate the pain and opioid dependency associated with traditional pancreatitis treatment options and Kyslecel™ therapy may reduce the need for insulin shots.

Historically, TP procedures with IAT have been performed locally at hospitals that have made significant capital investment to establish the capability to provide islet-isolation. Prior to the introduction of Kyslecel™, no IAT product had been successfully developed and commercialised to widely serve medical facilities and hospitals throughout the U.S. There are 72,000 to 95,000 patients who are diagnosed or receive treatment for chronic or acute recurrent pancreatitis annually in the United States. Yet, at present, Koligo is not aware of any other business or enterprise that sells IAT products as a commercial for-profit endeavour. Koligo believes a significant clinical need therefore exists in the U.S. for IAT products in this under-served patient population. Koligo commercialised Kyslecel™ in order to meet this pressing clinical need.

6.1.2 Kyslecel™

To manufacture Kyslecel™, a surgeon at a qualified hospital removes the patient’s diseased pancreas (i.e., the source of pain and inflammation) and ships it to Koligo’s FDA-registered facility in Louisville, Kentucky, USA. Koligo isolates the pancreatic islets and uses them to manufacture Kyslecel™ for the specific patient. Koligo then ships Kyslecel™ back to the surgeon for re-infusion into the patient’s liver, where the islets are intended to engraft and produce insulin needed to regulate blood sugar.

Koligo believes the market for Kyslecel™ in the U.S. is significant. Since there is currently limited competition in the U.S. for IAT products, Koligo believes it has the potential to capture a substantial part of this market.

Kyslecel™ was developed based on research conducted by Koligo’s founders into cell transplant technologies at the University of Louisville, a global leader in regenerative medicine, beginning in 2011. In November 2017, Koligo exclusively (for a limited period of time) licensed the intellectual property related to the development and manufacturing of Kyslecel™ from the University of Louisville’s research foundation and commenced product sales of Kyslecel™. The team responsible for Kyslecel™’s development at the University of Louisville later joined Koligo, thereby bringing their significant know-how and other intellectual property to Koligo.

Koligo is currently developing Kyslecel™ v2.0, an improved formulation of Kyslecel™ that is intended to extend its shelf life. Kyslecel™ v2.0 is expected to launch in the second half of 2019, subject to completion of its development, and is intended to allow Koligo to ship Kyslecel™ over longer distances, including international markets (subject to meeting foreign regulatory requirements). Koligo believes the worldwide market for Kyslecel™ v2.0 is larger than the market for Kyslecel™, given that Kyslecel™ v2.0 is expected to be available to more patient groups and is expected to be shipped over longer distances, including to international markets (subject to meeting foreign regulatory requirements).

Koligo’s production facilities are strategically located in Louisville, Kentucky, USA, a major shipping hub in the eastern U.S. and the worldwide air hub for the United Parcel Service (UPS). Given the time sensitivity involved in shipping live human cells and tissue, Koligo utilises UPS Express Critical and other qualified shippers who have the capabilities to transport and handle human cell and tissue products.

Koligo has determined that Kyslecel™ is a minimally-manipulated autologous human cell, tissue and cellular- and tissue-based product (HCT/P), regulated by the U.S. Food and Drug Administration (FDA) under Title 21 of the U.S. Code of Federal Regulations (CFR) 1271.10(a) and Section 361 of the Public Health Services Act. FDA pre-market approval for minimally-manipulated autologous cell-based products that meet the criteria of 21 CFR 1271.10(a), like Kyslecel™, is not required. Refer to the Legal Report in Section 10 of further details. Kyslecel™ is produced and distributed in accordance with FDA’s current good tissue practice (cGTP) requirements, and otherwise complies with all applicable U.S. federal and state regulations.

In January 2019, Koligo formed a wholly-owned U.S.-based subsidiary, Koligo Surgical, LLC (refer to Section 6.2.10 for further details of this company).

6.1.3 3D-V Technology Platform

Koligo also intends to develop and commercialise a range of cell therapy, 3D bioprinted tissue and other regenerative medicine products. These products are based on the 3D-V technology platform which Koligo is developing. It is intended that these products will utilise 3D bioprinting of adipose-derived cells (regenerative cells derived from fat tissue), and other tissue processing techniques to engineer tissue to replace damaged or diseased tissue or organs. Koligo believes its approach to cell therapy and tissue engineering of bioprinting pre-vascularized 3D tissue constructs that contain functional cells and tissue may allow for more efficacious and safer transplant of functional cell and tissue types than current transplant therapies. Investors should note that Koligo has not yet commercialised its 3D-V technology platform, which is still subject to the completion of its development, clinical testing and regulatory approval.

Current technology for the transplantation of tissue and cells for therapeutic applications suffers from many limitations. These issues relate to the growth of blood vessels in transplanted tissue or cells, the revascularisation of transplantable tissue or cells, the formation of 3D structures necessary for transplanted tissue or cell viability and the potential for adverse patient immune response to the transplanted tissue or cells.

The Company believes Koligo’s 3D-V technology platform has the potential to address a number of issues in current transplantation technology by facilitating:

- rapid formation of vessels (revascularization) that provide blood to the transplanted cell and tissue;
- maintenance of a three-dimensional structure important for the viability of transplanted cell and tissue; and
- protection from adverse immune response from the recipient, which may reduce the risk of rejection and potentially reduce the need for anti-rejection drugs.

This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
Koligo believes its 3D-V technology platform could thus represent a significant advance in the transplant field.

The 3D-V technology platform is principally based on research and development conducted by Stuart Williams, PhD (Koligo’s now Chief Technology Officer and Company director) while a faculty researcher at the University of Arizona and later the University of Louisville.

Koligo’s 3D-V technology platform has shown early scientific success. Specifically, Dr. Williams’ pre-clinical work in the areas of 3D bioprinting and cell and tissue transplantation has shown that adipose-derived cells obtained from a patient induce vascularization of the cells or tissue for transplant.

Koligo will seek to use its 3D-V technology platform to develop a pipeline of novel engineered tissue products containing pancreatic islets for the treatment of pancreatitis, type 1 diabetes, and other pancreatic diseases. Koligo’s pipeline includes:

- **KT-CP-203** is an engineered tissue product containing 3D bioprinted autologous (patient derived) pancreatic islets to treat chronic and acute recurrent pancreatitis.
- **KT-DM-103 (Stylecel-L)** is an engineered tissue product containing 3D bioprinted allogeneic (donor derived) pancreatic islets to treat type 1 diabetes with hypoglycaemic unawareness and other pancreatic diseases.

Investors should note that KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development and, as such, have not been commercialised.

Longer term, it is intended that Koligo’s technology platform may support the development of novel products for liver failure, neurological diseases, metabolic disorders, and genetic disorders.

Koligo’s proprietary cell therapy, 3D bioprinting, and tissue engineering technologies are protected by patents exclusively licensed by Koligo, a patent application filed by Koligo and non-patented proprietary databases, processes, and know-how.
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).

6.1.4 Exchange

On 22 November 2018, the Company entered into the Exchange Agreement with the current shareholders of Koligo to acquire 100% of the issued and outstanding shares of common stock of Koligo in consideration for the issue of an aggregate of 75,000,000 Shares and 25,000,000 Performance Shares to the current shareholders of Koligo, such issue to be conditional upon, and to occur concurrently with the Company issuing the Shares under the Public Offer (the Exchange). The terms and conditions of the Performance Shares to be issued pursuant to the Exchange are set out in Section 13.5.

The effect of the Exchange Agreement is that, upon the Company obtaining the Listing Approval, raising the minimum subscription and issuing the Shares under the Offers, the current members of Koligo will own approximately 71.4% of the Shares of the Company (or, in the event full oversubscriptions are raised under the Public Offer, the current members of Koligo will own approximately 68.2% of the Shares of the Company) and Koligo will be a wholly owned subsidiary of the Company. Please refer to Section 12.1 for a summary of the key terms of the Exchange Agreement.

The Company has attracted a Board and management team whose members have experience in Koligo’s industry, the regenerative medicine industry, and small-cap companies (refer to Sections 3.18 and 11.1 for further details).

6.2 Kyslecel™ and Kyslecel™ v2.0

6.2.1 The Problem – Chronic or Acute Recurrent Pancreatitis

Chronic or acute recurrent pancreatitis is a painful, long-standing inflammation of the pancreas that alters the organ’s normal structure, gets worse over time and leads to permanent damage. The disease eventually impairs a patient’s ability to digest food and make pancreatic hormones which are critical to controlling energy levels in the blood. Chronic or acute recurrent pancreatitis has increased worldwide due to better diagnosis, increasing obesity, and increasing alcohol consumption in the developed world.

In the U.S., chronic or acute recurrent pancreatitis affects approximately 128,000 people, with an estimated 16,000 to 39,000 new diagnoses each year. Chronic or acute recurrent pancreatitis accounts for over 56,000 hospitalisations in the U.S. annually, at a significant cost to the health care system. Patients experience decreased quality of life due primarily to pain (80-94% of chronic or acute recurrent pancreatitis) and have a mortality rate 3.6 times higher than the general population.

Most chronic or acute recurrent pancreatitis patients will eventually develop diabetes mellitus (50% after 10 years and 83% after 25 years from CP diagnosis) and 3-6% will develop pancreatic cancer.

In addition, most patients have few pharmacologic, endoscopic, or surgical options for the treatment of chronic pancreatitis. Various reports confirm that many patients eventually become dependent on chronic opiate therapy to manage their pain symptoms, with up to 80% of chronic pancreatitis patients in the US resorting to opioids to manage pain, with up to 18% of these patients becoming addicted. Further, chronic pancreatitis patients in the U.S. suffer from a mortality rate that is estimated to be between 3 to 4 times higher than the general population.

6.2.2 TP-IAT

There are several medical treatments available for the treatment of chronic or acute recurrent pancreatitis. One such treatment undertaken by patients is a TP, which involves the surgical removal of a patient’s entire pancreas. TP is effective at reducing pain in 85-94% of patients; however, it immediately results in type 3c diabetes due to removal of the regions of the pancreas (islets) that produce insulin, and results in other complications. Therefore, TP has traditionally been considered a last resort for patients.

TP results in immediate diabetes for the patient. In order to ameliorate this effect, a patient may undergo IAT to preserve insulin secretory capacity (i.e., pancreatic islets) after TP and therefore reduce the risk of diabetes from TP. In an IAT, a patient’s own pancreatic islets are isolated from the pancreas and re-infused back into the patient’s liver.

TP-IAT has emerged as a promising long-term treatment for CP patients since maintenance of the function of the islets may lead to glycaemic control after the procedure is complete. TP-IAT reduces the risk of type 3c diabetes and has been demonstrated to have favourable safety and efficacy rates, reduces pain\(^1\), increases quality of life\(^2\) and reduces dependency on insulin drugs\(^3\). TP-IAT offers a potential treatment option for sufferers of chronic or acute recurrent pancreatitis.

**Total Pancreatectomy (TP)**
- TP is a surgical procedure which involves the removal of a patient's entire pancreas.
- The procedure reduces pain in 85-94% of patients\(^1\).
- However, it also results in brittle diabetes (type 3c) given that the pancreatic islets are the regions of the pancreas that contain endocrine cells which secrete insulin.
- TP has traditionally been considered a last resort.

**Islet Auto - Transplantation (IAT)**
- During an IAT a patient's own islets are isolated from the pancreas and reinserted back into the patient's liver.
- IAT reduces risk of type 3c diabetes and has been demonstrated to have favorable safety and efficacy rates.
- Also allows patients to pursue earlier intervention for CP and enhances quality of life.

**TP combined with IAT has been proven to result in numerous benefits to the patient**
- Improved pain in 94% of patients at year 1\(^2\).
- Improved Health Related Quality of Life in 85% of patients at year 1\(^2\).
- 70% of patients would recommend TP-IAT to other patients\(^4\).
- 67% of patients have some islet function; 33% insulin-free at year 3\(^2\).
- 30% increase in quality adjusted life year (QALY) survival: 11.5 to 14.9 year\(^3\).
- 23% savings to payors over traditional CP management (USD$42,000 savings)\(^3\).

Sources:

---


This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
TP-IAT entails the (1) total surgical resection of the pancreas; (2) isolation and purification of the islets from the pancreatic tissue; (3) transplant of the islet product back into the patient’s liver (or secondarily the peritoneal cavity); and (4) close management of the patient after TP-IAT to monitor glycaemic control and insulin needs.

Academic studies have demonstrated the cost-effectiveness of TP-IAT in the United States. As compared to traditional management of chronic pancreatitis, TP-IAT had been shown to confer a modeled improvement in quality-adjusted life years (QALY) in the U.S. from 11.5 to 14.9 years (30% increase) and reduced medical cost from US$196,042 (approximately $278,000) to US$153,575 (approximately $218,000) (22% cost reduction).

6.2.3 Limited TP-IAT access

Despite the demonstrated clinical success and cost-effectiveness of TP-IAT, TP-IAT is only available at a handful of academic institutions (approximately 12 to Koligo’s knowledge) in the United States which have access to specialised laboratories and technicians. While the interest from physicians and patients in this treatment has increased, only approximately 100 patients per year (about 2% of the addressable market) in the U.S. receive TP-IAT. Koligo is not aware of any other companies providing IAT products for this indication to hospitals and patients as a commercial for-profit endeavour.

The Company believes that the risk, expense and uncertainty of establishing in-house cell laboratories to produce IAT products has prevented hospitals and surgeons throughout the U.S. from adopting TP-IAT. However, without access to TP-IAT, patients generally have limited treatment option, such as therapeutic endoscopy, partial pancreatic resections, and pain management with powerful opioids, that provide limited relief to patients.

Koligo believes that a significant clinical need therefore exists in the U.S. for IAT products in this under-served patient population. Koligo has commercialised Kyslecel™ to meet the clinical need.

6.2.4 Kyslecel™ product

Koligo believes that Kyslecel™ can solve the limitations with TP-IAT that have prevented its widespread adoption for the treatment of chronic pancreatitis. Kyslecel™ is made from a patient’s own pancreatic islets (i.e., the cells that produce insulin). As at the date of this Prospectus, Koligo has supply agreements in place with two hospitals and medical centres and is actively exploring opportunities to supply further hospitals and other facilities that have not established their own TP-IAT programs.

The manufacturing process for Kyslecel™ begins with a patient’s surgeon removing the pancreas and shipping it to Koligo. Koligo then isolates the pancreatic islets from the patient’s pancreas, and prepares it for shipment back to the patient surgeon, who reinfuses Kyslecel™ into the patient.
Kyslecel™ is manufactured by Koligo’s team at a centralised, FDA-registered establishment in Louisville, Kentucky, USA, in accordance with published best practices for IAT and reliant on certain methods, know-how, and the experience of Dr. Balamurugan Appakalai. Further, Koligo has implemented quality systems that help assure industry-standard consistency of production and safety standards. With Koligo’s manufacturing and distribution capabilities, Koligo is able to efficiently receive and process pancreases from hospitals and deliver Kyslecel™ back to them for transplantation into the patients.

Koligo’s facilities are located in a major shipping hub in the eastern U.S. and the worldwide air hub for the United Parcel Service (UPS). Given the time sensitivity involved in shipping live human cells and tissue, Koligo utilises UPS Express Critical and other qualified shippers who have the capabilities to transport and handle human cell and tissue products.

A key aspect of the Company’s business strategy is to centralize the manufacturing and distribution of its cell and tissue transplant products in order to achieve scalability and ensure the highest quality of its products. Further, having centrally located manufacturing and distribution capabilities allows for timely, cost-effective, and dependable scheduling and is viewed as a key advantage for Koligo and a potential competitive barrier to entry.

6.2.5 Kyslecel™ development and intellectual property

Beginning in 2011, Koligo’s scientific founders led research and development into Kyslecel™. Based on this work in 2015, the first patients were successfully treated by Mike Hughes, MD (Koligo’s now Chief Medical Officer) at KentuckyOne’s Jewish Hospital in Louisville, Kentucky. The pancreas and islets for these patients were processed at a University of Louisville laboratory directed by Balamurugan Appakalai, PhD (Koligo’s now Chief of Manufacturing). Between 2015 and November 2017, prior to the commencement of sales by Koligo, this program treated numerous patients at Jewish Hospital.

In November 2017, Koligo exclusively licensed know-how, data, manufacturing procedures, and other intellectual property related to Kyslecel™ from the University of Louisville Research Foundation, Inc. (the Foundation) for two years on a world-wide basis. After the two-year term, the license will convert to a non-exclusive, perpetual license, giving Koligo flexibility to further develop the Kyslecel™ product range, including Kyslecel™ v2.0, without having to pay royalties to the Foundation.

Since November 2017, Koligo has continued its research and development efforts, in part as a result of the scaling up of its production and distribution capabilities of Kyslecel™. These improvements include proprietary
know-how developed by Koligo relating to specific concentrations of enzymes used in the processing of pancreases, methods of injecting enzymes into pancreatic tissue, variable timing of pancreatic tissue processing, and developments in the duration of exposure of pancreatic tissue to digestive enzymes. The details of this proprietary know-how are commercially sensitive and are considered confidential information of Koligo.

In November 2018, Koligo filed a provisional patent application in the U.S. regarding the specific concentrations of enzymes used in the processing of pancreases for Kyslecel™.

6.2.6 Benefits of Kyslecel™

Koligo believes Kyslecel™ is a significant advancement in the expansion of access to TP in the treatment of chronic or acute recurrent pancreatitis. Kyslecel™ is available to be sold at local qualified hospitals or other treatment facilities of the patient’s choosing, which provides access to a large part of the U.S. population. Further, Kyslecel™ is centrally manufactured at an FDA-registered facility with robust quality systems designed to assure industry-standard consistency of production and safety standards, therefore increasing the likelihood of favourable treatment outcomes for patients.

Kyslecel™ also provides numerous benefits to patients suffering from chronic pancreatitis. Kyslecel™ can offer the chance to potentially become pain-free, opioid-free, and have good glycaemic control post procedure, thereby providing the potential for a vastly improved quality of life.

Kyslecel™ can also provide a number of benefits to medical providers, including:

- increasing the number of patients that can be treated by providing a proven treatment option for CP;
- creating an additional revenue stream to gastroenterologists when other treatments are no longer an option;
- removing the risks, expenses, and uncertainty of establishing a facility that can conduct TP-IAT procedures; and
- assisting the provider in obtaining accreditation by The National Pancreas Foundation.

In addition, Koligo can provide guidance to providers for patient selection and post-procedure support, which are critically important for clinical success.

Although there have been no head-to-head studies to compare patient outcomes between those that received Kyslecel™ versus those that received IAT products from alternative sources such as academic institutions, patient data indicates that Kyslecel™ outperforms competitive IAT products. Internal data has also shown that patients treated with Kyslecel™ (both during the period when this was a University of Louisville program and since it has been a Koligo product) have outperformed published benchmarks for glycaemic control, pain relief, length of hospital stay, and reduction in opioid use.

6.2.7 Kyslecel™ v2.0

Koligo is currently developing Kyslecel™ v2.0, an improved formulation of Kyslecel™ that is intended to extend its shelf life and thus increase the number of patients who can be treated with Kyslecel™. The Company intends to use a portion of the capital raised under the Public Offer for the clinical development and validation of Kyslecel™ v2.0. Koligo expects that Kyslecel™ v2.0 will enable the product to extend its shelf life from its current 6 hours to 24 hours or possibly longer. A longer shelf life will allow Koligo to reach more patients at more hospitals and to ship Kyslecel™ over longer distances, including markets in the U.S. and other countries (subject to satisfying foreign regulatory requirements), and will allow treating physicians more flexibility with regards to the timing of Kyslecel™ infusions. Koligo expects to launch Kyslecel™ v2.0 with an extended shelf life in the second half of 2019, subject to completion of its development.

Koligo believes the worldwide market for Kyslecel™ v2.0 is larger than the market for Kyslecel™. However, it is not possible to reliably quantify the size of this market in terms of potential revenue. Koligo continually improves its manufacturing and distribution processes with the goal of improving isolation, quality, and costs. Koligo believes that the continued investment to improve Kyslecel™ will help increase product sales over time and solidify its position as the leader in this field. Koligo intends to file patent applications related to improvements in islet manufacturing.

6.2.8 Market assessment

Koligo is of the opinion there is currently limited competition in the U.S. for pancreatic IAT products and that Koligo can capture a significant part of the market for this product. This is due, in part, to the fact that Koligo knows of no other business or enterprise that is widely selling a product similar to Kyslecel™ as a commercial for-profit endeavour.

Kyslecel™ is centrally manufactured and is currently sold at two hospitals and medical centres in the United States. Koligo is actively seeking to expand its customer base to include additional hospitals, centres accredited by The National Pancreas Foundation (NPF Pancreatitis Centers) and gastroenterology practices. Koligo believes the market for Kyslecel™ in the U.S. is significant. However, it is
not possible to reliably quantify the size of this market in terms of potential revenue. Since there is currently limited competition in the U.S. for IAT products, Koligo believes it can capture a substantial part of this market.

Koligo believes this is nevertheless a conservative estimate given that numerous patients do not satisfy Koligo’s current patient criteria, which include the following large patient groups:

- patients over 65 years old;
- patients who are active substance abusers;
- children under 18 years of age;
- patients with pre-existing type 1 diabetics or type 3c diabetics; and
- patients that should not undergo major surgery for other reasons.

Current scientific literature suggests that some of these patient groups will likely benefit from TP-IAT, but conclusive evidence in this regard is limited.

Subject to completion of its development, with the launch of Kyslecel™ v2.0, Koligo believes it will be able to explore market opportunities outside of the U.S. that are even greater. The Company may explore these international opportunities through licensing and collaboration agreements for specific countries and regions, subject to product stability, licensing, and other regulatory matters.

There remains a scarcity of data concerning the incidence and prevalence of chronic or acute recurrent pancreatitis, particularly studies investigating the changes in disease over time. While incidence provides information on the risk of developing a disease within a specified period of time, prevalence provides information on how widespread the disease is in the population. Globally, the prevalence of chronic pancreatitis is estimated to be 50 per 100,000 persons demonstrated by greater numbers of hospital admissions for acute and chronic pancreatitis. Increases in the prevalence of chronic pancreatitis could

PREVALENCE OF CHRONIC PANCREATITIS (all causes)
Population studies in various countries over 30+ years

![Prevalence map](image)
result from greater availability of high-quality cross-sectional imaging techniques that can detect morphological changes in the pancreas, as well as greater awareness of chronic or acute recurrent pancreatitis and alcohol consumption.

Chronic pancreatitis is an increasing issue in Asia. Alcohol consumption has been increasing in developing countries such as China and India due to rapid urbanisation and increased affluence. Alcohol consumption remains the most common cause of chronic pancreatitis worldwide, although the cause of CP is deemed multifactorial and genetic factors also play a very important role in the pathogenesis of chronic pancreatitis.

In China, chronic pancreatitis increased yearly from 1996 to 2003 in an extensive study. Etiologies were primarily alcohol related. Similarly, prevalence estimates in Japan increased from 28.5 per 100,000 people in 1994 to 52.4 per 100,000 people in 2014. The prevalence of chronic pancreatitis was found to be very high in southern India (114-200 per 100,000 people) with idiopathic pancreatitis the most common type where alcohol is not the major cause. Rather, it is attributed to protein malnutrition, mineral deficiency, dietary toxins and environmental agents.

6.2.9 Marketing and sales plan

Kyslecel™ customers are U.S.-based hospitals, clinics, and physician groups (providers) where TP-IAT procedures will be performed. Kyslecel™ is currently used at two hospitals and medical facilities where these procedures are performed, and Koligo is in active negotiations with several additional medical facilities for the sale of Kyslecel™. The Company expects to be paid directly by these providers who will, in turn, invoice a patient’s health plan and/or the patient. Prior to providing Kyslecel™, the Company will qualify each provider to assure that they are equipped to perform TP-IAT and provide the necessary follow-up care to each patient. The Company generally enters into master contracts with providers prior to providing Kyslecel™.

Kyslecel™ is currently reimbursed by Kentucky Medicaid, U.S. Veterans Affairs, and most commercial health insurers. Medicare (i.e., the U.S. federal government health care program for the elderly) does not currently reimburse for TP-IAT. Koligo’s preliminary meetings with Medicare personnel indicate that further data is required to support claims of improvement in quality adjusted life years and cost-effectiveness in the over-65 population. The Company intends to work with other institutions to provide the necessary evidence to eventually qualify for Medicare reimbursement.

In one case to date, at the request of the patient’s insurance carrier, Koligo contracted with and invoiced the insurance carrier directly. This billing model may become more common in the future.

Kyslecel™ is generally priced per unit for each specific patient. Koligo’s standard pricing terms include shipping costs of the pancreas to its Louisville facility, all manufacturing activities and materials, delivery of Kyslecel™ back to the provider, and consultation to the treating physician to support billing, patient selection, and adverse
event management. Koligo may also provide providers with additional consultation to monitor post-procedure glycaemic control. On a customer-by-customer basis, Koligo may provide certain volume discounts. Under certain circumstances, when a Kyslecel™ product cannot be manufactured for biological reasons, Koligo may provide a partial refund to customers.

Koligo is also reviewing options to assist low-income patients with potential co-pays and co-insurance for which they may be responsible, in accordance with applicable U.S. federal and state laws. Such assistance programs may include discounts or financing options, which would reduce the Company’s revenue per unit of Kyslecel™.

### 6.2.10 Growth plan for Kyslecel™

Koligo’s goal with Kyslecel™ is to make TP-IAT an accessible procedure to all eligible patients – first in the U.S. and then internationally. Kyslecel™ is currently sold at two hospitals and medical facilities and is available to be sold to qualified hospitals and medical facilities in the Eastern half of the U.S. within approximately six hours transport time from Louisville, Kentucky, USA. Subject to completion of its development, the Company intends to launch Kyslecel™ v2.0 in the second half of 2019, and expects that it will have a longer shelf life of at least 24 hours. The Company believes that an extended shelf life will allow Kyslecel™ v2.0 to be made available to a significantly greater number of eligible patients.

The Company believes that there is substantial opportunity for growth in the use of Kyslecel™ by:

a. Increasing the number of medical facilities that use Kyslecel™ by focusing on marketing the product to its target customers, with an emphasis on securing marquee customers, namely:
   i. NPF Pancreatitis Centers, which are generally academic centres recognised for providing high-quality multi-disciplinary care to chronic pancreatitis patients, but that have not invested in the ability to perform TP-IAT procedures; and
   ii. Large gastroenterology practices that treat the majority of chronic pancreatitis patients in the U.S. but are not able to perform TP-IAT procedures;

b. Expanding the number of government insurance carriers who provide for reimbursement of Kyslecel™, particularly U.S. governmental (Medicare and Medicaid) insurance carriers;

c. Continuing to engage with the chronic pancreatitis patient community by:
   i. Working with the NFP to expand awareness of Kyslecel™;
   ii. Sponsoring NFP events and publishing educational literature explaining Kyslecel™;
   iii. Organising social media “town halls” to conduct patient question and answer sessions with medical experts in the field;

d. Subject to completion of its development, launching Kyslecel™ v2.0 (which Koligo expects will have a longer shelf life of at least 24 hours) to expand the geographic markets that Koligo serves; and

e. Subject to completion of its development, evaluating international opportunities for Kyslecel™ v2.0 through potential licensing and collaboration agreements for specific countries and regions.

Commensurate with Kyslecel™ sales growth, Koligo is reviewing options to establish multiple strategically-located production facilities to best serve customers.

In January 2019, Koligo formed a wholly-owned subsidiary, Koligo Surgical, LLC, as a single-member limited liability company. It is intended that Koligo Surgical, LLC, will be a medical provider for Kyslecel™ and other related pancreatic surgical services in Louisville, Kentucky, and that Mike Hughes, MD, will be the treating physician for Koligo Surgical, LLC. It is intended that the formation of Koligo Surgical, LLC will enable Dr. Hughes to perform TP-IAT with Kyslecel™, and other related pancreatic surgical services, at multiple hospitals in the Louisville, Kentucky area and not limit his practice to the Jewish Hospital or any other hospital.

### 6.2.11 Competition

Kyslecel™ competes with other medical facilities who offer TP-IAT procedures. As of the date of this Prospectus, TP-IAT procedures are offered by less than 15 academic institutions in the United States, who collectively serve approximately 100 patients per year. Further, Koligo knows of no other business or enterprise that is widely selling a product similar to Kyslecel™ as a commercial for-profit endeavour.

### 6.2.12 Regulatory environment

The products that are derived from human tissue, including Kyslecel™, are regulated in the United States by the U.S. Food and Drug Administration (FDA). As discussed below, Koligo has determined that Kyslecel™ meets the criteria specified in Title 21 of the U.S. Code of Federal Regulations (CFR) Part 1271.10(a) to be regulated solely under Section 361 of the U.S. Public Health Service Act and 21 CFR Part 1271 as a human cell, tissue and cellular
and tissue-based product (HCT/P). Therefore, and on this basis, Kyslecel™ is not required to have received premarket clearance or approval by FDA.

FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called 361 HCT/Ps) are not subject to any premarket clearance or approval requirements (i.e., FDA review for safety and effectiveness under a drug, device, or biological product marketing application is not required), but are subject to a variety of regulatory requirements – refer to Section 10 for further details.

To be a 361 HCT/P, a product must meet all four of the following criteria that are set forth in 21 CFR Part 1271.10(a):

- it must be minimally manipulated;
- it must be intended for homologous use;
- its manufacture must not involve combination with another article, except for water, crystalloids or a sterilising, preserving or storage agent; and
- (i) the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or (ii) the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and (a) is for autologous use; (b) is for allogeneic use in a first-degree or second-degree blood relative; or (c) is for reproductive use.

Koligo has determined that Kyslecel™ meets the criteria to be regulated as a 361 HCT/P and therefore is qualified for sale in the United States without FDA premarket clearance or approval. Similar to Kyslecel™, the Company expects Kyslecel™ v2.0 to meet the requirements to be regulated as a 361 HCT/P. Therefore, the Company expects that FDA pre-market approval for Kyslecel™ v2.0 will not be required.

Nevertheless, if Kyslecel™ or Kyslecel™ v2.0 does not, in FDA’s view, meet the criteria for regulation as a 361 HCT/P, Koligo would need FDA approval to lawfully market Kyslecel™ or Kyslecel™ v2.0 in the United States as a biological product. See Section 7.2(b) for further information regarding the risks associated with Kyslecel™ or Kyslecel v2.0™ not being regulated solely under Section 361 of the Public Health Service Act.

361 HCT/Ps such as Kyslecel™ must be listed with FDA, and the establishments that manufacture them must be registered with FDA. Kyslecel™ is currently so listed and Koligo is currently so registered. Registration means that FDA may periodically inspect the manufacturing facilities and processes, including to determine compliance with FDA’s current Good Tissue Practice (cGTP) requirements. If FDA identifies any deficiencies that Koligo fails to adequately respond to, FDA could issue a public warning letter and/or take other regulatory action, including but not limited to finding that Kyslecel™ is adulterated and/or misbranded and therefore prevent the sale of Kyslecel™ in the U.S.

Kyslecel™ is produced and distributed in accordance with FDA’s cGTP requirements, and otherwise complies with all applicable U.S. federal and state regulations.

The U.S. Federal Trade Commission (FTC) ensures that product advertising is truthful and not misleading. It is possible that the FTC could identify issues with Kyslecel advertising, through the Koligo website or otherwise, that would require Koligo to amend those advertising materials.

Koligo collects, handles and maintains patient-identifiable healthcare information. The U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the U.S. Health Information Technology for Economic and Clinical Health Act, as well as U.S. state laws, regulate the use and disclosure of patient-identifiable health information, including requiring specified privacy and security measures. Koligo also collects, handles and maintains other sensitive personal information that is subject to U.S. federal and state laws protecting such information.

### 6.2.13 Clinical validation

Significant pre-clinical and clinical work has been conducted to assess the safety and efficacy of TP-IAT with Kyslecel™ – both by third-parties and by members of Koligo’s management team. Scientific literature suggests several factors for successful TP-IAT: islet production isolation, patient selection criteria, and close follow-up of patients after the procedure. Koligo is dedicated to performing above benchmarks on all three of these success factors with Kyslecel™.

Dr. Appakalai has a demonstrated track record of safe and effective islet isolation and consistent manufacturing and Dr Appakalai’s manufacturing outcomes compare favourably to published benchmark outcomes.

Further, Dr. Hughes has a demonstrated track record of successful clinical outcomes as compared to published benchmarks, with appropriate patient selection and close follow-up with referring physicians. After follow-up of the first patients he treated, 50% were insulin independent at 6 months and 86% were opioid free at 12 months.

Further clinical data on the most recent patient outcomes is being compiled for publication in the near future.
6.2.14 Manufacturing and distribution

Koligo’s facilities are located at the Cardiovascular Innovation Institute (CII) of the University of Louisville in Louisville, Kentucky, USA. Koligo licenses manufacturing facilities and equipment at the CII, at the centre of a 34-state distribution area in the eastern United States, with close proximity to 65% of the United States population. Koligo currently has a license until 20 May 2019 to these facilities. Thereafter, Koligo intends to pursue the proposed expansion of its manufacturing facilities, as described below. Refer to Section 12.5 for further details of the terms of this license.

Koligo has easy access to the UPS Worldport at the Louisville International Airport, and uses UPS Express Critical Shipping, UPS’ fastest shipping service for urgent and emergency shipments, and other third-party shippers that are able to handle human cell and tissue products.

Kyslecel™ is manufactured by Dr. Appakalai and his team at Koligo. Dr. Appakalai has performed numerous human islet isolations at various academic institutions and is highly experienced in the field of islet isolations.

The Company intends to use the proceeds from the Public Offer to secure larger facilities commensurate with the anticipated sales growth of Kyslecel™. Koligo is also assessing other locations besides, or in addition to, Louisville, Kentucky production. With the anticipated launch of Kyslecel™ v2.0, the timing of Kyslecel™ shipments is expected to become less urgent, which will allow for production facilities in other locations. Koligo currently expects to develop at least two production facilities in the United States to ensure reliable production in case of issues at one location occur. In addition, depending on the needs of potential paediatric patients in the future, it may be necessary to invest in satellite production facilities in proximity to paediatric providers.

6.3 Research and product development

6.3.1 3D-V Technology Platform

Koligo also intends to develop a pipeline of innovative cell and transplant products in the treatment of serious unmet medical needs. This pipeline is based on Koligo’s 3D-V technology platform, which Koligo is developing and which utilises 3D bioprinting, adipose-derived cells (regenerative cells derived from fat tissue) and other tissue processing techniques to develop novel cell therapy and engineered tissue products. Investors should note that Koligo has not yet commercialised its 3D-V technology platform, which is still subject to the completion of its development, clinical testing and regulatory approval.

Based on the development of its 3D-V technology platform, Koligo aims to develop its next generation of islet transplant products for pancreatitis, type 1 diabetes, and other pancreatic diseases. Specifically, Koligo’s next two pipeline products under development are KT-CP-203 and
KT-DM-103 (Stylecel-L), KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development.

Koligo believes its 3D-V technology platform could potentially represent a significant advancement in the production of engineered tissue. Current technology for the transplantation of tissue and cells for therapeutic applications suffers from many limitations. These issues relate to the growth of blood vessels in transplanted tissue or cells, the revascularisation of transplantable tissue or cells, the formation of 3D structures necessary for transplanted tissue or cell viability and the potential for adverse patient immune response to the transplanted tissue or cells. Alternative methods to direct injection do not appear to promote the cell migration and proliferation necessary for the transplantation of a bioengineered tissue.

Koligo's 3D-V technology platform seeks to address the issues with current transplantation technology by facilitating:

- rapid formation of vessels (revascularization) that provide blood to the transplanted cell and tissue;
- maintenance of a three-dimensional structure important for the viability of transplanted cell and tissue; and
- protection from recipient immune response to improve engraftment, which may reduce the risk of rejection and potentially reduce the need for anti-rejection drugs.

Koligo's aim is that its 3D-V technology platform will result in cellular and tissue-based products that are more efficacious and safer than current cellular and tissue-based transplant therapies.

The 3D-V technology platform is principally based on research and development conducted by Stuart Williams, PhD, (now Koligo’s Chief Technology Officer and a Director of the Company) while a faculty researcher at the University of Arizona and later the University of Louisville. Koligo’s 3D-V technology platform incorporates advanced regenerative technology developed by Dr. Williams and the other scientific founders of Koligo. This technology is described further below.

### 6.3.2 Adipose-derived Cells and Vascularization

One of the primary challenges in the transplantation of bioengineered cells and tissue is ensuring sufficient blood supply to the transplanted cells or tissue. Rapid and scalable production of bioengineered tissue requires the enhancement of blood vessel growth (referred to as vascularization) to accelerate the integration of the transplanted cells or tissue. Koligo’s 3D-V technology platform utilises adipose-derived cells to overcome these challenges.

Adipose-derived cells have been shown to have a multitude of regenerative properties for clinical applications and are being used in numerous human clinical trials for the treatment of multiple diseases. Adipose-derived cells consist of several cell types, such as adult stem cells, vascular endothelial cells, and vascular smooth muscle cells, among others. These cells contribute, for example, to wound repair through a variety of mechanisms by promoting blood vessel growth and blocking cell death.

Koligo’s 3D-V technology platform uses stromal vascular fraction cells (SVF) and/or micro-vascular fragments (MVF) of adipose cells, as well as other adipose-derived cells, to promote the vascularization in bioengineered tissue used for transplant. Koligo's scientific founders have conducted research that shows that using adipose-derived cells can facilitate the creation of a network of blood vessels in tissue for the proper delivery, circulation and drainage of blood within engineered tissue. Indeed, significant functional vessel growth has been observed after about 10 days, and improved function (better engraftment) has been observed in animal studies.

Koligo has exclusively licensed patented technology that involves the exposure of functional tissue or cells to adipose-derived cells to promote the pre-vascularization of cells or tissue prior to implantation. Koligo’s 3D-V technology platform utilises adipose-derived cells obtained from a patient to induce vascularization of islets in the laboratory, prior to implant.

Pre-vascularization is expected to dramatically increase the rates of successful transplant and function of the islets as compared to current clinical approaches. Further, pre-vascularization facilitates the scalable in production and adaptable for other treatment indications.

In addition, the biological function of bio-printing pre-vascularized 3D structures has been tested with islets transplanted into mice. See Section 6.3.4 for further information regarding the pre-clinical validation of the 3D-V technology platform that has been conducted to date.

### 6.3.3 3D Bioprinting

Using 3D bioprinting to produce complex biological structures for implantation is a promising area of regenerative medicine. 3D bioprinting of tissue provides for a physiologically-relevant system for the creation of engineered tissue for implantation. In the body, tissues are composed of multiple cell types and cells are organised in specific spatial arrangements providing orientation of cells into geometries specific to organ functions. 3D bioprinting seeks to replicate those arrangements in the production of engineered tissue.

Koligo has exclusively licensed patented 3D bioprinting technology for the creation of three-dimensional, self-suspended, shelf-stable spheroids used in engineered tissue. The 3D bioprinted tissue provides a biodegradable scaffold for delivery of the functional cells (such as pancreatic islets) or tissue. Further the spheroids contain SVF, MVF and other adipose-derived cells to enhance vascularization. These bioprinted spheroids can then be implanted under a patient’s skin or muscle to offer a strategy to increase the therapeutic effect of cell or tissue transplants for regenerative purposes via improved cellular localization and retention.

Koligo’s aim is that its 3D bioprinting technology will have the ability to rapidly fabricate tissue comprised of adipose-derived cells and functional tissue to fit within a point of care clinical setting. These 3D bio-printed structures in which cells are suspended allow for better vascularization and may be implanted in an organ-like structure, rather than be infused where cells could be lost. Further, Koligo expects that its technology could result in cellular and tissue-based products that are more efficacious and safer than current cellular and tissue-based transplant therapies.
Koligo’s 3D-V technology platform is intended to be adaptable to other cellular and tissue-based products for numerous indications. The technical feasibility of bio-printing pre-vascularized 3D structures has been also established with multiple cell and tissue types, including pancreatic islets, Purkinje cells (large neurons), hepatocytes, parathyroid tissue, and cardiomyocytes. See Section 6.3.10 for potential longer-term product development opportunities using Koligo’s 3D-V technology platform.

### 6.3.4 Pre-Clinical validation

Koligo’s 3D-V technology platform has shown early scientific success. Specifically, Dr. Williams’ pre-clinical work in the areas of 3D bioprinting and cell and tissue transplanting has shown that adipose-derived cells obtained from a patient induce vascularization of the cells or tissue for transplant. Animal studies in these areas have also established improved function of transplanted cells, and preliminary data indicates that culture of autologous (donor-derived) cells with recipient adipose-derived cells may reduce potential for host rejection of the transplant.

In mice, for example, the transplantation of 3D bioprinted pancreatic islet spheroids with SVF with pre-vascularization (developed based on Koligo’s 3D-V technology platform) have demonstrated the ability to reverse diabetes, function normally after transplant and maintain glycemic control for extended time similar to the control mice, as demonstrated in the graph below. In fact, 3D bioprinted pancreatic islet spheroids with SVF demonstrated more rapid reversal of diabetes (the blue line in the graph below) than islets bioprinted in 3D spheroids without SVF (i.e., pre-vascularization). Koligo expects that this data will translate into meaningful clinical results for patients in the long-term insulin-free control of diabetes.

Further, the graph below shows that, when challenged with high levels of glucose ("HG" columns), 3D bioprinted pancreatic islet spheroids with SVF (i.e., pre-vascularization) and without SVF shows a similar ability to secrete insulin as the control group (i.e., naked islets). This data indicates that 3D bioprinted pancreatic islet spheroids with SVF (i.e., pre-vascularization) will function normally and do not lose insulin secretory capacity, which therefore supports Koligo’s continued development of its 3D-V technology platform.

### 6.3.5 Intellectual Property

Koligo has exclusive licenses to patents associated with its 3D-V technology platform from the University of Arizona and the University of Louisville. See Sections 12.7 and 12.6 for further information regarding these license agreements.

### 6.3.6 Product Pipeline

Koligo will seek to use its 3D-V technology platform to develop novel pancreatic islet cellular products for the treatment of pancreatitis, type 1 diabetes, and other pancreatic diseases. Koligo’s product development pipeline consists of KT-CP-203 and Stylecel-L.
6.3.7 KT-CP-203 – novel IAT product for chronic pancreatitis

KT-CP-203 is an engineered tissue product containing 3D bioprinted autologous (patient derived) pancreatic islets to treat chronic and acute recurrent pancreatitis.

As compared to Kyslecel™, and as compared to other known treatments under development, it is intended that KT-CP-203 will yield major improvements in safety and efficacy for patients who undergo TP-IAT for pancreatitis.
KT-CP-203 is planned to be formulated as approximately 100,000-200,000 biodegradable spheroids, each containing 20-30 autologous pancreatic islets that have been pre-vascularized using cells harvested from a patient’s fat. These pre-vascularized islet spheroids, in total, would comprise approximately 10 cubic centimetres of space for subcutaneous (under the skin) implant.

As compared to current TP-IAT approaches, it is intended that KT-CP-203 will:

- substantially reduce TP-IAT complications as compared to intraportal (liver) infusions;
- reduce hospitalisation duration for TP-IAT patients;
- ensure higher rates of islet engraftment leading to improved rates and longer duration of insulin independence for TP-IAT patients;
- lead to faster islet engraftment and insulin production since KT-CP-203 is pre-vascularized;
- improve efficacy outcomes for patients since Koligo believes that fewer islets would be necessary (versus traditional IAT products) to provide for clinically meaningful insulin production; and
- be easier and faster for physicians to administer as compared to intraportal infusion.

Koligo intends to commence pre-clinical safety studies of 3D bio-printed islets. These studies are a pre-requisite to commencing human clinical trials, and if conducted, will form the basis for a Phase 1 Investigational New Drug Application (IND) submitted to FDA. FDA review and, if successful, acceptance of an IND would then allow Koligo to begin human clinical trials for KT-CP-203. The goal of pre-clinical studies is to demonstrate that a product such as KT-CP-203 is safe enough to begin human testing. The precise contents of an IND will vary for each product, depending upon the novelty of the product, the extent of previous studies on the product, known and suspected product risks, and the product development phase.

Common IND elements include information on pharmacology, toxicology, and chemistry, manufacturing, and controls (CMC). CMC includes the development of manufacturing procedures that satisfy FDA’s current Good Manufacturing Practice (cGMP) and cGTP guidelines. The amount of CMC data known about a product and submitted to FDA will evolve as more is learned about the product. Before FDA will ultimately approve a marketing application for KT-CP-203, Koligo will be required to complete manufacturing process development, with detailed and controlled documentation, describing all aspects of the product’s manufacture, resulting in the potential to repeatedly manufacture product to target specifications. See Section 7.2(f) for further requirements related to the regulation of KT-CP-203 by FDA. Koligo currently expects to commence human clinical trials of KT-CP-203 in 2021, after completion of additional product developmental work, completion of pre-clinical safety studies, and FDA review and acceptance of the IND.

Clinical development of novel biotechnology products can be risky and complicated. Although Koligo does not expect KT-CP-203 to introduce unexpected safety concerns or alter the biological function of islets, products such as KT-CP-203 and the associated production techniques are novel, and FDA’s experience with such products is evolving. Koligo must conduct the appropriate pre-clinical and clinical studies to produce data that is submitted to FDA for FDA approval. Koligo hopes to conduct a single phase 1 clinical trial to assess safety of KT-CP-203 and then conduct a single phase 3 clinical trial which, if successful, could lead to marketing authorisation from FDA and other regulatory agencies. FDA may disagree, and Koligo intends to meet and consult with FDA to ensure that there is a mutual understanding of the requirements for FDA approval.

The Company also intends to identify licensees or strategic commercial partners to bring KT-CP-203 for final clinical validation, regulatory approval and distribution.

### 6.3.8 Stylecel-L (KT-DM-103) – novel type 1 diabetes treatment

Stylecel-L is an engineered tissue product containing 3D bioprinted allogeneic (donor derived) pancreatic islets to treat type 1 diabetes with hypoglycaemic unawareness and other pancreatic diseases. Allogeneic transplantation of islets derived from deceased organ donors (allo-islet transplant) to treat type 1 diabetics has been extensively studied worldwide and has demonstrated clinically meaningful results for certain severe type 1 diabetics. In the United States, these studies have been conducted in the context of limited clinical trials since no organisation has yet obtained a marketing license from FDA. To the best of Koligo’s knowledge, two academic-affiliated organisations are in the process of filing for a marketing license from FDA.

Despite positive clinical data, allogenic islet transplantation, as currently practiced, has significant limitations that prevent widespread adoption. Similar to autologous islet transplantation, there are very few facilities capable of producing allogenic islets. Those facilities are limited to academic centres that historically have not focused on scaling up production for commercial purposes. Moreover, production experience at these academic centres indicate that approximately 40% of production runs fail to provide the requisite “dose” of islets (i.e., they fail to isolate an adequate number of islets that meet product specifications.
quality-control release measures). Koligo believes that this outcome prevents a commercially scalable solution using traditional technology.

Koligo’s approach to allogenic islet transplantation with allogeneic pancreatic cells and to cryo-banking cells to establish an inventory of product available when a patient needs Stylecel-L. If successfully developed, Koligo believes that this approach would represent an improvement to current industry practice that waits to match recipients on a waiting list to deceased organ donors. Koligo believes that this current practice is a root cause of many of the current production failures and puts significant strain on the patient, treating physicians, and production team to meet very tight timelines.

In addition to cryo-banking islets, it is intended that Stylecel-L will utilise Koligo’s 3D-V technology platform for bio-printing pre-vascularized 3D spheroids. If successfully developed, Koligo believes that this approach may increase the likelihood of a safe and efficacious treatment for type 1 diabetics with hypoglycaemic unawareness which the Company aims to develop with the following key attributes:

- shelf-stable formulation available when a patient needs Stylecel-L;
- substantial reduction in allo-islet transplant complications as compared to intraportal (liver) infusions;
- increased rates of islet engraftment, as compared to current practice, aimed at achieving improved rates and longer duration of insulin independence;

Stylecel-L is intended to mitigate the issues with current practice and to improve upon previously reported safety and efficacy outcomes.

Koligo intends to develop a cryo-preservation system for
• faster islet engraftment and insulin production since Stylecel-L is pre-vascularized;

• easier and faster for physicians to administer, as compared to intraportal infusion;

• possible reduction in the need for anti-rejection drugs, as compared to current practice, since the islets are sensitised to the recipient immune system by introduction of recipient-derived cells during production; and

• possible reduction in the necessary “dose” of islets to achieve clinical success since it is expected subcutaneous implant to Stylecel-L will improve engraftment rates. If successfully developed, this improvement could lead to fewer production failures as compared to current practice and increase the number of treatable patients with current organ donor availability.

Koligo intends to leverage the pre-clinical safety studies conducted for KT-CP-203 for the development of Stylecel-L. These studies must be completed before commencing human clinical trials, and will enable Koligo to submit an IND and begin human clinical trials for Stylecel-L. These studies are similar to the studies described above for KT-CP-203.

Koligo expects to commence human trials of Stylecel-L in 2021, after optimisation of production techniques and completion of non-clinical safety studies (as described above for KT-CP-203), as well as establishment of its islet cryo-bank. See Section 7.2(f) for further requirements related to the regulation of Stylecel-L by FDA.

Clinical development of novel biotechnology products can be risky and complicated; however, Stylecel-L relies, in part, on significant published data that has established a safety and efficacy profile of allo-islet transplant.

Koligo intends to file for “orphan drug” designation for Stylecel-L with FDA and the European Medicines Agency (EMA) in 2019 to treat type 1 diabetes with hypoglycaemic unawareness. For FDA marketing approval, Koligo expects to conduct a single pivotal clinical trial in accordance with FDA’s written guidelines for development of allo-islet products. This single clinical trial is expected to include an initial safety assessment, after which a single-arm efficacy trial would be conducted. Koligo intends to meet and consult with FDA to ensure there is a mutual understanding of the requirements for FDA approval.

The Company also intends to identify licensees or strategic commercial partners to bring Stylecel-L for final clinical validation, regulatory approval and distribution.

6.3.9 Market Assessment

a. Stylecel-L

The annual market for type 1 diabetes therapeutics in the “major markets” of U.S., Japan, Germany, UK, Spain, and Italy was estimated at $4.9 billion in 2014 and is expected to grow19.

There is no cure for type 1 diabetes and the only approved therapeutics are currently insulin and insulin analogues. Some drugs in development (e.g., farxiga) which have been used for type 2 diabetes may be approved for use in type 1 diabetics over the next few years. Koligo hopes that Stylecel-L will offer a potentially curative option to type 1 diabetics who also suffer from severe hypoglycaemic unawareness. The potential sales for Stylecel-L are likely to be constrained by the overall availability of human islets from deceased organ donors.

b. KT-CP-203

The total annual market for chronic pancreatitis is difficult to assess because of limited data in some countries. The total annual cost to care for chronic pancreatitis in the United States is estimated at US$3.5 billion (approximately $5 billion) and in the UK at GBP 450 million (approximately $820 million)20. Koligo believes that KT-CP-203 has the potential to be a safe and effective product for a large percentage of chronic pancreatitis patient population.

6.3.10 Longer-term product development opportunities

Longer term, Koligo intends to leverage its 3D-V technology platform to develop a range of cellular and tissue-based products identified in the table below, subject to development and success of the technology.

<table>
<thead>
<tr>
<th>DISABILITY, DISORDER OR DISEASE</th>
<th>PRODUCT DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurodegenerative diseases (e.g., Parkinson’s, Lou Gehrig’s and Huntington’s diseases)</td>
<td>Pre-vascularized neurons and/or neural progenitors for transplant</td>
</tr>
<tr>
<td>Chondral lesions (e.g., knees, hips and other joints)</td>
<td>Pre-vascularized chondrocytes for transplant</td>
</tr>
<tr>
<td>DiGeorge syndrome</td>
<td>Pre-vascularized thymus for transplant</td>
</tr>
<tr>
<td>Acute liver failure (liver based metabolic disorders)</td>
<td>Pre-vascularized hepatocytes for transplant</td>
</tr>
</tbody>
</table>
The development of products for the treatment of any of these disabilities, disorders or diseases, would represent a significant opportunity for the Company.

6.3.11 Regulation of products based on the 3D-V technology platform

The Company expects that the products under development that utilise the 3D-V technology platform will not satisfy the requirements to be regulated solely under Section 361 of the Public Health Service Act as 361 HCT/Ps. Therefore, these products will be regulated as biologics and, in order to be lawfully marketed in the United States, will require an FDA-approved application, most likely a biologics license application (BLA).

The typical steps for obtaining FDA approval of a BLA to market a biologic product in the U.S. include those listed below:

- completion of preclinical laboratory tests, animal studies and formulations studies under FDA's good laboratory practices regulations;
- submission to FDA of an Investigational New Drug Application (IND) for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board (IRB) approval at each clinical site before the trials may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to FDA of a BLA for marketing the product, which includes, among other things, reports of the outcomes and full data sets of the clinical trials, proposed labelling and packaging for the product, and complete manufacturing information;
- satisfactory review of the contents of the BLA by FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility at which the product is produced to assess compliance with current Good Manufacturing Practices (cGMP) regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality, purity, and potency; and
- FDA approval of the BLA, including agreement on post-marketing commitments, if applicable.

FDA's experience with regenerative medicine products continues to grow and evolve, however, and additional requirements or variations of these requirements may be imposed.

Generally, drug and biologic clinical trials are conducted in three phases, though the phases may overlap or be combined. Phase I trials typically involve a small number of healthy volunteers and are designed to provide information about the product safety and to evaluate the pattern of distribution and metabolism within the body. Phase II trials are conducted in a larger but limited group of patients afflicted with a particular disease or condition in order to determine preliminary efficacy, dosage tolerance and optimal dosing and to identify possible adverse effects and safety risks. Dosage studies are designated as Phase IIA and efficacy studies are designated as Phase IIB. Phase III clinical trials are generally large-scale, multi-centre, comparative trials conducted with patients who have a particular disease or condition in order to provide statistically valid proof of efficacy, as well as safety and potency. In some cases, FDA will require Phase IV, or post-marketing trials, to collect additional data after a product is on the market. All phases of clinical trials are subject to extensive record keeping, monitoring, auditing, and reporting requirements.

The process of obtaining an approved BLA requires the expenditure of substantial time, effort and financial resources and may take years to complete. The fee for filing a BLA and the annual user fees payable with respect to any establishment that manufactures biologics and with respect to each approved product are substantial.

In addition, the Company’s use of HCT/Ps from allogeneic donors, such as with Stylecel™, will trigger additional regulatory requirements on the Company, such as meeting the donor eligibility portion of Title 21 of the U.S. Code of Federal Regulations (CFR) Part 1271.

6.4 Clinical Advisory Committee

The Company has appointed Marlon F. Levy, MD, the Chairman of Surgery at Virginia Commonwealth University (VCU) School of Medicine, Chairman of VCU Health's Division of Transplant Surgery and director of the VCU Hume-Lee Transplant Center, who is a leader in pancreatic islet cell research, as a medical advisor to the Company. In consultation with Dr Levy, the Company intends to appoint a clinical advisory committee comprising recognised experts and opinion leaders the field of islet transplantation.

6.5 Progress to Date and Business Plan Execution

Below are the key milestones achieved by Koligo to date:

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human islet isolation lab established at the University of Louisville.</td>
<td>September 2011</td>
</tr>
<tr>
<td>Jewish Heritage Fund for Excellence grant awarded to start clinical islet lab in Louisville, Kentucky, USA.</td>
<td>May 2014</td>
</tr>
<tr>
<td>First patient treated with TP-IAT therapy in Louisville, Kentucky, USA, at the Jewish Hospital.</td>
<td>January 2015</td>
</tr>
<tr>
<td>Koligo established to commercialise islet transplant technologies.</td>
<td>March 2016</td>
</tr>
<tr>
<td>Koligo enters into license agreement with the University of Louisville and commences commercial operations. First patient treated with Kyslecel™</td>
<td>November 2017</td>
</tr>
<tr>
<td>Kentucky Jewish Hospital is reimbursed by private insurance and Koligo receives its first payment for Kyslecel™</td>
<td>January 2018</td>
</tr>
<tr>
<td>Long Hill Capital V, LLC agrees to make a US$2,000,000 (approximately $2,800,000) investment in Koligo</td>
<td>March 2018</td>
</tr>
<tr>
<td>Koligo obtains the exclusive option to license the rights to patents from the University of Louisville Research Foundation, Inc. relating to the 3D-V technology platform</td>
<td>June 2018</td>
</tr>
<tr>
<td>Koligo exclusively licenses the rights to patents held by the University of Arizona relating to the 3D-V technology platform</td>
<td>October 2018</td>
</tr>
<tr>
<td>Koligo filed a provisional patent with the United States Patent and Trademark Office relating to improvements made by Koligo to Kyslecel™</td>
<td>November 2018</td>
</tr>
</tbody>
</table>

It is also part of the Company’s business model that it will consider expanding its business through the acquisitions (either outright or through licensing) of other complementary and enhancing technologies and businesses in appropriate geographies. The Company notes however that it is not in negotiations for any such acquisitions as at the date of this Prospectus.
Transplantation of Kylescel™ into a patient’s liver
7. RISK FACTORS

7.1 Introduction

The Securities offered under this Prospectus are considered highly speculative. An investment in the Company is not risk free, and the Directors strongly recommend potential investors consider the risk factors described in Section 3.7 of this Prospectus in addition to those listed below, together with information contained elsewhere in this Prospectus, before deciding whether to apply for Securities and to consult their professional advisers before deciding whether to apply for Securities pursuant to this Prospectus.

There are specific risks which relate directly to the Company’s business. In addition, there are other general risks, many of which are largely beyond the control of the Company and the Directors. The risks identified in this Section, or other risk factors, may have a material impact on the financial performance of the Company and the market price of the Shares.

The following is not intended to be an exhaustive list of the risk factors to which the Company is exposed.

7.2 Company-Specific Risks

a. Limited History

The Company was only recently incorporated and has limited operating history and limited historical financial performance. Further, Koligo has a limited operating history and has operated at a loss since its inception in March 2016. In the financial years ending 31 December 2017 and 31 December 2018, Koligo had net losses of $127,321 and $2,967,804, respectively. Please refer to the financial information in Section 9 for further details.

Although members of Koligo’s management team have experience with islet production, transplantation, biotechnology product development, and other aspects of Koligo’s business, much of this experience was gained as employees of other entities. There is no guarantee that the past individual experiences of the Company’s management team will translate into success for the Company.

No assurance can be given that the Company will achieve commercial viability through the sale of Kyslecel™ with total pancreatectomy, the development of the products in Koligo’s pipeline, or otherwise. Koligo has sold a limited number of units of Kyslecel™ since it commenced sales in November 2017. Unless widespread adoption of Kyslecel™ as a treatment for chronic or acute recurrent pancreatitis is achieved, the Company is likely to incur ongoing operating losses.
Further, the Company’s commercial viability will depend on its ability to develop and commercialise the products in Koligo’s pipeline, including KT-CP-203 and Stylecel-L. There is no certainty that the Company can successfully commercialise any of the products Koligo intends to develop.

In addition, the Company is subject to risks common to early-stage companies, including increasing market share and brand recognition, developing its product pipeline, expanding its manufacturing facilities, competing with alternative treatments and satisfying regulatory requirements imposed on the Company and its products. Investors should consider the Company’s business and prospects in light of the risks that it may face as an early-stage business with a limited history. If the Company is not successful in addressing such risks, the Company’s business prospects and financial performance may be materially and adversely affected, and the Company may never become profitable.

b. Regulatory risks for Kyslecel™

Kyslecel™ is regulated by the U.S. Food and Drug Administration (FDA). As described below, Koligo has determined that Kyslecel™ meets the criteria specified in Title 21 of the U.S. Code of Federal Regulations (CFR) Part 1271.10(a) to be regulated solely under Section 361 of the U.S. Public Health Service Act and 21 CFR Part 1271 as a human cell, tissue and cellular- and tissue-based product (HCT/P) – refer to Section 10 for further details.

FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called 361 HCT/Ps) are not subject to any premarket clearance or approval requirements, but are subject to a variety of other regulatory requirements. To be a 361 HCT/P, a product must meet the following criteria that are set forth in 21 CFR Part 1271.10(a):

- it must be minimally manipulated;
- it must be intended for homologous use;
- its manufacture must not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent, as long as the addition does not raise new clinical safety concerns for the HCT/P; and
- either (1) it does not have a systemic effect and is not dependent on metabolic activity of living cells for its primary function, or (2) it has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and it is for autologous use, for allogeneic use in a first- or second-degree relative, or for reproductive use.

Koligo has determined that Kyslecel™ satisfies these criteria and thus is regulated as a 361 HCT/P. Similarly, Koligo expects Kyslecel™ v2.0 to meet the requirements to be regulated as a 361 HCT/P and, therefore, will not require FDA premarket clearance or approval. However, any failure to meet these criteria may result in Kyslecel™ being adulterated and/or misbranded and therefore prevent the sale of Kyslecel™ in the U.S., which would materially and adversely affect the Company’s business prospects and financial performance.

If Kyslecel™ or Kyslecel™ v2.0 does not, in FDA’s view, meet the criteria for regulation as a 361 HCT/P, Koligo would need FDA approval to lawfully market Kyslecel™ or Kyslecel™ v2.0 in the United States as a biological product. Further, the development of Kyslecel™ v2.0 may result in it no longer qualifying as a 361 HCT/P. In addition, FDA’s regulation of minimally-manipulated autologous HCT/Ps is subject to change, which may result in Kyslecel™ or Kyslecel™ v2.0 not satisfying the criteria to be regulated as a 361 HCT/P.

If Kyslecel™ or Kyslecel™ v2.0 were to no longer satisfy the criteria to be regulated as 361 HCT/Ps, Koligo will be required to undertake clinical trials, or be subject to other testing requirements, which would significantly interrupt the sales of Kyslecel™ or Kyslecel™ v2.0 (or, in the case of Kyslecel™ v2.0, delay its launch), or could render the continued manufacture and sale of Kyslecel™ or Kyslecel™ v2.0 unfeasible, which would materially impact the Company’s business and revenues.

The distribution of Kyslecel™ to certain U.S. states is subject to licensing requirements beyond FDA regulation. Koligo has obtained the necessary licenses in states where Kyslecel™ is currently distributed and plans to obtain requisite licenses in additional states, where required, prior to distribution of Kyslecel™ to those states. However, sales of Kyslecel™, will (if such additional licenses are not obtained), or could (if such state licensing requirements changed) be prevented or delayed, materially impacting the Company’s business and revenues.

Establishments that manufacture 361 HCT/Ps such as Kyslecel™ are subject to periodic inspection by FDA. If FDA identifies any deficiencies that Koligo fails to adequately respond to, FDA could issue a public warning letter and/or take other regulatory action, including but not limited to finding that Kyslecel™ is adulterated and/or misbranded, and therefore prevent the sale of Kyslecel™ in the U.S., which would materially and adversely affect the Company’s business prospects and financial performance.
c. Market adoption and ongoing acceptance of Kyslecel™

The Company is heavily dependent on the success of Kyslecel™. The Company’s commercialisation strategy for Kyslecel™ relies on medical specialists, medical facilities and patients adopting TP with Kyslecel™ as an accepted treatment. However, medical specialists are historically slow to adopt new treatments, regardless of perceived merits, when older treatments continue to be supported by established providers. Overcoming such resistance often requires significant marketing expenditure or definitive product performance and/or pricing superiority. The cost of allocating resources for such requirements might severely impact the potential for profitability of Kyslecel™.

There is no guarantee that patient acceptance of TP with Kyslecel™ will be substantial. Further, there is no guarantee that Koligo will be able to achieve patient acceptance or obtain enough customers (clinical providers) to meet its sales objectives. If the Company does not meet its sales objectives, the Company’s business prospects and financial performance will be materially and adversely affected.

Further, the Company is partially reliant on published clinical trials and scientific research conducted by third parties to justify the patient benefit and safety of TP with Kyslecel™ and, as such, it relies, in part, on the accuracy and integrity of those third-parties to have reported the results and correctly collected and interpreted the data from all clinical trials conducted to date. If published data turn out to later be incorrect or incomplete, the Company’s business prospects and financial performance may be materially and adversely affected.

d. Intellectual property protection for Kyslecel™ and the 3D-V technology platform

Koligo has exclusively licensed non-patented intellectual property related to Kyslecel™ from the University of Louisville Research Foundation, Inc. (the Foundation) under the Knowledge License Agreement between the Foundation and Koligo (the Knowledge License Agreement), for a period ending on 20 November 2019, after which Koligo’s license to the intellectual property becomes royalty-free and non-exclusive. The limited exclusivity period is important to Koligo because it provides a pathway to the successful commercialisation of Kyslecel™ and development of successor products, such as Kyslecel™ v2.0, without burdening Koligo with lengthy royalty obligations. The intellectual property that is licensed under the Knowledge License Agreement was developed by Drs. Williams, Appakalai, and Hughes, who are currently members of Koligo’s management team. Refer to Section 12.4 for further information in respect of the Knowledge License Agreement.

Koligo has also entered into the following agreements relating to the patented intellectual property associated with its 3D-V technology platform:

i. Zan exclusive license to certain patents held by the University of Arizona under an Exclusive Patent License Agreement between the University of Arizona and Koligo (the Arizona Patent License Agreement). This license is exclusive during the period in which the patents have been granted patent protection (i.e. through to 2026); and

ii. an exclusive license to certain patents held by the Foundation under an Exclusive License Agreement between the Foundation and Koligo (the Louisville License Agreement). This license is exclusive during the period in which the patents have been granted patent protection (i.e. through to 2034).

In this Prospectus, the Knowledge License Agreement, the Arizona Patent License Agreement and the Louisville License Agreement are referred to collectively as the Koligo License Agreements (refer to summaries of the Koligo License Agreements in Sections 12.4, 12.7 and 12.6 respectively). There is no guarantee that the Koligo License Agreements or the intellectual property licensed thereunder will not be challenged, or that the licensors under the Koligo License Agreements will comply with their respective Koligo License Agreement (including the fact that the intellectual property has been exclusively licensed by Koligo).

The Company cannot guarantee that Koligo will be able to comply with the terms of the Koligo License Agreements, including terms that require Koligo to achieve certain research and development or commercial milestones. The failure to meet these milestones or otherwise comply with the terms of the Koligo License Agreements could result in a licensor exercising its right to terminate a Koligo License Agreement, which would adversely affect the Company’s business and revenue.

The periods during which Koligo has the exclusive right to the intellectual property licensed under the Koligo License Agreements, and in particular the Knowledge License Agreement, are finite. After the exclusive period under a Koligo License Agreement expires, the licensor will have the right to make the intellectual property available to third parties.

The defence and prosecution of intellectual property rights are costly and time consuming and their outcome is uncertain. Litigation taken to enforce any such intellectual property rights, or the failure to succeed in protecting any such rights, may adversely affect the business, operating results and financial condition of the Company. The
intellectual property is protected primarily by confidentiality agreements and the Koligo License Agreements and, with respect to the 3D-V technology platform, patent protection. There can be no assurance that the measures Koligo has implemented to protect its interests as the licensee of the intellectual property licensed under the Koligo License Agreements have been or will be sufficient.

There is a risk that third parties might knowingly or unknowingly infringe the intellectual property licensed by Koligo under the Koligo License Agreements. The intellectual property associated with Kyslecel™ that is the subject of the Knowledge License Agreement is not patented, and it would be difficult for the Company to prevent a competitor from manufacturing and marketing substantially the same product.

The Arizona License Agreement and the Louisville License Agreement involve the license interests in certain patent claims held by the Foundation and the University of Arizona, as the case may be. There is no guarantee that the Foundation’s or the University of Arizona’s patent claims will be held to be valid and enforceable. In particular, the patent position of biotechnology companies can be highly uncertain and frequently involve complex legal and scientific evaluation. Neither the breadth of claims allowed in biotechnology patents nor their enforceability can be predicted. Further, the grant of patent rights does not guarantee that the rights of others are not infringed or that competitors will not develop competing technologies that circumvent such patent rights.

Because the licensors of the Koligo License Agreements are either state institutions or related to state institutions, the Company’s and/or Koligo’s ability to claim damages from the licensors in the event of a breach of the Koligo License Agreements is significantly limited by state law. In addition, under the Koligo License Agreements, there are further risks arising from Koligo’s license to the intellectual property being subject to third party interests, including the government of the United States of America as described in Sections 12.4, 12.6 and 12.7.

Koligo currently has one patent application in the United States. There is a risk that this application will not be granted. There is a further risk that the claims of this patent application, as filed, may change in scope during examination by the United States Patent and Trademark Office (USPTO). Further, if and where a patent is granted, there can be no guarantee that such patent is valid or enforceable or that the patent will be granted in countries other than the United States. Koligo currently does not hold any patents or patent applications outside of the United States. Please refer to the Intellectual Property Report in Section 8 for further details.

The Company is subject to the risk of third parties making intellectual property infringement, unfair competition or like claims against the Company or Koligo under patent, trade secret or other laws, as well as other disputes. If a third party commences litigation against the Company or Koligo for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending such action, whether or not it ultimately prevails. In addition, parties making claims against the Company or Koligo may be able to obtain injunctive or other equitable relief that could prevent the Company or Koligo from continuing to manufacture and sell Kyslecel™ and products based on the 3D-V technology platform. In the event of a successful claim of infringement against the Company or Koligo, it may be required to pay damages and obtain one or more licenses from the prevailing third party. The Company and/or Koligo may not be able to obtain these licenses at a reasonable cost or terms, if at all.

The Company also relies on Koligo’s trade secrets developed independently of the Koligo License Agreements, which include information relating to the development and manufacture of Kyslecel™. The protective measures that the Company employs may not provide adequate protection for its trade secrets. Disclosure of its trade secrets would erode the Company’s competitive advantage and materially harm its business. The Company cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology, or that the Company or Koligo will be able to meaningfully protect its trade secrets and unpatented know-how and keep them secret.

e. Product development and commercialisation risk for Kyslecel™ v2.0

Kyslecel™ v2.0 is currently under developments, and further research and development is required before it can be made available for sale. There are many risks inherent in the development and commercialisation of new cell and tissue-based products. The development of Kyslecel™ v2.0 may be delayed beyond the second half of 2019, testing may fail to show that the benefits of Kyslecel™ v2.0 (e.g., extended shelf life) are realised, or further research may show that Kyslecel™ v2.0 is not viable for numerous scientific, regulatory or commercial reasons. Further, as described in Section 7.2(b), Kyslecel™ v2.0 may not satisfy the criteria to be regulated as a 361 HCT/P, which would significantly delay the launch of Kyslecel™ v2.0 and could render the development of Kyslecel™ v2.0 unfeasible. If any of these events were to occur, the Company’s ability to achieve its growth objectives by expanding the number of patients who can receive Kyslecel™ v2.0 and accessing international markets may be materially impaired.
f. Product development for the Company's product pipeline

KT-CP-203 and Stylecel-L are currently in pre-clinical stages of development and have yet to be tested in humans. The Company expects that these products will not be 361 HCT/Ps, and will instead require FDA pre-approval of a marketing application. The success of these products will depend on, among other things, the Company's ability to develop and commercialise these products, and obtain the necessary marketing approvals from the FDA and other regulatory authorities.

There are many risks inherent in the development of new cell and tissue-based products, particularly where the products are in the early stages of development. These products must still undergo a range of pre-clinical tests as well as clinical trials and these tests and trials may show that these potential products do not work in a safe and effective manner and so cannot proceed further. Products under development can be delayed or fail to demonstrate any benefit, or research may cease to be viable for a range of scientific, regulatory, and/or commercial reasons. The Company cannot guarantee that the research and development work being undertaken will result in the successful development of any products, or even if they do, that the products will be marketed or commercially successful.

Moreover, new products must obtain approval by regulators, if required, to be marketed for sale. Before obtaining regulatory approval of a product for a target indication, substantial evidence must be gathered in controlled human clinical trials and, with respect to approval in the U.S., to the satisfaction of FDA that the product candidate is safe and effective for use for that target indication in the intended patient population. Similar satisfaction must be achieved from the relevant regulatory authorities in each country in which the product may be made available. There is no guarantee that FDA or any other regulatory agencies will allow the Company to undertake such clinical trials. Moreover, such trials can be expensive, time consuming, may be delayed or may fail by showing that a product does not work in a safe and effective manner, which may delay the commercialisation of the product. The Company cannot guarantee that the regenerative medicine products under development by the Company will result in an effective product, or even if they do, that the product will be approved by regulatory authorities.

Also, the Company has limited experience in submitting biologic products for marketing approval by regulatory authorities. If any potential products fail pre-clinical or clinical trials or do not gain regulatory approval, suffer significant delay in development or if market acceptance is not achieved due to lack of consumer demand or otherwise and commercialisation is not successful, the Company may never become profitable and may need to cease operations.

The time required to develop and obtain regulatory approval for marketable products can be uncertain and, in some cases, very long and is subject to inherent risks. Significant funding will be needed to undertake clinical trials of Koligo’s products under development and it is unlikely that the Company will be able to fund these clinical trials from sales of Kyslecel™. The Company will likely need to raise additional funds by issuance of additional shares or by licensing product rights to other parties in order to fund ongoing development of these products which would reduce future income or be dilutive to shareholders.

Even if regulatory approval is obtained to market a product, potentially costly follow-up or post-marketing clinical trials may be required as a condition of approval to further substantiate safety or efficacy. Any such marketed product will also be subject to ongoing regulatory requirements governing the manufacturing, labelling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information.

g. Manufacturing risk

Production of Kyslecel™ is expensive, time-consuming, difficult to implement, and involves an uncertain outcome. Kyslecel™ requires trained and experienced technicians working in FDA-registered clean-room facilities with specific technical equipment. The Company cannot guarantee it will be able to recruit and train sufficient numbers of technicians to meet production needs. The Company may experience significant disruptions in production if it is unable to secure the requisite technicians, facilities and equipment for Kyslecel™ manufacturing.

Because Kyslecel™ is made for each patient individually from that patient’s pancreas, and because human tissue is inherently variable in biological function, the Company cannot guarantee that it will be able to produce a safe and effective product for each patient.

Any of the above manufacturing difficulties may cause the Company to incur unexpected costs, result in difficulties in gaining acceptance in the market, or otherwise harm its business.

Further, the remote processing of a patient’s pancreas and the manufacturing and transportation of Kyslecel™ introduces risks of delay, contamination, temperature fluctuations, and transport conditions that may adversely impact the quality of the product. If Koligo is unable to implement effective logistics management systems, the Company’s business and revenues may be adversely affected.
h. Supplier risk

Some of the critical materials used in the manufacturing of Kyslecel™ are patented by third parties or are otherwise supplied by a single source and thus are subject to supply constraints. An inability to obtain these critical materials on favourable terms to the Company, if at all, could adversely affect the Company’s business and profitability. The Company may also be delayed or incur significant costs if manufacturers of such materials discontinue those products.

i. Facilities risk

Kyslecel™ is required to be produced and distributed in accordance with FDA’s current Good Tissue Practice (cGTP) requirements, and otherwise comply with all applicable U.S. federal and state regulations. Failure to meet these standards could result in FDA or other regulatory authorities ordering the Company to cease the production of Kyslecel™ or to make improvements to the Company’s practices or facilities that are costly.

Currently, Koligo has a license from the CII to use the facilities that are used in the production of Kyslecel™. If Koligo were to lose access to these facilities, even temporarily, its ability to produce Kyslecel™ would be adversely impacted, which could impact the Company’s revenues. No assurance can be given that Koligo would be able to secure replacement facilities on terms favourable to Koligo, if at all.

Kyslecel™ has not yet been produced on a large scale, and there are risks inherent in the scale-up to a manufacturing environment. If the Company is unable to manufacture it in sufficient quantities or at an appropriate cost level, it may not be able to meet demand for its product which may adversely impact commercial sales of the product.

j. Product liability risk

The sale of Koligo’s products involves the risk of product liability claims being brought against the Company or Koligo, including in the event of death, injury or damage to property caused due to the sale, marketing, use or manufacture of Koligo’s products. Koligo seeks to limit its liability for such claims in its agreements with its customers (medical facilities and hospitals) and is also entitled to be indemnified by its customers in various circumstances. However, limitations of liability are not necessarily effective at law, and indemnification may not always be available.

Koligo has obtained product liability insurance in respect of its products, however, Koligo may not be able to obtain additional or maintain existing insurance for product liability on reasonable terms in the future and, in addition, Koligo’s insurance may not be sufficient to cover large claims, or the insurer could disclaim coverage on claims.

k. Customer risk

Koligo currently derives, and expects to continue to derive, a significant portion of its revenues from a limited number of customers. The loss of, or a significant decrease in, business from any significant customer could seriously harm the Company’s business and revenues.

One hospital, the Jewish Hospital, located in Louisville, Kentucky, USA, in close proximity to Koligo’s facilities, and where Dr. Michael Hughes, Koligo’s Chief Medical Officer, is a member of the TP-IAT program and performs TP procedures, has historically been, and is expected, in the short-term, to remain, Koligo’s most significant customer. No assurance can be given that the Jewish Hospital will remain a customer of Koligo, particularly if the Jewish Hospital were to be sold, enter bankruptcy or close its TP-IAT program. If Jewish Hospital were to no longer be a customer of Koligo, or Michael Hughes were to no longer be affiliated with the Jewish Hospital, the Company’s business and revenues could be adversely affected.

In order to mitigate the foregoing risks, in January 2019, Koligo formed a wholly-owned U.S.-based subsidiary, Koligo Surgical, LLC. It is intended that the formation of Koligo Surgical, LLC will enable Dr. Hughes to perform TP-IAT with Kyslecel™, and other related pancreatic surgical services, at multiple hospitals in the Louisville, Kentucky area and not limit his practice to the Jewish Hospital or any other hospital (refer to Section 6.2.10 for further details of this company).

l. Transportation risk

Prior to the launch of Kyslecel™, pancreatic islet auto-transplant products were typically manufactured at, or in close proximity to, the surgical centre where the patient had undergone total pancreatectomy (complete removal of the pancreas). Although there is both published and unpublished data to support Koligo’s packaging and shipping procedures (including published experiences shipping over medium distances within California and within New England), and further although the Company has shipped Kyslecel™ to other states, the Company may discover unexpected issues with the long-distance transportation of islets that would reduce the reach of Koligo, and consequently, the size of the markets in which Koligo operates.

Also, there is a risk that the Company will be unable to transport human tissue in a manner consistent with the standard operating procedures for the manufacture of Kyslecel™ (for example, due to weather conditions, flight delays, or other factors beyond the Company’s control).
The Company is reliant on the fact that its shipper, the United Parcel Service (UPS), has located its Worldport Hub in Louisville, Kentucky, USA. While UPS has invested in meeting the regulatory requirements for shipping human cell and tissue, as well as the procedures and personnel to conduct this activity (“Express Critical” service), there is no guarantee that UPS will continue to provide this service in the future. If UPS decides to discontinue its Express Critical service, or substantially increases its rates for such service, or moves its Worldport Hub from Louisville, or declines to provide this service to Koligo, the Company’s business may be adversely impacted.

m. Transplant risk

There are also inherent risks in undertaking a cell or tissue transplant procedure, such as infection or procedure deviation, that may adversely impact the patient experience and treatment outcome. For example, there is a significant risk that either a patient’s pancreas or Kyslecel™ manufactured from a patient’s pancreas does not pass acceptance testing or is rejected for quality control reasons. If this were to occur, the Company’s reputation could be materially and adversely affected, which could adversely affect adoption of the Company’s products by medical professionals. An inability for the Company to maintain a high level of quality and safety in the procedure will adversely affect the adoption of its products.

n. General regulatory risks

The healthcare industry is highly regulated. Koligo is subject to significant regulation, including oversight by the U.S. Food and Drug Administration (FDA), U.S. state and local public health agencies, and others. In the future, these regulators may require additional or unanticipated manufacturing controls, additional unexpected safety information, additional clinical trial data related to Koligo’s products, or impose other unexpected regulatory burdens on Koligo that may increase its costs, limit its ability to market the its products, or otherwise harm the Company’s business and revenues.

Koligo is required to obtain and hold permits, licenses and other regulatory approvals from, and to comply with the standards of, numerous governmental bodies. Failure to maintain or renew necessary permits, licenses or approvals, or to comply with required standards, could have an adverse effect on the Company’s business and revenues.

Koligo’s relationship with patients, physicians, and payors is subject to several regulations which may expose the Company to unforeseen regulatory costs or penalties for failure to comply. Such laws include, among others, the U.S. federal Anti-Kickback statute, the civil U.S. False Claims Act, the U.S. Health Insurance Portability and Accountability Act, the U.S. Health Information Technology for Economic and Clinical Health Act, and the federal U.S. Physician Payment Sunshine Act. The failure to comply with any of these laws could have an adverse effect on the Company’s business and revenues.

The Company is subject to various other laws and regulations, including, without limitation, product liability laws, environmental laws, tax laws, anti-corruption laws, and export laws and regulations.

The Company expects to do business around the world. The Company’s operations will therefore be subject to a number of risks inherent in global operations, including political and economic instability in foreign markets, inconsistent product regulation by foreign agencies or governments, imposition of product tariffs and burdens, cost of complying with a wide variety of international and U.S. laws and regulatory requirements. Additionally, operating an international business with sales in a number of legal jurisdictions will necessarily require substantial input from a variety of legal counsel and expose the Company to legal costs that may be disproportionately high relative to its revenues, and will be incurred regardless of whether the Company derives revenues from a given jurisdiction or at all.

The failure by the Company to comply with the laws and regulations in any jurisdiction in which it manufactures, exports and sells its products could result in the loss of access to those and other markets. In addition, compliance with government regulations may also subject the Company to additional fees and costs. Further, the introduction of new laws and regulations, or changes to existing laws and regulations (including interpretation and enforcement of those laws and regulations), or the failure by the Company to remain current with those developments, in any jurisdiction which governs the Company’s operations or contractual obligations, could adversely affect the Company’s business, operations and financial performance.

o. Reimbursement risk

In the U.S., healthcare is paid for either by the consumer directly, or more commonly the payer is a third-party private or governmental payer. Usage of Koligo’s products, including Kyslecel™, is likely to be influenced by the availability and rate of reimbursement of patients’ medical expenses by third party payer organisations including government agencies, private health care insurers and other health care payers. Before approving a new medical technology for reimbursement, private and governmental payers analyse clinical and economic data to determine the clinical value and cost-effectiveness as compared to other available products and procedures. Kyslecel™ is not currently reimbursed by Medicare (the U.S. federal government healthcare insurance program covering elderly people) and the status of reimbursement...
by Medicaid (the U.S. federal government healthcare insurance program covering impecunious and disabled people) and by additional U.S. state insurance programs is uncertain. There is no assurance that reimbursements for Koligo’s products or services will be available to patients at all or without substantial delay.

Even if such reimbursement is provided, the approved reimbursement amounts may not be sufficient to enable the Company to sell products developed on a profitable basis. Negotiation with insurers and other payors can be a difficult process as most of these organisations are larger and have more resources than the Company. Further, while the cost of Kyslecel™ is currently reimbursable by a number of private and government insurers, there is no assurance that its cost will be reimbursable in the future at current rates or at all. Private and government insurers have the power to amend reimbursement rates for healthcare expenses and can implement price control to reduce costs. If such changes were to be made, they will alter the cost of Kyslecel™ and therefore alter its demand in the market, which will adversely affect the Company’s revenues and profitability.

If third-party payors and/or patients do not reimburse providers (hospitals or physicians) promptly, payments from the providers to the Company may be delayed. Delays in receiving payments may affect the Company’s cash flow.

**p. Key personnel risk**

The Company’s success will substantially depend on the continued employment or retention of senior executives, scientific and technical staff and other key personnel by Koligo, including Matthew Lehman, Stuart Williams, PhD, Mike Hughes, MD, and Balamurugan Appakalai, PhD. As of the date of this Prospectus, Drs. Hughes and Williams are employed by the University of Louisville (and affiliated entities) and have negotiated the ability to work part-time for Koligo. Dr. Appakalai is on an extended leave of absence from the University of Louisville while he works full-time for Koligo. The loss of any of these people’s services could have a significant adverse effect on the Company and may hinder the ability of the Company to conduct research and development, commercialise and manufacture its products, and achieve its growth objectives.

Competition for personnel in the regenerative medicine industry is intense, and there are a limited number of persons with knowledge of, and experience in, this industry. The Company’s growth objectives will require the services of additional scientific, technical, sales and managerial staff. There can be no assurance that the Company will be able to attract and retain the services of such people, particularly given the competitive and specialised nature of the industry in which the Company operates and this may adversely affect the Company’s ability to grow.

**q. Future profitability risk**

The Company’s business will require significant expenditure on marketing, research and development, pre-clinical and clinical trials and regulatory approvals, as well as substantial capital investment in the expansion of manufacturing facilities. Accordingly, the Company may not reach profitability and, to the extent such expenditure and investment continue, may suffer a shortage of working capital.

**r. Reputational risk**

The reputation of the Company and its individual brands is important in attracting medical specialists, medical facilities and patients, and key employees. Reputational damage could arise due to a number of circumstances, including:

i. unsatisfactory clinical outcomes for patients, or the failure to otherwise meet the expectations of patients, medical facilities or other partners;

ii. defects, delays or problems in the production of its products;

iii. error, malpractice or negligence of the Company’s employees; or

iv. error, malpractice or negligence of the medical professionals who are using the Company’s products.

Negative publicity could adversely impact the Company’s reputation which may potentially result in a fall in the number of patients seeking the Company’s products.

**s. Third party relationship risk**

The Company is dependent in part upon Koligo’s relationships and alliances with academic institutions, medical facilities and other industry participants. Some of Koligo’s partners do or may in the future assist Koligo in the development or sale of its products through testing, research and development, contract manufacturing or supplier arrangements. If any of Koligo’s existing relationships with partners were impaired or terminated, or if the Company was unable to implement additional partnering arrangements it may require from time to time, the Company could experience significant delays in the development or commercialisation of products and would incur additional costs.

Additionally, the Company may take a credit risk with regard to its customers. Kyslecel™ is an expensive product to manufacture and it may incur significant upfront costs to purchase materials for manufacturing many months prior to being paid. In the event of the Company’s
customers failing to meet its obligations to the Company on time or at all, the Company may be adversely affected.

\textit{t. Competition risk}

The industry in which the Company participates is competitive and subject to rapid technological change. The Company faces significant competition from academic and clinical institutions, and other biotechnology, medical device, and pharmaceutical companies. With respect to Kyslecel™, such competition includes academic centres that currently manufacture similar products to Kyslecel™ and companies with products in development that may prove to be safer or more effective than Kyslecel™ in the future.

Research and development of products in the transplant field is very active with many companies seeking to commercialise products. There is no assurance that competitors will not succeed in developing products which would render the Company’s products obsolete and/or otherwise uncompetitive or which can be introduced before the Company’s products are able to reach the market. The Company may be unable to compete successfully against future competitors. The Company competes with larger companies in the transplant field who have greater resources (including financial, technical, human, research and development, and marketing resources).

\textit{u. Concentration of ownership and dilution risk}

The Company currently has 1 Share on issue and will issue 75,000,000 Shares and 25,000,000 Performance Shares in the Exchange, meaning that the maximum number of Shares issued under the Public Offer will represent up to approximately 31.82% of the issued Share capital of the Company on completion of the Offers (assuming the full oversubscription is raised). Further, assuming only the minimum subscription is raised under the Public Offer, the number of Shares issued will represent approximately only 28.57% of the issued Share capital of the Company on completion of the Offers.

Assuming only the minimum subscription is raised, the Performance Shares convert into Shares and no other Shares are issued in the Company, the number of Shares issued under the Public Offer will represent approximately only 23.08% of the issued capital of the Company. There will therefore be a concentration of ownership within the existing members of Koligo on completion of the Offers (and on any conversion of the Performance Shares). Some investors may consider that this increases the risk of participating in the Public Offer. Conversion of the Performance Shares into Shares (should the relevant milestones be achieved in the future) will also dilute the holdings of existing Shareholders at the time.

In the future, the Company may elect to issue Shares or other securities. While the Company will be subject to the constraints of the ASX Listing Rules regarding the issue of Shares or other securities, Shareholders may be diluted as a result of issues of Shares or other securities. Further, on the conversion of Performance Shares (issued under the Exchange Agreement) into Shares, Shareholders will be further diluted.
v. Liquidity

As noted above, 75,000,000 Shares and 25,000,000 Performance Shares in the Company will be issued to the existing owners of Koligo in the Exchange. All of these Shares and Performance Shares are likely to be classified by the ASX as restricted securities and be placed into escrow. Please refer to Section 3.14 for further details. Some investors may consider that there is an increased liquidity risk as a large portion of issued capital may not be able to be traded freely for a period of time.

There is currently no public market through which Shares may be sold. On completion of the Offers, there can be no guarantee that an active market in the Shares will develop or that the price of the Shares will increase or not decrease. There may be relatively few or many potential buyers or sellers of the Shares on ASX at any time. This may increase the volatility of the market price of the Shares and may prevent investors from acquiring more Shares or disposing of Shares they acquire under the Offers. It may also affect the prevailing market price at which the Shareholders are able to sell their Shares. This may result in Shareholders who acquire Shares under the Public Offer receiving a market price for their Shares that is less or more than the Public Offer price.

w. US Taxation Risk

The acquisition, ownership and disposal of Securities may have tax consequences for investors, which may vary depending on the individual financial affairs and tax residence of each investor. Due to the circumstances of the Company’s formation, its acquisition of Koligo and the continuation of Koligo shareholders as shareholders of the Company, the Company will be treated as a U.S. domestic corporation for U.S. tax purposes, and will therefore be subject to U.S., as well as Australian, tax laws. All potential investors in the Company are urged to obtain independent professional taxation and financial advice about the consequences of acquiring and disposing of Securities from a taxation viewpoint and generally. Please refer to Section 5.8 for a general summary of potential taxation consequences facing investors based on the applicable taxation law as at the date of this Prospectus.

x. Additional requirements for capital

The Company’s capital requirements depend on numerous factors. Depending on the Company’s ability to generate income from its operations, the Company may require further financing in addition to amounts raised under the Public Offer. Further, additional expenditures may need to be incurred that have not been taken into account in the estimates summarised in Section 3.11. Incurring such additional expenditures may adversely affect the expenditure proposals of the Company. In addition, additional funding will be required in connection with the development and commercialisation of the products in Koligo’s pipeline. Additional funding may also be required in the event costs exceed the Company’s estimates and to effectively implement its business and operations plans in the future, to take advantage of business opportunities and to meet any unanticipated liabilities or expenses which the Company may incur.

The Company may seek to raise further funds through equity or debt financing, joint ventures, collaborations with other life science companies, licensing arrangements, production sharing arrangements or other means. The Company’s capital requirements depend on numerous factors and, having regard to the early stage of development of Koligo’s technology platform, the Company is currently unable to precisely predict if, and what amount of, additional funds may be required. In addition to any funds raised pursuant to the Public Offer, funds may be required to conduct additional research and trials, obtain additional regulatory approvals or to commercially launch any future product. Failure to obtain sufficient financing for the Company’s activities and future projects may result in delay and indefinite postponement of their activities and potential research and development programmes. There can be no assurance that additional finance will be available when needed or, if available, the terms of the financing might not be favourable to the Company and might involve substantial dilution to Shareholders. Factors which may influence the Company’s possible need for further capital include such matters as:

- the nature, scale, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effects of competing product, clinical, technological and market developments; and
- the terms, timing and consideration, if any, of collaborative arrangements or licensing of products.

Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations and scale back development and research programmes as the case may be. There is however no guarantee that the Company will be able to secure any additional funding or be able to secure funding on terms favourable to the Company.
y. Strategic partnerships risk

The Company's growth strategy may involve pursuing strategic business relationships with other organisations in relation to potential products and services. There can be no assurance that the Company will be able to attract such prospective organisations and to negotiate appropriate terms and conditions with these organisations or that any potential agreements with such organisations will be complied with. Further, the Company will experience competition in making strategic business relationships from larger companies with significantly greater resources.

z. Integration

Integration of the Company's and Koligo's operations (and the operations of the Company and any of its further potential acquisitions) will be complex, time-consuming and expensive and may adversely affect the results of the Company's operations.

aa. Strategies

There are no limits on strategies that the Company may pursue. The strategy discussed in this Prospectus may evolve over time due to, among other things, market developments and trends, technical challenges, the emergence of new products and competitors, changing regulation and/or industry practice, and otherwise in the Company's sole discretion. As a result, the strategy, approaches, markets and products described in this Prospectus may not reflect the strategies, approaches, markets and products relevant to, or pursued by, the Company at a later date.

Further, a change in strategy may involve material and as yet unanticipated risks, as well as a high degree of risk, including a higher degree of risk than the Company's strategy in place as of the date hereof.

ab. Contractual risk

Koligo relies on the continuation of:

i. the Knowledge License Agreement between the Foundation, and Koligo for access to intellectual property associated with Kyslecel™;

ii. the Limited License Agreement (the Facilities License Agreement) between the University of Louisville and Jewish Heritage Fund for Excellence Cardiovascular Innovation Institute (CII) and Koligo for access to certain premises, facilities and equipment that Koligo uses as its manufacturing facilities to produce Kyslecel™ and to conduct research and development;

iii. the Exclusive Patent License Agreement between the University of Arizona and Koligo for access to patents associated with Koligo's 3D-V technology platform and

iv. the Exclusive License Agreement between the Foundation and Koligo for access to patents associated with Koligo's 3D-V technology platform.

Refer to Sections 12.4 to 12.7 for further details in respect of these agreements. These contracts include certain obligations which Koligo must comply with, including achieving certain development milestones at certain times. There is no guarantee that such obligations will be met or that such milestones will be achieved or that Koligo's licenses might not be terminated by the counterparty. Any termination of these agreements may have a material adverse effect on the Company and its operations.

Moreover, Koligo is party to the Facilities License Agreement with CII to provide Koligo with access to certain premises and equipment that Koligo uses for manufacturing its products. Because of the unique legal status of the CII, CII has not indemnified Koligo for damages that it may incur as a result of CII's negligence or misconduct. Instead, under the laws of the Commonwealth of Kentucky, Koligo would be required to seek compensation for CII's negligence or misconduct from the Kentucky Claims Commission. No assurance can be given as to whether Koligo would be able to make a successful claim to the Kentucky Claims Commission for compensation for CII's negligence or misconduct.

The Company and/or Koligo is party to a number of contracts with providers of key vendors and suppliers, and the Company expects to enter into a number of contracts for services relating to development of its products, including pre-clinical and clinical studies. The Company is subject to the risk that the parties to these contracts will not adequately or fully comply with their respective contractual rights and obligations or that these contractual relationships may be terminated.

There are a number of other risks associated with contracts entered into by the Company or Koligo, including the risk that those contracts may contain unfavourable provisions, or be terminated, lost or impaired, or renewed on less favourable terms.

ac. Litigation

The Company and Koligo are each exposed to possible litigation risks including, but not limited to, product liability claims, intellectual property ownership disputes, contractual claims, environmental claims, occupational health and safety claims and employee claims. Further,
the Company and Koligo may be involved in disputes with other parties in the future which may result in litigation. Any such claim or dispute if proven, may impact adversely on the Company’s operations, financial performance and financial position. Neither the Company nor Koligo is currently engaged in any litigation.

ad. Force majeure events

Force majeure events, or events beyond the control of the Company or Koligo, may occur within or outside the United States of America that could affect the world economy, the operations of the Company and the price of the Shares. These events include war, acts of terrorism, civil disturbance, political intervention and natural events such as floods, earthquakes, fires and severe weather conditions.

Further, the Company and Koligo are exposed to the risk of catastrophic loss to necessary laboratory equipment, computer equipment or other facilities which would have a serious impact on their operations. The Company gives no assurance that all such risks will be adequately managed through insurance policies to ensure that catastrophic loss does not have an adverse effect on its performance.

ae. Data loss, theft or corruption

Each of the Company and Koligo stores data in its own systems and networks and also with a variety of third-party service providers. Exploitation or hacking of any of these systems or networks could lead to corruption, theft or loss of the data which could have a material adverse effect on the Company’s business, financial condition and results. Further, if the Company’s or Koligo’s systems, networks or technology are subject to any type of ‘cyber’ crime, their technology may be perceived as unsecure which may lead to a decrease in the number of customers.

af. Foreign exchange

The Company may be operating in a variety of jurisdictions, including the United States of America and Australia, and as such, expects to generate revenue and incur costs and expenses in more than one currency. Consequently, movements in currency exchange rates may adversely or beneficially affect the Company’s results or operations and cash flows. For example, the appreciation or depreciation of the U.S. dollar relative to the Australian dollar would result in a foreign currency loss or gain. Any depreciation of currencies in foreign jurisdictions in which the Company operates may result in lower than anticipated revenue, profit and earnings of the Company.

ag. Insurance coverage

The Company faces various risks in conducting its business and may lack adequate insurance coverage or may not have the relevant insurance coverage. Koligo has obtained, and intends to maintain, insurance coverage for its employees, as well as professional indemnity, product liability and third-party liability insurance, however it does not currently propose to arrange and maintain business interruption insurance or insurance against claims for certain property damage. The Company will need to review its insurance requirements periodically. If the Company incurs substantial losses or liabilities and its insurance coverage is unavailable or inadequate to cover such losses or liabilities, the Company’s financial position and financial performance may be adversely affected. The Company intends to maintain insurance covering its operations in accordance with industry practice. The occurrence of an event that is not covered or fully covered by insurance could have a material adverse effect on the business, financial condition and results of the Company.

7.3 General Risks

a. Reputation of regenerative medicine

Regenerative medicine is an emerging industry experiencing rapid growth. There may be negative news flow or controversies in relation to the use of regenerative medicine products, including stem cells, that may impact the market acceptance of the Company’s products.

b. Economic conditions and other global or national issues

General economic conditions, laws relating to taxation, new legislation, trade barriers, movements in interest and inflation rates, currency exchange controls and rates, national and international political circumstances (including wars, terrorist acts, sabotage, subversive activities, security operations, labour unrest, civil disorder, and states of emergency), natural disasters (including fires, earthquakes and floods), and quarantine restrictions, epidemics and pandemics, may have an adverse effect on the Company’s operations.

c. Market conditions

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

- general economic outlook;
- introduction of tax reform or other new legislation;
- interest rates and inflation rates;
• changes in investor sentiment toward particular market sectors;
• the demand for, and supply of, capital; and
• terrorism or other hostilities.

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

Further, the value of the Shares may fluctuate more sharply than that of other securities, given the low per Share pricing of the Shares under the Prospectus, and the fact that investment in the Company is highly speculative.

d. Price of Shares

As a publicly-listed company on ASX, the Company will be subject to general market risk that is inherent in all securities listed on a stock exchange. This may result in fluctuations in its Share price. The price at which Shares are quoted on ASX may increase or decrease due to a number of factors. These factors may cause the Shares to trade at prices below the Public Offer price. There is no assurance that the price of the Shares will increase or not decrease following the commencement of quotation on ASX, even if the Company’s earnings increase.

The Share price will be quoted in Australian dollars. As such, any investment in the Shares by a non-Australian investor will result in the investment being subject to the risk that the value of the Australian dollar depreciates relative the investor’s local currency.

Further, after the end of the relevant escrow periods affecting Shares in the Company, a significant sale of then tradeable Shares (or the market perception that such a sale might occur) could have an adverse effect on the Company’s Share price. Please refer to Section 3.14 for further details on the Securities likely to be classified by the ASX as restricted securities.

e. Privacy risks

The Company collects, handles and maintains patient-identifiable healthcare information and other sensitive personal information, which are subject to U.S. federal, state and foreign laws that regulate the use and disclosure of such information. Violations of U.S. federal, state or foreign laws concerning privacy and data protection could subject the Company to civil or criminal penalties, breach of contract claims, costs for remediation and harm to its reputation.

7.4 Investment speculative

The risk factors set out in this Prospectus ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company. These 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. There is the risk of loss of all of an investor’s capital with no dividends or other returns.

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 this Prospectus.
8. INTELLECTUAL PROPERTY REPORT

January 29, 2019

The Board of Directors
Koligo Therapeutics Limited
Level 5
126 Phillip Street
Sydney, NSW 2000
Australia

Intellectual Property Report: Koligo

I. REPORT SUMMARY

This intellectual property report (“Report”) has been prepared at the request of the Directors of Koligo Therapeutics Limited (the “Company”), a public company registered in Australia which has agreed to acquire the entire stock in Koligo Therapeutics, Inc. (“Koligo”). The Report summarizes the current status of U.S. and foreign patents and applications owned and licensed by Koligo and the status of Koligo’s U.S. trademark rights. The Report is for inclusion in an IPO Prospectus to be lodged by the Company at the Australian Securities & Investments Commission for the purpose of raising funds through the issue of securities and listing on the Australian Securities Exchange Limited.

Section II below provides general information regarding aspects of the patent system including risks in the patent system, limitations of patent protection, and information related to the license of patents.

Section III provides an overview of the patents and applications owned and licensed by Koligo.

Section IV below provides general information regarding aspects of the trademark system including risks in the trademark system, and limitations of trademark protection.

Section V provides an overview of the trademarks owned by Koligo.

Section VI provides limitations and qualifications regarding patents and trademarks in general, the patents/applications owned and licensed by Koligo, and the trademarks owned by Koligo.
Sections II and IV of this Report are meant to provide only a high level summary of the patent and trademark systems and should not be interpreted as providing an exhaustive description of patent or trademark law or of related risks regarding patents or trademarks.

II. GENERAL INFORMATION REGARDING PATENTS

Generally, “intellectual property” refers to a group of registrable and non-registrable rights, including rights in patents, designs, trademarks, plant varieties, copyright, confidential information, and trade secrets. Intellectual property has many of the characteristics possessed by real and personal property. In particular, intellectual property is an asset, which may be bought, sold, licensed, exchanged, or otherwise transferred. Accordingly, an intellectual property owner has the right to prevent the unauthorized use, manufacture, import, or sale of its property.

A. Patents in General

Patent rights constitute one component of intellectual property. Patents cover inventions and authorize the owner to exclude others from practicing the claims of the patent without the owner’s permission. This right is granted to the patent owner in exchange for an inventor’s full disclosure of the invention to the public. Typically, a patent may only be granted to inventor(s), or to a person who has entitlement to the invention by way of an assignment.

A patent may provide protection for novel (new), inventive (non-obvious), and useful inventions for a fixed period, which is typically up to 20 years from filing for utility patents in the United States and most other countries. Design patents filed in the United States after May 13, 2015 typically provide protection for 15 years from the date of grant (design patents filed before this date have a term of 14 years from the date of grant). Patents may be granted in relation to a wide range of subject matter, such as new or improved products. Such subject matter typically should have an industrial application or be useful in connection with a product or a service. Utility patents typically cover a process (a series of steps), a machine (device consisting of parts), a manufacture (an article produced from raw or prepared materials), or a composition of matter (compositions of two or more substances). In contrast, design patents typically cover a visual ornamental design embodied in an article of manufacture.

A patent cannot be granted on a worldwide basis. Rather, patents must be obtained in every country where protection is required. Although there is a certain amount of harmonization between the patent granting procedures and standards throughout the world, there are differences regarding the test for patentability. Accordingly, the scope of a patent may vary from country to country and indeed a patent may not be granted in a particular country for failure to comply with the relevant standards. In addition, to maintain a pending application or patent in force, certain countries require the payment of renewal or maintenance fees on a periodic basis.
B. Process for Obtaining a Patent

In most countries of the world, the process of protecting patent rights begins with the submission of a patent application comprising (i) a patent specification describing the invention, (ii) drawings illustrating the invention, and (iii) claims specifying the scope of the invention. Filing a patent application (provisional or non-provisional) in the United States, Australia, or other countries that permit such a filing satisfies this requirement. In some countries, such as the United States, a provisional patent application may be filed.

A provisional patent application is oftentimes less formal than a non-provisional patent application, but should include a written description of the invention and any drawings necessary for the understanding of the invention. A provisional application does not require claims and is not examined. The provisional patent application can function as a placeholder until a non-provisional patent application can be filed. In contrast, a non-provisional patent application includes a formal description of the invention and a complete claim set that is examined. Generally, countries that allow provisional patent applications require that a non-provisional be filed within a year of the filing of the provisional.

A fundamental requirement of all patent systems is that an invention be novel and inventive at the time of filing, relative to what was publicly known or used at the date of the application. It is important that the specification (including the drawings) of the patent application contains a full disclosure and description of the invention. A patent application also includes claims that define the scope of the invention. The description of the invention typically includes references to drawings that illustrate the invention and different examples of the invention. The description also typically provides background information, such as a description of existing products, manufacturing or testing methods, or processes and related problems, which enable an examiner and others to assess the application for inventiveness.

Pursuant to an International Treaty called the Paris Convention, once the initial utility application has been filed, further applications in foreign countries must be filed within twelve (12) months, otherwise rights to the invention may be lost in those countries. The filing of an initial patent application establishes a priority date for the invention in all other countries which are party to the Paris Convention, including countries such as the United States, Japan, Australia, China, Canada, Mexico, and countries within the European Union.

The filing of further patent applications in foreign countries may be pursued individually or in some instances by filing an application with a regional patent office that does the work for a number of countries, such as the European Patent Office and the African Regional Industrial Property Organization. Under such regional systems, an applicant requests protection for the invention in one or more countries, and each country decides as to whether to offer patent protection within its borders. The World Intellectual Property Organization-administered Patent Cooperation Treaty (“PCT”) provides for the filing of a single international utility patent application, which can serve as a placeholder, for up to 31 months from the earliest filing date, until the applicant decides whether to file national applications in the designated countries. An
The Board of Directors
Koligo Therapeutics Limited
January 29, 2019

applicant seeking protection may file one utility application and request protection in as many
signatory states as needed.

It should be noted that at present there are 148 countries that are party to the PCT and if patent
protection is required in a country that is not party to the PCT then individual applications must
be filed in these countries by the twelve (12) month anniversary of the initially filed application.
An example of a country that is not a party to the PCT is Argentina.

Patent applications filed individually in countries rather than via the PCT are examined under the
national laws of those countries. However, a PCT application is considered under the terms of
the PCT. Once the PCT application has been filed, it is subjected to what is called an
“international search,” carried out by one of the major patent offices. The search results are then
communicated to the patent applicant in an “international search report,” which is a listing of
published documents that might affect the patentability of the invention claimed in the
international application. On the basis of the international search report the applicant may decide
to withdraw the application. However, if the PCT application is not withdrawn, it is, together
with the international search report, published by the International Bureau.

If the applicant decides to continue with the international application, then within thirty (30)
months of the provisional patent application filing date, national patent applications need to be
filed. In some countries such as Australia and regions such as Europe, the deadline is thirty-one
(31) months. The applicant can also request preliminary examination, which is a report prepared
by one of the major patent offices that gives a preliminary and non-binding opinion on the
patentability of the claimed invention.

Once the PCT process has been completed, the applicant nationalizes the PCT application in
certain regions or individual countries, as the PCT application itself does not mature into a
patent. The applicant may choose to enter one or more of the countries designated in the original
PCT application. Entry into the national phase is essentially the same as filing an application in
the first instance. Thus, the standard documentation and fee requirements will need to be
satisfied in each country. Many non-English speaking countries require a translation of the PCT
specification into the language of the relevant country. Failure to enter the national phase within
the thirty (30) (or thirty-one (31)) month period will result in abandonment of the ability to
secure patent protection in most PCT countries.

The national or regional applications progress under the jurisprudence and legislation of each
country or region. In most jurisdictions, such as Australia, Europe, United States and Japan,
examination by the relevant patent office comprises an examination of the art to which the
invention pertains as it existed at the priority date of the application. This examination
establishes what is referred to as the “state of the art.” The patent application is measured
against the state of the art and an assessment is made regarding whether the invention described
in the application is novel, inventive and useful. The patent application is also examined to
ensure the invention is directed to something more than an abstract idea. Once the patent
application is deemed to be novel, inventive, useful, and non-abstract, the patent office will
indicate the patent application is allowable. At this point, the applicant has to pay a grant or
issue fee and address any minor issues raised by the patent office. After the fee has been paid and those issues have been resolved, the patent office will grant a patent from the patent application. The time required to complete the process of examination differs from country-to-country and the scope or protection may differ depending upon the law of each country. In general, it will take several years from the date of application until the patent is actually granted.

With respect to regional applications, such as a European patent application, the applicant files a single application designating specific countries within the relevant region that are signatories to the Paris Convention. The single application is subjected to examination, and assuming that the application is allowed, it will proceed to the grant phase. The applicant can then elect to have patents granted in all or some of the designated countries. The individual patents function as though they were patents granted by the patent office of the designated country.

**C. Patent Grant Information**

After a patent has been granted, renewal or maintenance fees may need to be paid, otherwise the patent will cease or expire. Once a patent has been granted and subject to possible challenges as discussed in Section VI(B) below, the owner has the exclusive rights to exclude others from using the patented technology throughout the lifetime of a patent. This means that the owner can prevent others from using or selling the method or product covered by the claims of the granted patent. Alternatively, the owner can allow others to make or sell products or services covered by at least one claim of the patent under the terms of a license agreement. The terms of the license agreement generally define the limited scope of the use of the patent and the consideration to be paid for the use of the patent.

Enforcement of patent rights varies from country-to-country. The remedies for unauthorized use (patent infringement) available to the patent owner may include an injunction, which effectively stops further infringement of the patent, damages or accounting of profits, and costs. The cost of patent enforcement varies significantly from country-to-country in addition to the calculation for damages and the basis for determining whether to grant an injunction. Infringement proceedings typically cannot be initiated on the basis of a pending application.

**D. Patent License Information**

Patents and applications may be licensed to third-parties. Generally, the owner of the patent is referred to as a “Licensor” while the acquirer of patent rights from the Licensor is referred to as the “Licensee”. A patent license defines the terms on which patent rights (and other intellectual property rights) are granted by the Licensor to the Licensee. The terms of a license are negotiated between the Licensor and Licensee. Most patent licenses include provisions that define the term or duration of the License, identify the patents and other intellectual property that are being licensed, identify products of the Licensee that are covered by the license, specify patent rights conveyed through the License, define royalty payments and other consideration paid by the Licensee, specify termination provisions, and specify provisions for enforcement of the patents.
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019  

Patent licenses often convey to a Licensee the rights to make, have made, use, sell, import, and distribute products that are covered by the licensed patents. Some patent licenses may only grant a subset of these rights. Improvements to the patented technology made by the Licensee may be retained by the Licensee, conveyed to the Licensor, or jointly owned between the Licensee and Licensor.

A patent license may be provided on a worldwide basis or be limited to certain geographic locations or regions. Patent licenses that convey worldwide rights permit a Licensee to practice the licensed patents anywhere in the world. However, the enforceability of the patents is limited to the jurisdictions in which a patent has been obtained. For example, a worldwide license permits a Licensee to sell licensed products in New Zealand. However, a patent infringement lawsuit cannot be brought against a third-party selling infringing products in New Zealand if the Licensor does not have a New Zealand patent.

Patent licenses are provided for a fixed term. Some licenses will provide a short fixed term with options for renewals. Patent licenses having longer durations terminate when the last of the licensed patents expire. In some instances, the Licensor and Licensee will agree to extend the license past the expiration of the patents if certain technology or other intellectual property is licensed in addition to patents.

There are two types of patent licenses: exclusive and non-exclusive. An exclusive license specifies that a Licensee is the only party obtaining rights to licensed patents from the Licensor. This means the patent rights cannot be licensed to other parties and the Licensee has the same rights (subject to limitations in the license) as the Licensor. Many exclusive licenses permit a Licensee to bring a patent infringement suit against infringing third-parties on behalf of the Licensor. In addition, many exclusive licenses permit a Licensee to sublicense patent rights to third-parties. An exclusive license may be limited by a field of use, geography, or term.

A non-exclusive license specifies that the Licensor may license patent rights to multiple parties. Generally, a non-exclusive license conveys fewer patent rights to a Licensee because the patent rights are shared among a group of licensees. Non-exclusive licenses do not permit Licensees to bring infringement lawsuits against third-parties on behalf of a Licensor.

III. KOLIGO’S PATENT APPLICATION, LICENSE AGREEMENTS, AND LICENSED PATENTS

A. Patent Application

Koligo owns the rights to U.S. Provisional Application No. 62/760,709, titled “Methods and Compositions to Release Intact Islet Cells from Diseased Pancreata”. It was filed November 13, 2018 as a provisional application and lists Balamurugan Appakalai, Stuart K. Williams II, and Gopalakrishnan Loganathan as co-inventors. Per an assignment document, the inventors assigned their rights to Koligo. U.S. Patent Application No. 62/760,709 does not claim priority to any other patent applications.
The Board of Directors
Koligo Therapeutics Limited
January 29, 2019

The application is generally directed to methods for isolating islet cells (“islets”) from a diseased pancreas and to compositions used in these methods. The methods involve administering a mixture of two enzymes, a collagenase and a neutral protease, to a diseased pancreas to digest the pancreatic tissue and release the islets. The methods include assessing the relative quality of the diseased pancreas and altering the proportions of the two enzymes based on the assessment to improve the yield and quality of the isolated islets. The compositions include enzymatic mixtures of a collagenase and a neutral protease in targeted proportions. The isolated islets can be used for treating pancreatic disease by transplanting the isolated islets into a patient.

B. Knowledge License Agreement with University of Louisville Research Foundation, Inc. (“the Foundation”)

Koligo entered into a Knowledge License Agreement with the Foundation effective November 20, 2017. The Knowledge License Agreement is an exclusive license agreement having a term of two (2) years. After November 19, 2019, subject to Koligo having complied with all material terms and conditions of the license, the license becomes a fully paid-up, perpetual, non-exclusive, irrevocable, sub-licensable, royalty-free license. The license grants Koligo the right to manufacture, have made, use, offer for sale, import, and sell isolated human islets for autologous transplantation and to provide services using the isolated human islets. The license also provides Koligo with technical knowledge relating to the preparation, manufacture, use, and sale of isolated human islets for autologous transplantation.

Islets are cells that produce insulin in the pancreas. Patients with chronic pancreatitis may develop diabetes as the disease progresses and the pancreas degenerates. Autologous transplantation of human islets is a treatment procedure that involves surgical removal of a patient’s diseased pancreas, isolation of islets from the pancreas, manipulation of the isolated islets, and infusion of the manipulated isolates into the patient’s liver where they are intended to engraft and produce insulin.

Koligo’s KYSLECEL™ product is used for treatment of chronic or acute recurrent pancreatitis after pancreatectomy and contains pancreatic islets made from a patient’s own pancreas (autologous pancreatic islets) that are then infused into the patient’s liver where they are expected to function and produce the insulin needed to regulate the patient’s blood sugar.

C. Foundation License Agreement

Koligo entered into a License Agreement with the Foundation effective November 23, 2018. The Foundation License Agreement is an exclusive license agreement that grants Koligo rights to make, have made, use, offer for sale, import, export, and sell products, services, and methods that infringe, induce the infringement of, or contribute to the infringement of the licensed patent and patent applications listed below. The Foundation License Agreement is effective until the expiration of the last licensed patent to expire, subject to certain product development milestones being met.
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

The licensed patent and patent applications are directed to methods for making spheroids (or droplets) containing biologically-relevant materials dispersed within a biocompatible medium. The biologically-relevant materials include cells such as islets of Langerhans (also called pancreatic islets). The biocompatible medium serves as a three-dimensional substrate for the cells or other biologically-relevant materials. The spheroids can be implanted in tissue to provide restoration of tissue function.

The methods of making spheroids include methods of making pre-vascularized spheroids. The pre-vascularized spheroids contain a first suspension that is surrounded by a second suspension. The first suspension, or core, contains cells dispersed in a biocompatible medium. The second suspension contains microvessel fragments dispersed in a biocompatible medium. The microvessel fragments include smaller caliber vascular tissue such as arterioles, capillaries, and venules.

The licensed patent and patent applications also are directed to tissue constructs containing pancreas derived microvessel fragments and pancreatic islet cells. The microvessel fragments include smaller caliber vascular tissue such as arterioles, capillaries, and venules. The tissue constructs can be used for treating diabetes or symptoms associated with diabetes by increasing the production of insulin in a patient.

Koligo’s KYSLECCEL™ product contains islet cells that are infused into a patient’s liver where they are expected to function and produce the insulin needed to regulate the patient’s blood sugar. The islet cells are not in the form of spheroids and KYSLECCEL™ does not include microvessel fragments.

The licensed patent and applications are listed in the table below. The Foundation License Agreement provides a license to all United States and foreign patents that issue in the future from the patents and applications listed below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Application No. or Patent No.</th>
<th>Filing Date</th>
<th>Grant Date</th>
<th>Expiration Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>10,059,921 (patent granted)</td>
<td>8/21/14</td>
<td>8/28/18</td>
<td>9/9/2034</td>
<td>Methods of Making Spheroids Including Biologically-Relevant Materials</td>
</tr>
<tr>
<td>US</td>
<td>16/046,192</td>
<td>7/26/18</td>
<td>-</td>
<td>-</td>
<td>Methods of Making Spheroids Including Biologically-Relevant Materials</td>
</tr>
</tbody>
</table>

INTELLECTUAL PROPERTY REPORT
D. License Agreement with the University of Arizona (“UA”)

Koligo entered into a License Agreement with UA effective October 15, 2018. The UA License Agreement is an exclusive license agreement that grants Koligo rights to make, have made, import, use, market, offer for sale and sell products, services, or processes that embody or infringe any pending or issued claim of the licensed patents and patent application listed below. The license agreement is effective until the expiration of the last licensed patent to expire, subject to certain product development milestones being met.

The licensed patents and application are directed to an implantable device for providing a biologically active agent to a subject. The device includes a microvessel construct and a pouch that encapsulates cells or tissue capable of producing the biologically active agent. The microvessel construct contains vessels that are in contact with the pouch so as to provide a blood supply to improve the viability and function of the cells compared with cells transplanted without a microvessel construct. The cells may be islet cells, which are cells capable of producing insulin.

Koligo’s KYSLECEL™ product contains islet cells that are infused into a patient’s liver where they are expected to function and produce the insulin needed to regulate the patient’s blood sugar. The islet cells are not encapsulated in a pouch and KYSLECEL™ does not include a microvessel construct.

The licensed patents and application are listed in the table below. The UA License Agreement provides a license to all United States and foreign patents that issue in the future from the patents and applications listed below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Application No. or Patent No.</th>
<th>Filing Date</th>
<th>Grant Date</th>
<th>Expiration Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCT</td>
<td>PCT/US2006/021542</td>
<td>6/2/2006</td>
<td>-</td>
<td>-</td>
<td>Prevascularized Devices and Related Methods</td>
</tr>
</tbody>
</table>
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

E. Renewal Fees

Renewal or maintenance fees may need to be paid to maintain granted or issued patents with the granting national patent office. For example, maintenance fees in the United States are due at three-and-a-half (3.5), seven-and-a-half (7.5), and eleven-and-a-half (11.5) years from the time a patent is granted. As of the date of this Report, no such renewal or maintenance fees with respect to the patents or patent applications described in this Report are overdue.

F. Third-Party Patent Litigation

K&L Gates LLP is not representing Koligo in any pending litigation in which it is named as a defendant, or in any litigation that is overtly threatened in writing against Koligo by a potential claimant, that asserts that Koligo has infringed any patent owned by a third-party.

IV. General Information Regarding Trademarks

A. Trademarks in General

Trademark rights constitute a component of intellectual property. Trademarks cover words, symbols, phrases and/or designs used to identify the source of a good or service. Trademarks, also cover symbols, or phases used to identify a service, common referred to as a servicemark. Trademarks further cover visual, auditory, or scent aspects of a product, such as its color, smell, or packaging/shape, which are commonly referred to as trade dress.

In the United States, trademarks can be governed by both state and federal law. In other countries, trademarks are commonly only governed by national law. In the United States, trademark rights can arise from common law use (i.e., commercial sales of products with the trademark) or registration with the U.S. Patent and Trademark Office or a state trademark office (though state registrations are less common). Common law trademark rights obtained by such commercial sales are generally limited to the geographic area in which the trademark is used and known by the public. Trademark rights obtained through an individual state provide protection for that state, while trademark rights obtained at the national level provide protection for the entire country.

In order to serve as a trademark, a mark must be distinctive. This means the mark must be capable of identifying the source of a particular good. In determining whether a mark is distinctive, the mark is grouped into one of four categories, based on the relationship between the mark and the underlying product: (1) arbitrary or fanciful, (2) suggestive, (3) descriptive, or (4) generic. Because the marks in each of these categories vary with respect to their distinctiveness, the requirements for, and degree of, legal protection afforded a particular trademark will depend upon which category it falls within.

An arbitrary or fanciful mark is a mark that bears no logical relationship to the underlying product. Arbitrary or fanciful marks are inherently distinctive and capable of identifying an
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019  

underlying product. Accordingly, arbitrary or fanciful marks are given a high degree of protection.

A suggestive mark is a mark that evokes or suggests a characteristic of the underlying good. Some exercise of imagination is needed to associate the word with the underlying product. At the same time, however, the word is not completely unrelated to the underlying product. Like arbitrary or fanciful marks, suggestive marks are inherently distinctive and are given a high degree of protection.

A descriptive mark is a mark that directly describes, rather than suggests, a characteristic or quality of the underlying product (e.g., its color, odor, function, dimensions, or ingredients). In other words, a descriptive mark conveys something about the product. Unlike arbitrary or suggestive marks, descriptive marks are not inherently distinctive and are protected only if they have acquired "secondary meaning." Descriptive marks must clear this additional hurdle because they are terms that are useful for describing the underlying product, and giving a particular manufacturer the exclusive right to use the term could confer an unfair advantage.

A descriptive mark acquires secondary meaning when the consuming public primarily associates that mark with a particular producer, rather than the underlying product. The public need not be able to identify the specific producer; only that the product or service comes from a single producer. When trying to determine whether a given term has acquired secondary meaning, the following factors are often considered: the amount and manner of advertising; the volume of sales; the length and manner of the term's use; and results of consumer surveys.

A generic mark is a mark that describes the general category to which the underlying product belongs. Generic marks are entitled to no protection under U.S. and international trademark law. Generic terms are not protected by trademark law because they are simply too useful for identifying a particular product. Giving a single manufacturer control over use of the term would give that manufacturer too great a competitive advantage. Under some circumstances, terms that are not originally generic can become generic over time (a process called "genericity"), and thus become unprotected.

B. Process for Obtaining a Trademark

Trademark rights can be acquired through common law usage or registering the mark with the trademark office. The use of a mark generally means the actual sale of a product to the public with the mark on the product or provision of a service under the mark. For common law rights, the priority of the trademark is limited to the geographic area in which the mark is used. Similar or identical trademarks could be used in different geographic areas by third-parties without infringing, although this situation is rare with the promotion of products and services via the Internet.

Unlike use of a mark in commerce, registration of a mark with the U.S. Patent and Trademark Office gives a party nationwide priority in the mark, even if actual sales are limited to only a limited area. This right is limited to the extent the mark is already being used by others within a specific geographic area through common law use. In these circumstances, the prior user of the
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

mark retains the right to use that mark within that geographic area while the party registering the mark gets the right to use it everywhere else.

Registration with the U.S. Patent and Trademark Office confers a number of benefits to the registering party. Registration gives a party the right to use the mark nationwide, subject to prior common law usage. Registration also constitutes nationwide constructive notice to others that the trademark is owned by the party. Registration further enables a party to bring an infringement suit in a federal court. Moreover, registration enables a party to potentially recover treble damages, attorney fees, and other remedies. Finally, registered trademarks can, after five years, become "incontestable," at which point the exclusive right to use the mark is conclusively established.

To register a trademark, a trademark applicant files a trademark application with the U.S. Patent and Trademark Office. The applicant may file a use-based trademark application if the mark is used in commerce or an intent-to-use application if the applicant has a good faith intention to use the mark in the future. The trademark application must contain at least a reproduction of the mark and a list of the goods and services for which protection is sought. To obtain a registration, an applicant must prove use of the mark on the goods or services and provide evidence to the U.S. Patent and Trademark Office. An applicant may request extensions from the trademark office for three years after the application is “allowed” for registration.

The U.S. Patent and Trademark Office examines the mark and may reject a registration on any number of grounds. For example, marks can be refused for being generic or descriptive without having attained secondary meaning. Marks can also be refused for being immoral or scandalous, being a surname, including certain geographic locations, or causing confusion with an existing registration. The trademark applicant may counter a rejection by showing that the mark is arbitrary, fanciful, or suggestive, or by showing that the mark has acquired secondary meaning, or will not cause confusion with an existing mark. The process generally involves an initial and final office action, after which if the applicant does not satisfy the U.S. Patent and Trademark Office’s requirements, the application will be refused registration.

If the application is in order, the U.S. Patent and Trademark Office may grant a trademark registration.

C. International Trademark Registration Information

Registration of trademarks in multiple jurisdictions around the world is conducted on a country-by-country basis. Although two treaties, the Madrid Agreement and Madrid Protocol, provide a system for filing an “international registration” at the World Intellectual Property Office (WIPO) and designating multiple countries for protection, each country’s Trademark Office still examines the applications separately under their own laws. Depending on the strength of a home country application, a trademark owner can consider either direct filings with a specific Trademark Office or a Madrid registration.
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

D. Trademark Grant Information

After a trademark has been granted, renewal or maintenance fees may need to be paid or continued use demonstrated, otherwise the trademark will cease or expire. Once a trademark has been granted, the owner has the exclusive rights to exclude others from using the registered mark in the jurisdiction of the registration subject to prior common law use by others where applicable. This means that the owner can prevent others from using the registered mark with goods or services. Alternatively, the owner can allow others to make or sell products or services covered by the registered mark under the terms of a license agreement. The terms of the license agreement generally define the limited scope of the use of the trademark and the consideration to be paid for the use of the trademark.

Enforcement of trademark rights varies from country-to-country. The remedies for unauthorized use (trademark infringement) available to a trademark owner may include an injunction, which effectively stops further infringement of the trademark, damages or accounting of profits, and costs. The cost of trademark enforcement varies significantly from country-to-country in addition to the calculation for damages and the basis for determining whether to grant an injunction. Infringement proceedings typically cannot be initiated on the basis of a pending application.

V. KOLIGO’S TRADEMARKS

A. Koligo Therapeutics

Koligo filed trademark applications with the United States Patent and Trademark Office on November 13, 2018 for the mark (“KOLIGO THERAPEUTICS”) and its logo design (“KOLIGO THERAPEUTICS Marks”). The trademark applications were assigned Application Nos. 88192728 and 88192725. The applications for the KOLIGO THERAPEUTICS Marks list the following products and services for trademark coverage: cell therapy services for the treatment of pancreatic diseases; administration of cell therapy services for the treatment of pancreatic diseases; research and development services in the field of cell therapies; cell therapy products; and cell therapy products, namely, cell therapies for the treatment of pancreatic diseases. Per the trademark applications, Koligo has sold products under the KOLIGO THERAPEUTICS Marks since March 2016.

The KOLIGO THERAPEUTICS Marks are used in connection with a minimally-manipulated autologous cell therapy product that is regulated by the U.S. Food and Drug Administration (“FDA”) under Section 361 of the PHS Act and 21 C.F.R. 1271.
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019  

B. Kyslecel  

Koligo filed a trademark application with the United States Patent and Trademark Office on November 13, 2018 for the mark (“KYSLECEL”). The trademark application was assigned Application No. 88192721. The application for the KYSLECEL Mark lists the following products for trademark coverage: cell therapy products; and cell therapy products, namely, cell therapies for the treatment of pancreatic diseases. Per the trademark application, Koligo has sold products under the KYSLECEL Mark since March 2016.

The KYSLECEL Mark is used in connection with a minimally-manipulated autologous cell therapy product that is regulated by the U.S. FDA under Section 361 of the PHS Act and 21 C.F.R. 1271. Under its intended use in the FDA application, Koligo indicates that “KYSLECEL is a suspension comprising minimally manipulated autologous pancreatic islets for intraportal or intraperitoneal infusion intended to preserve beta-cell mass and insulin secretory capacity in chronic or acute recurrent pancreatitis patients after pancreatectomy.”

C. Stylecel-L  

Koligo uses the mark “STYLECEL-L” on its website (www.koligo.net) and in publications in connection with an engineered tissue product containing 3D bioprinted allogeneic (donor derived) pancreatic islets to treat type 1 diabetes with hypoglycaemic unawareness and other pancreatic diseases. As of January 29, 2019, Koligo has yet to sell products under the STYLECEL-L Mark and accordingly has not yet acquired common law trademark rights in that mark. Koligo has not filed a trademark application for the STYLECEL-L Mark with the United States Patent and Trademark Office or under the Madrid Protocol.

VI. LIMITATIONS AND QUALIFICATIONS  

A. Third-Party Rights  

Filing a patent or trademark application, or receiving a patent or trademark, does not give the owner the right to freely commercially practice the patent or use the trademark. It is possible that intellectual property rights of another party may be infringed by a product, service, or brand of the patent/trademark owner. Typically, third-party rights may be identified by conducting a Freedom to Operate (“FTO”) search in the country or counties it is proposed to commercialize an invention. K&L Gates LLP has not conducted any FTO on behalf of Koligo or the Company.

B. Validity of Patents and Trademarks  

The grant of a patent or a trademark does not guarantee that the patent or trademark is valid or enforceable. Various legal mechanisms exist to challenge the validity of patents, trademarks, patent applications, and trademark applications including challenges (i) during examination, (ii) in an opposition or post-grant proceeding once the application has been found allowable, (iii) in a court during a revocation or invalidity proceeding brought by a third-party, or (iv) in an infringement proceeding initiated against an alleged infringer. Successful challenges to a patent application may result in some or all of the claims of an application being refused. Successful
opposition proceedings to a granted patent may result in some or all of the claims being cancelled or restricted in scope. Successful challenges to a trademark application may result in the mark of an application being refused. Successful opposition proceedings to a granted trademark may result in the mark being cancelled or restricted in scope.

As some of Koligo’s owned and licensed patent applications are still under examination, it cannot be assumed that they (or any applications stemming from them) will proceed to grant or, if grant is achieved, that the claims will remain in their present form. It is possible, for example, that the scope of the claims of the patent applications may be restricted during examination of the applications. K&L Gates LLP provides no assurance that Koligo’s owned and licensed patent applications will be granted or that they will be held valid and enforceable if they are granted.

Additionally, as Koligo’s trademarks have not yet been registered, it cannot be assumed that they (or any applications stemming from them) will proceed to grant or, if grant is achieved, that the mark will cover the desired goods or services. It is possible, for example, that the mark of a filed trademark application may be restricted or rejected during examination. K&L Gates LLP provides no assurance that Koligo’s trademarks will be registered or that they will be held valid and enforceable if they are granted.

C. Information Sources

In preparing this Report, in addition to reviewing our internal databases, we have relied upon information contained in relevant publicly available databases including the United States Patent and Trademark Office databases and the World Intellectual Property Office databases. We have not independently verified the information in such databases, and we are not responsible for the accuracy of that information. The databases were last searched at 10:00 AM on January 29, 2019 to verify the information provided in this Report.

K&L Gates LLP is not rendering any opinion as to the enforceability of any agreements, licenses, or other contracts described in this Report. References herein to a party owning patent or trademark rights means that the party is listed as the owner or assignee in the relevant United States Patent and Trademark Office databases or the World Intellectual Property Office databases. K&L Gates LLP has not conducted an independent assessment regarding the ownership of the patent or trademark rights discussed in this Report.

D. Jurisdictional Requirements

Each jurisdiction has its own laws and particular requirements that need to be met for the grant and maintenance of a patent or trademark. Accordingly, the assessment of patentability and ability to use a particular mark varies from jurisdiction-to-jurisdiction, and inventions or trademarks, which may be granted and registrable in one jurisdiction, may be excluded from grant and registration in another.

Moreover, the different jurisdictional requirements may result in variation of the scope of patent or trademark protection obtained for the same patent or trademark in different jurisdictions. The outcome of examination of a patent or trademark application by the office of one jurisdiction is
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

not binding on the office of any other jurisdiction. Similarly, international searches and examination reports are not binding on national patent applications during examination in the national phase. Examination of patent and trademark applications often occurs at different times in different jurisdictions. This means there is also a risk that a patent or trademark may be granted on an application in one jurisdiction, and that a third-party patent or similar mark may subsequently be cited as pertinent prior art during examination of another patent or trademark application that has been filed elsewhere.

In some jurisdictions there is a duty to disclose certain information to the relevant patent office. This information can include relevant prior art information known to the applicant or its agents or search results issued in respect of corresponding foreign applications. Failure to disclose such information may adversely affect the validity and/or enforceability of a patent or trademark.

We further note that there may be changes to patent or trademark law in a particular jurisdiction from time-to-time, which may have an impact on patents or trademarks in the relevant country. For example, the Australian Government enacted the Intellectual Property Law Amendments (Raising the Bar) Act 2012 (Cth), which represented a significant amendment to earlier Australian patent law. In particular, the Act raises the requirement for patentability and the description requirements for patent specifications. It applies to all Australian patent applications for which a request for examination was filed on or after 15 April 2013. In another example, in 2014 the United States Supreme Court in *Alice Corp. Pty. Ltd. v. CLS Bank Int’l et al.*, clarified the definition of what constitutes an abstract idea.

E. Search Limitations

A patentability search, such as international searches carried out by various patent offices under the PCT procedure, cannot be guaranteed to locate all prior art that may exist that is potentially relevant to the assessment of novelty and inventive step of a claimed invention. Additionally, a trademark search, such as international searches carried out by various trademark offices under the Madrid procedures, cannot be guaranteed to locate all similar marks that may exist that is potentially relevant to the assessment of uniqueness of a particular trademark.

Patent and trademark searches are generally computer-based searches and are dependent on the database search strategy and the coverage provided by the databases used. For example, the databases may not cover older published documents and/or certain jurisdictions. Further, all patentability and trademark searches are subject to the accuracy of records, as well as the indexing and classification of the subject matter comprising the records. The scope of each search is also dependent on the search strategy utilized and, for example, the keyword(s) selected for the search.

Accordingly, although patentability searches provide a reasonable indication of patentability and trademark searches provide a reasonable indication of registration, it is not possible to guarantee that every relevant prior art record, mark, or use has been located and considered. As a result, any conclusions regarding the validity of the claims of a particular patent or trademark based on patent or trademark office searches should be regarded as indicative rather than conclusive.
The Board of Directors
Koligo Therapeutics Limited
January 29, 2019

Further, non-provisional patent applications are not normally published until at least eighteen (18) months from the earliest acceptable priority date. Accordingly, a patentability search would not normally identify any third-party patent application that is potentially relevant to the assessment of patent ability that have a priority date which is less than eighteen (18) months prior to the date of the patentability search. Delays between official publication and the incorporation of information into the relevant database can also occur, which means that some documents may not be located in a patentability search.

K&L Gates has not conducted a patentability search for any of the patents or patent applications owned or licensed by Koligo.

F. Patentability of an Invention Limitations

Besides published prior art, public use of an invention and non-confidential oral disclosures before the priority date of a patent application may also be relevant to the assessment of patentability of invention to which the patent application relates. As patentability searches are conducted on published documents, they may not locate such other forms of prior art disclosures.

Commercialization or secret use of an invention in a jurisdiction by, or with the authority of, a patent applicant (or their predecessor in title) before the priority date of a patent application that has been filed in the jurisdiction by the applicant in respect of the invention, can also be relevant to the patentability of an invention and the validity of any patents that may ultimately be granted on the application. Such commercial exploitation or secret use would not normally be identified by documentary patentability searches of publicly accessible databases.

G. Entitlement to Claimed Priority Data Limitations

In Australia and the United States, for subject matter contained in a non-provisional patent application to be entitled to the priority date established by a corresponding priority patent application (including provisional patent applications) there must be a real and reasonably clear disclosure of the subject matter in the priority application. Similar provisions apply in other jurisdictions. Subject matter disclosed in a non-provisional patent application that is not contained in a corresponding priority application is generally only entitled to the filing date of the non-provisional application as a priority date.

H. Qualifications and Independence

K&L Gates LLP is a global law firm with fully integrated offices located on five continents. With approximately 200 intellectual property attorneys worldwide and over 100 United States Patent and Trademark Office registered professionals, K&L Gates LLP provides comprehensive intellectual property services including intellectual property procurement, litigation, counseling, and management. The firm is one of the top filers of patent and trademark applications in the United States and Australia.
The Board of Directors  
Koligo Therapeutics Limited  
January 29, 2019

K&L Gates LLP has no interest in Koligo or the Company, other than fees for professional work done. K&L Gates LLP expects to receive a fee of approximately US$13,000.00 based on time spent at normal professional rates for the preparation of this Report.

Except as otherwise expressly stated, all information contained in this Report is as of the date hereof, and K&L Gates LLP assumes no obligation to update this Report based on future developments of law or fact or information that may come to the attention of K&L Gates LLP at a future date.

K&L Gates LLP has no involvement in the preparation of the Company’s Prospectus, other than the preparation of this Report. K&L Gates LLP gives its consent for inclusion of this Report in the Prospectus.
FINANCIAL INFORMATION AND INDEPENDENT LIMITED ASSURANCE REPORT
9. FINANCIAL INFORMATION AND INDEPENDENT LIMITED ASSURANCE REPORT

9.1 Introduction

The Company was incorporated on 27 June 2018 for the primary purpose of acquiring Koligo. Simultaneous with the completion of the Public Offer, the Company will acquire 100% of the issued shares of Koligo under the Exchange Agreement. The consolidated group (Group), consists of the parent entity, the Company, and, subsequent to the completion of the Exchange Agreement, the Company’s wholly owned subsidiary, being Koligo, and Koligo’s wholly owned subsidiary, Koligo Surgical, LLC.

The financial information in this Section 9 includes:

The **Statutory Historical Financial** Information, being the:

a. Statutory Historical Statement of Comprehensive Income of Koligo for the financial year ended 31 December 2017 (**FY2017**) and the financial year ended 31 December 2018 (**FY2018**);

b. Statutory Historical Statements of Cash Flows of Koligo for **FY2017** and **FY2018**; and


The **Pro Forma Historical Financial Information** being:


The Statutory Historical Financial Information and the Pro Forma Historical Financial Information are collectively referred to as the Financial Information.

Koligo has a 31 December financial year end. As such, any references in this Section to “FY” refer to a 31 December financial year end and any references in this Section to “HY” refer to the half year ended 30 June.

Also summarised in this Section 9 are:

a. the basis of preparation and presentation of the Financial Information (see Section 9.2);

b. a description of Koligo’s significant accounting policies;

c. the Group’s indebtedness and contingent commitments; and

d. the Company’s proposed dividend policy (see Section 9.9).

The Financial Information has been reviewed and reported on by HLB Mann Judd Corporate (NSW) Pty Ltd whose Independent Limited Assurance Report is contained in this Section 9. Investors should note the scope and limitations of that report.

The information in this Section 9 should also be read in conjunction with the risk factors set out in Sections 3.7 and 7 of the Prospectus and other information contained in this Prospectus.

Amounts disclosed in tables are presented in both US Dollars (US$) as disclosed in the audited financial statements of Koligo and converted into Australian Dollars (AUD$) at the relevant foreign exchange rate as detailed in Section 9.2.4.
9.2 Basis of preparation and presentation of the Financial Information

9.2.1 Overview

The Financial Information set out in this Section 9 has been prepared and presented in accordance with the recognition and measurement principles prescribed under US Generally Accepted Accounting Principles (US GAAP) as Koligo is incorporated in the United States of America.

Koligo originates from and is based in the United States of America, and therefore prepares financial statements in accordance with US GAAP. The accounting standards applied under US GAAP have some differences to the Australian equivalents to International Financial Reporting Standards (AIFRS), which are required, by the ASX (Listing Rule 1.3.5), to be used for the preparation of financial information presented in a prospectus. In accordance with ASX Listing Rule 1.3.5, the differences between the financial information prepared under US GAAP and the financial information prepared under AIFRS have been reviewed and are not considered material.

The Financial Information is presented in an abbreviated form insofar as it does not include all the presentation and disclosures required by US GAAP or AIFRS and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act.

Koligo’s key accounting policies have been consistently applied throughout the periods and are set out in Section 9.6.

The Directors have considered ASIC Regulatory Guide 170 (RG170) and the requirements for the disclosure of prospective information and note any prospective financial information would contain a broad range of potential outcomes and possibilities such that the Directors have concluded the Company should not include prospective financial information in this Prospectus.

9.2.2 Preparation of Historical Financial Information

The Statutory Historical Financial Information has been prepared for the purpose of inclusion in this Prospectus and is a summarised version of the audited statutory financial statements of Koligo for FY2017 and FY2018. The statutory financial statements have been audited by CohnReznick LLP and an unqualified audit opinion was issued in relation to both FY2017 and FY2018.

The Pro Forma Consolidated Historical Financial Information has been prepared solely for the purpose of inclusion in this Prospectus. The Pro Forma Consolidated Historical Financial Information has been derived from the audited statutory financial statements of Koligo as at 31 December 2018 and adjusted to illustrate the impact of the Offers, the Koligo Acquisition and other relevant adjustments.

Refer to Section 9.4 for a reconciliation between the audited Statutory Historical Statement of Financial Position of Koligo and the Pro Forma Consolidated Historical Statement of Financial Position of the Company as at 31 December 2018.

9.2.3 Explanation of certain non-IFRS and other financial measures

Koligo uses certain measures to manage and report on its business that are not recognised under US GAAP or AIFRS (Non-IFRS Measures). These measures are provided in addition to the US GAAP and AIFRS measures and not as a substitute. The Non-IFRS Measures do not have a prescribed meaning under AIFRS or US GAAP and may be calculated differently to the way that other companies calculate similarly titled measures. Readers should therefore not place undue reliance on the Non-IFRS financial information.

In the disclosures in this Prospectus, Koligo uses the following non-IFRS Measures of performance to assist prospective investors in understanding the trends in financial performance and profitability.

a. gross profit is calculated as revenue less costs of sales (excluding depreciation);

b. EBITDA is earnings before interest, tax, depreciation and amortisation expenses; and

c. EBIT is earnings before interest and tax expenses.
9.2.4 Foreign currency conversion

The functional currency of Koligo is US Dollars (USD$) as its current operations are located and conducted in the United States of America. Consequently, the Financial Information has been presented in US dollars in line with the audited financial statements. For each table within this Section 9 the relevant information has been restated in Australian dollars (AUD$) in line with ASX Listing Rule 1.3.5.

Transactions and balances in USD$ have been converted in accordance with International Accounting Standard 21 - The Effects of changes in Foreign Exchange Rates (IAS 21). A summary of the rates and methods applied is provided in the table below:

<table>
<thead>
<tr>
<th>FOREIGN CURRENCY CONVERSION RATES USD$ TO AUD$ EXCHANGE RATE</th>
<th>31 DECEMBER 2017</th>
<th>31 DECEMBER 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average rate used in translating the statutory historical income statement and statement cash flows</td>
<td>1.304201</td>
<td>1.337352</td>
</tr>
<tr>
<td>Exchange rate used in translating the statutory historical and proforma historical statement of financial position</td>
<td>1.278527</td>
<td>1.420455</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOREIGN CURRENCY CONVERSION RATES UFOR HISTORICAL EQUITY</th>
<th>DATE</th>
<th>RATE</th>
<th>USD$</th>
<th>AUD$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue of 4,905 shares</td>
<td>15/12/2017</td>
<td>1.307190</td>
<td>4,905</td>
<td>6,412</td>
</tr>
<tr>
<td>Issue of 10 shares</td>
<td>19/12/2017</td>
<td>1.307360</td>
<td>4,000</td>
<td>5,229</td>
</tr>
<tr>
<td>Conversion of notes and warrant</td>
<td>19/11/2018</td>
<td>1.369300</td>
<td>2,089,745</td>
<td>2,861,488</td>
</tr>
</tbody>
</table>
9.3 Statutory Historical Statement of Comprehensive Income

9.3.1 Overview

The table below sets out the Statutory Historical Statement of Comprehensive Income of Koligo for FY2017 and FY2018. The Statutory Historical Statements of Comprehensive Income are in USD$, with a translation of the figures to AUD$ as illustrated in the table below.

<table>
<thead>
<tr>
<th>Table 9.3.1 - Historical Statements of Comprehensive Income</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Revenue</td>
</tr>
<tr>
<td>Cost of sales</td>
</tr>
<tr>
<td>Gross profit</td>
</tr>
<tr>
<td>Operating expenses</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
</tr>
<tr>
<td>Selling and marketing</td>
</tr>
<tr>
<td>Research and development</td>
</tr>
<tr>
<td>EBITDA</td>
</tr>
<tr>
<td>Depreciation &amp; Amortisation</td>
</tr>
<tr>
<td>EBIT</td>
</tr>
<tr>
<td>Net interest</td>
</tr>
<tr>
<td>Net Profit/(Loss) before tax</td>
</tr>
<tr>
<td>Income Tax Expense</td>
</tr>
<tr>
<td>Net Profit/(Loss) after tax</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
</tr>
<tr>
<td>Total Comprehensive Income</td>
</tr>
</tbody>
</table>
## 9.4 Statutory Historical and Pro Forma Consolidated Historical Statement of Financial Position

### 9.4.1 Overview

The table below sets out the Statutory Historical Statement of Financial Position of Koligo as at 31 December 2017 and as at 31 December 2018.

<table>
<thead>
<tr>
<th>Table 9.4.1 - Historical Statements of Financial Position</th>
<th>31-DEC-17 USD</th>
<th>31-DEC-18 USD$</th>
<th>31-DEC-17 AUD$</th>
<th>31-DEC-18 AUD$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>2,853</td>
<td>7,218</td>
<td>3,648</td>
<td>10,253</td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>83,000</td>
<td>-</td>
<td>106,118</td>
<td>-</td>
</tr>
<tr>
<td>Prepayments</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Other current assets</td>
<td>6,064</td>
<td>28,342</td>
<td>7,753</td>
<td>40,259</td>
</tr>
<tr>
<td><strong>Total Current Assets</strong></td>
<td>91,917</td>
<td>35,560</td>
<td>117,518</td>
<td>50,511</td>
</tr>
<tr>
<td><strong>Non Current Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>-</td>
<td>11,111</td>
<td>-</td>
<td>15,783</td>
</tr>
<tr>
<td>Intangible Assets</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Non Current Assets</strong></td>
<td>-</td>
<td>11,111</td>
<td>-</td>
<td>15,783</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>91,917</td>
<td>46,671</td>
<td>117,518</td>
<td>66,294</td>
</tr>
<tr>
<td><strong>Current Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due to affiliate</td>
<td>-</td>
<td>15,957</td>
<td>-</td>
<td>22,666</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>40,881</td>
<td>85,856</td>
<td>52,267</td>
<td>121,955</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>57,966</td>
<td>52,975</td>
<td>74,111</td>
<td>75,249</td>
</tr>
<tr>
<td>Financial instrument</td>
<td>-</td>
<td>99,023</td>
<td>-</td>
<td>140,658</td>
</tr>
<tr>
<td>Other payables</td>
<td>74,167</td>
<td>-</td>
<td>94,825</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Current Liabilities</strong></td>
<td>173,014</td>
<td>253,811</td>
<td>221,203</td>
<td>360,527</td>
</tr>
<tr>
<td><strong>Non Current Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible notes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Warrant liability</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>7,500</td>
<td>11,000</td>
<td>9,589</td>
<td>15,625</td>
</tr>
<tr>
<td><strong>Total Non Current Liabilities</strong></td>
<td>7,500</td>
<td>11,000</td>
<td>9,589</td>
<td>15,625</td>
</tr>
<tr>
<td><strong>Total Liabilities</strong></td>
<td>180,514</td>
<td>264,811</td>
<td>230,792</td>
<td>376,152</td>
</tr>
<tr>
<td><strong>Net Assets</strong></td>
<td>(88,597)</td>
<td>(218,140)</td>
<td>(113,274)</td>
<td>(309,858)</td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share Capital</td>
<td>9,027</td>
<td>2,098,650</td>
<td>11,800</td>
<td>2,873,130</td>
</tr>
<tr>
<td>Reserves - FX trans</td>
<td>-</td>
<td>-</td>
<td>2,248</td>
<td>(87,863)</td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>(97,624)</td>
<td>(2,316,790)</td>
<td>(127,321)</td>
<td>(3,095,125)</td>
</tr>
<tr>
<td><strong>Total Equity</strong></td>
<td>(88,597)</td>
<td>(218,140)</td>
<td>(113,274)</td>
<td>(309,858)</td>
</tr>
</tbody>
</table>
9.4.2 Commentary on major items included in the Historical Statement of Financial Position of Koligo

The key items included in the Statement of Financial Position of Koligo as at 31 December 2018 are:

a. Cash and cash equivalents – these funds are held by local financial institutions in interest bearing accounts and are readily available for use by Koligo. Koligo considers cash to consist of highly liquid investments with original maturities of less than three months when purchased and cash held at financial institutions.

b. Due to affiliates – this liability is owed by Koligo to the Company and its classification is due to the majority shareholder being common to both entities.

c. Financial instrument - Pursuant to the Knowledge License Agreement between Koligo and the University of Louisville Research Foundation (Foundation), the Foundation was originally entitled to receive equity in Koligo. However, in satisfaction of this obligation, (and in lieu of the Foundation’s right to receive equity in Koligo), the Company has undertaken to issue 1,041,903 Shares to the Foundation on the date which is two years from the date the Company is admitted to the Official List. These Shares will be issued for no additional consideration. The fair value of Shares which the Foundation is entitled to receive was USD$99,023 (AUD$140,658) at 31 December 2018.

The table below sets out the Pro Forma Consolidated Historical Statement of Financial Position of the Company as at 31 December 2018.

The Pro Forma Consolidated Historical Statement of Financial Position is provided for illustrative purposes only and is not represented as being necessarily indicative of the Company’s view of its future position.

| Table 9.4.2 - Pro Forma Consolidated Historical Statements of Financial Position |
|---------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|---------------------|
|                                | 31-DEC-17 USD $    | 31-DEC-18 USD $    | 31-DEC-17 AUD $    | 31-DEC-18 AUD $    | % (UNDILUT-ED)      | % (FULLY DILUTED)    |
| Current Assets                 |                    |                    |                    |                    |                    |                     |
| Cash and cash equivalents      | 7,218              | 10,253             | 4,703,475          | 4,713,728          | 5,642,102           | 5,652,355           |
| Other current assets           | 28,342             | 40,259             | -                  | 40,259             | -                   | 40,259              |
| Total Current Assets           | 35,560             | 50,511             | 4,703,475          | 4,753,987          | 5,642,102           | 5,692,613           |
| Non Current Assets             |                    |                    |                    |                    |                     |                     |
| Property, plant and equipment | 11,111             | 15,783             | -                  | 15,783             | -                   | 15,783              |
| Total Non Current Assets       | 11,111             | 15,783             | -                  | 15,783             | -                   | 15,783              |
| Total Assets                   | 46,671             | 66,294             | 4,703,475          | 4,769,769          | 5,642,102           | 5,708,396           |
| Current Liabilities            |                    |                    |                    |                    |                     |                     |
| Due to affiliate               | 15,957             | 22,666             | (22,666)           | -                  | (22,666)            | -                   |
| Accounts payable               | 85,856             | 121,955            | -                  | 121,955            | -                   | 121,955             |
| Accrued expenses               | 52,975             | 75,249             | -                  | 75,249             | -                   | 75,249              |
| Financial instrument           | 99,023             | 140,658            | -                  | 140,658            | -                   | 140,658             |
| Total Current Liabilities      | 253,811            | 360,527            | (22,666)           | 337,861            | (22,666)            | 337,861             |
| Non Current Liabilities        |                    |                    |                    |                    |                     |                     |
| Other long-term liabilities    | 11,000             | 15,625             | -                  | 15,625             | -                   | 15,625              |
| Total Non Current Liabilities  | 11,000             | 15,625             | -                  | 15,625             | -                   | 15,625              |
Table 9.4.2 - Pro Forma Consolidated Historical Statements of Financial Position

<table>
<thead>
<tr>
<th></th>
<th>31-DEC-17 $USD</th>
<th>31-DEC-18 $USD</th>
<th>31-DEC-17 AUD$</th>
<th>31-DEC-18 AUD$</th>
<th>% (UNDILUTED)</th>
<th>% (FULLY DILUTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Liabilities</td>
<td>264,811</td>
<td>376,152</td>
<td>(22,666)</td>
<td>(22,666)</td>
<td>353,486</td>
<td>353,486</td>
</tr>
<tr>
<td>Net Assets</td>
<td>(218,140)</td>
<td>(309,858)</td>
<td>4,726,141</td>
<td>4,416,283</td>
<td>5,664,768</td>
<td>5,354,910</td>
</tr>
<tr>
<td>Equity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share Capital</td>
<td>2,098,650</td>
<td>2,873,130</td>
<td>5,651,715</td>
<td>8,524,845</td>
<td>6,635,130</td>
<td>9,508,260</td>
</tr>
<tr>
<td>Share options reserve</td>
<td>-</td>
<td>-</td>
<td>978,897</td>
<td>978,897</td>
<td>995,482</td>
<td>995,482</td>
</tr>
<tr>
<td>Reserves - FX trans</td>
<td>-</td>
<td>(87,863)</td>
<td></td>
<td>(87,863)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>(2,316,790)</td>
<td>(3,095,125)</td>
<td>(1,904,471)</td>
<td>(4,999,596)</td>
<td>(1,965,844)</td>
<td>(5,060,968)</td>
</tr>
<tr>
<td>Total Equity</td>
<td>(218,140)</td>
<td>(309,858)</td>
<td>4,726,141</td>
<td>4,416,283</td>
<td>5,664,768</td>
<td>5,354,910</td>
</tr>
</tbody>
</table>

9.4.3 Notes to the Pro Forma Consolidated Historical Statement of Financial Position

The Pro Forma Consolidated Historical Statement of Financial Position of the Company as at 31 December 2018 is derived from the Statutory Historical Statement of Financial Position of Koligo as at 31 December 2018 and adjusted for the following:

a. the inclusion of the Statement of Financial Position of the Company, which was not audited as it not considered material to require detailed disclosure in the Prospectus. The Company's financial position as at 31 December 2018 reflects the accrual of expenses of the Offers and the salaries of the Company's employee which are netted off by the drawdown of funds from a non-interest bearing loan extended to the Company from Long Hill Capital V, LLC (Lender) in the aggregate maximum amount of AUD$300,000 (of which it was not fully drawndown at 31 December 2018). This loan was provided for the sole purpose to pay the expenses of the Offers, the salaries of the Company's employee and such other purposes as are agreed in writing between the parties. The loan shall become repayable in cash by the Company to the Lender as follows:

i. in the event the Company is admitted to the Official List of ASX, from the proceeds of the Public Offer within 14 days of the date the Company is admitted to the Official List;

ii. in the event the Company is not admitted to the Official List of ASX by 1 May 2019, within 14 days of such date; or

iii. immediately in the event an Event of Default has occurred.

Further, on January 11, 2019, Koligo entered a line of credit with a director and shareholder (Stuart Williams, a Director of the Company) for USD$50,000 (AUD$71,023), with a maturity date of May 31, 2019. The line of credit bears interest at 3% per annum. This line of credit will be repaid in its entirety from the proceeds of the Public Offer. As at 31 December 2018, the line of credit was not drawn or utilised.

b. Exchange Agreement – the acquisition of 100% of the issued share capital in Koligo by the Company in consideration of the issue of 75,000,000 Shares and 25,000,000 Performance Shares in the Company to the existing members of Koligo. The terms of the Exchange Agreement are set out in Section 12.1.

c. The net impact of the proposed capital raising under the Public Offer and Options and Performance Shares issued by the Company. These include the following:

i. a minimum subscription of AUD$6,000,000 (30,000,000 Shares at AUD$0.20 each) under the Public Offer, and the full oversubscription of AUD$7,000,000 (35,000,000 Shares at AUD$0.20 each) under the Public Offer respectively;

ii. payment to the Joint Lead Managers and Brentridge Capital Pty Ltd of a transaction success fee fixed at AUD$200,000 (exclusive of GST);

iii. payment to the Joint Lead Managers and Brentridge Capital Pty Ltd of a management
fee equal to 1% of the amount raised under the Public Offer, and a selling fee equal to 5% raised under the Public Offer. Both fees are exclusive of GST. This amounts to AUD$360,000 (Minimum subscription) and AUD$420,000 (Oversubscription) respectively (refer to Sections 12.2 and 12.3);

iv Options equalling 2.5% of the number of Shares on issue after completion of the Offers will be issued to each Joint Lead Manager on the terms and conditions set out in Section 13.4 (as remuneration for services). The Joint Lead Manager Options have an exercise price of AUD$0.30 each within 36 months of the issue date. The Joint Lead Manager Options have been valued at AUD$348,285 (Minimum subscription) and AUD$364,870 (Oversubscription) or approximately AUD$0.06634 per Option using the Black-Scholes model utilising inputs that are relevant at the date of this Prospectus. However, in line with the Australian accounting standards, an option’s value can only be measured using inputs relevant at the time of the option’s issue. As such, this value is purely indicative and may change at the date the Company is admitted to the Official List; and

v 11,071,023 Options to be issued to Directors, Management and a Medical Advisory Consultant (as remuneration for services). The Options have an exercise price of AUD$0.30 each with differing exercise and vesting dates (refer to Sections 3.12 and 3.20). Collectively the Options have been valued at AUD$630,612 using the Black-Scholes model utilising inputs that are relevant at the date of this Prospectus. However, in line with the Australian accounting standards, an option’s value can only be measured using inputs relevant at the time of the option’s issue. As such, this value is purely indicative and may change at the date the Company is admitted to the Official List.

9.4.4 Pro forma cash reconciliation

The table below details the reconciliation of the pro forma cash balance of Koligo as at 31 December 2018, reflecting the actual cash at bank at the date and reflecting the impact of the pro forma adjustments as set out in Section 9.4.3.

<table>
<thead>
<tr>
<th>CASH RECONCILIATION</th>
<th>MINIMUM SUBSCRIPTION (AUD$)</th>
<th>FULL SUBSCRIPTION (AUD$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash as at 31 December 2018</td>
<td>10,253</td>
<td>10,253</td>
</tr>
<tr>
<td>Capital raising</td>
<td>6,000,000</td>
<td>7,000,000</td>
</tr>
<tr>
<td>Remaining drawdown of loan</td>
<td>275,034</td>
<td>275,034</td>
</tr>
<tr>
<td>Repayment of Loan</td>
<td>(371,023)</td>
<td>(371,023)</td>
</tr>
<tr>
<td>Expenses of offer</td>
<td>(1,200,536)</td>
<td>(1,261,909)</td>
</tr>
<tr>
<td>Pro forma cash balance</td>
<td>4,713,728</td>
<td>5,652,355</td>
</tr>
</tbody>
</table>

9.4.5 Pro forma issued capital reconciliation

The table below details the reconciliation of the pro forma issued capital balance of Koligo as at 31 December 2018, reflecting the actual issued capital balance at the date and reflecting the impact of the pro forma adjustments as set out in Section 9.4.3.

<table>
<thead>
<tr>
<th>ISSUED CAPITAL RECONCILIATION</th>
<th>MINIMUM SUBSCRIPTION (AUD$)</th>
<th>FULL SUBSCRIPTION (AUD$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issued capital balance as at 31 December 2018</td>
<td>2,873,130</td>
<td>2,873,130</td>
</tr>
<tr>
<td>Subscription of new capital</td>
<td>6,000,000</td>
<td>7,000,000</td>
</tr>
<tr>
<td>Lead manager options granted</td>
<td>(348,285)</td>
<td>(364,870)</td>
</tr>
<tr>
<td>Pro forma issued capital balance</td>
<td>8,524,845</td>
<td>9,508,260</td>
</tr>
</tbody>
</table>
9.4.6 Pro forma retained earnings reconciliation

The table below details the reconciliation of the pro forma retained earnings balance of Koligo as at 31 December 2018, reflecting the actual retained earnings balance at the date and reflecting the impact of the pro forma adjustments as set out in Section 9.4.3.

Table 9.4.6 - Pro forma retained earnings reconciliation

<table>
<thead>
<tr>
<th>RETAINED EARNINGS RECONCILIATION</th>
<th>MINIMUM SUBSCRIPTION (AUD$)</th>
<th>FULL SUBSCRIPTION (AUD$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retained earnings balance at 31 December 2018</td>
<td>(3,095,125)</td>
<td>(3,095,125)</td>
</tr>
<tr>
<td>Options expense / valuation</td>
<td>(630,612)</td>
<td>(630,612)</td>
</tr>
<tr>
<td>Expenses of the Offer (P&amp;L portion)</td>
<td>(1,200,536)</td>
<td>(1,261,909)</td>
</tr>
<tr>
<td>Consolidation adjustment - Due from affiliate &amp; Loans</td>
<td>(73,323)</td>
<td>(73,323)</td>
</tr>
<tr>
<td>Pro forma retained earnings balance</td>
<td>(4,999,596)</td>
<td>(5,060,969)</td>
</tr>
</tbody>
</table>

9.5 Statutory Historical Statements of Cash Flows

9.5.1 Overview

The table below sets out the Statutory Historical Statements of Cash Flows of Koligo for FY2017 and FY2018. The Statutory Historical Statements of Cash Flows are in USD$, with a translation of the figures to AUD$ as illustrated in the table below.

Table 9.5.1 - Historical Statements of Cash Flows

<table>
<thead>
<tr>
<th>Cash flows from operating activities</th>
<th>31-DEC-17 $USD</th>
<th>31-DEC-18 $USD</th>
<th>31-DEC-17 AUD$</th>
<th>31-DEC-18 AUD$</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBITDA</td>
<td>(97,624)</td>
<td>(1,425,250)</td>
<td>(127,321)</td>
<td>(1,906,060)</td>
</tr>
<tr>
<td>Movement in working capital</td>
<td>95,572</td>
<td>144,897</td>
<td>124,645</td>
<td>193,778</td>
</tr>
<tr>
<td>Net cash inflow/(outflow) from operating activities</td>
<td>(2,052)</td>
<td>(1,280,353)</td>
<td>(2,676)</td>
<td>(1,712,282)</td>
</tr>
</tbody>
</table>

Cashflows from investing activities

| Payments for the purchase of property and equipment | - | (12,500) | - | (16,717) |
| Payments for the purchase of other assets | - | - | - | - |
| Net cash inflow/(outflow) from investing activities | - | (12,500) | - | (16,717) |

Cashflows from financing activities

| Proceeds from issue of debt instruments | 4,905 | 1,300,000 | 6,397 | 1,738,557 |
| interest expense | - | (56) | - | (75) |
| Deferred financing costs | - | (2,725) | - | (3,644) |
| Net cash inflow/(outflow) from financing activities | 4,905 | 1,297,219 | 6,397 | 1,734,838 |

Net increase / (decrease) in cash and cash equivalents

| Net increase / (decrease) in cash and cash equivalents | 2,853 | 4,366 | 3,721 | 5,839 |
| Increase / (decrease) on FX rate differences/translation | - | - | (73) | 766 |
| Cash and cash equivalents at the beginning of the period | - | 2,853 | - | 3,648 |
| Cash and cash equivalents at the end of the period | 2,853 | 7,219 | 3,648 | 10,253 |
9.6 Summary of Significant Accounting Policies

The significant accounting policies set out below are those applied by Koligo over the Historical period reviewed and will be applied by the Company going forward in all material respects.

9.6.1 Use of estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. On an ongoing basis, management evaluates estimates, assumptions and judgments, including those related to accrued expenses. Actual results could differ from those estimates.

9.6.2 Revenue Recognition

Koligo’s revenue is derived principally from the sale of products and performance of services to hospitals. Revenue is earned and recognised when product and services are received by the customer. In limited circumstances, Koligo has agreed to provide products and services in return for specific promotional and marketing services performed by its customers and recognised as revenue based upon fair value of services rendered.

9.6.3 Cash and Cash Equivalents

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

9.6.4 Research and Development

Koligo expenses Research and Development (R&D) costs as incurred. To date, R&D efforts have focused on Kyslecel™ version 2.0 which is expected to have extended shelf life over the current version.

9.6.5 Accounts Receivable

Account receivables are recognised at original invoiced amount / fair value, less provisions for impairment. The provision includes amounts that are not considered to be recoverable from debtors. Collectability of receivables is reviewed on an ongoing basis. A provision for impairment of accounts receivables is established when there is objective evidence that Koligo will not be able to collect all amounts due according to the original terms of the receivables.

9.6.6 Accounts Payable

Trade and other payables represent the liabilities for goods and services received by Koligo that remain unpaid at the end of the reporting period. The balance is recognised as a current liability.

9.6.7 Credit risk

Koligo’s assets that are exposed to a concentration of credit risk consist primarily of cash and accounts receivable. Koligo’s cash balances may at times exceed Federal Deposit Insurance Corporation (FDIC) limits. Cash balances are maintained at high-credit quality financial institutions. Koligo believes the credit risk related to these cash balances is minimal. Accounts receivable consists primarily of amounts due from hospitals. Historically, Koligo has not experienced significant losses related to accounts receivable and therefore believes the credit risk related to these accounts is minimal.

9.6.8 Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid upon transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. The fair value should be calculated based on assumptions that market participants would use in pricing the asset or liability, not on assumptions specific to the entity. In addition, the fair value of liabilities should include consideration of non-performance risk including Koligo’s own credit risk.

Koligo follows ASC Topic 820, Fair Value Measurements and Disclosures, or ASC 820, for application to financial assets. In addition to defining fair value, the standard expands the disclosure requirements around fair value and establishes a fair value hierarchy for valuation inputs. The hierarchy prioritises the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of the three levels which are determined by the lowest level input that is significant to the fair value measurement in its entirety.
These levels are:

a. Level 1: Observable inputs such as quoted prices in active markets for identical assets the reporting entity has the ability to access as of the measurement date;

b. Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

c. Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The assumptions, assessments and projections utilised in determining fair value are subject to uncertainties and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to the Company's financial statements.

9.6.9 Principles of Consolidation

The consolidated statements incorporate the assets and liabilities of all subsidiaries of the Company and the results of all subsidiaries for each applicable period then ended.

The subsidiaries are all entities over which the Company has the power to govern the financial and operating policies of those subsidiaries. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are de-consolidated from the date control ceases. The acquisition method of accounting is used to account for business combinations made by the Company.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Company.

Investments in subsidiaries are accounted for at cost in the individual financial statements of the investing entity.

9.6.10 Foreign Currency Transactions and Balances

The functional currency of Koligo is measured using the currency of the primary economic environment in which that entity operates. The consolidated financial statements of the Company are presented in Australian dollars, and the financial statements of Koligo are presented in USD, which are the respective entities’ presentation and functional currency. The Pro Forma Consolidated Statement of Financial Position has been presented in Australian dollars using the exchange rate prevailing at the reporting date, i.e. 31 December 2018.

The financial results and position of Koligo’s operations whose functional currency is different from the Company’s presentation currency is translated as follows:

a. assets and liabilities are translated at year or other period end exchange rates prevailing at the reporting date.

b. income and expenses are translated on the average exchange rate for the related period i.e. the average exchange rate from 1 January to 31 December 2018 has been used to translate the income and expenses for the 12-month period ending 31 December 2018; the average exchange rate from 1 January 2017 to 31 December 2017 has been used to translate the income and expenses for the year ended 31 December 2017.

c. retained earnings are the sum of all prior year profits or losses as translated applying the average exchange rate over the relevant period.

d. issued capital is translated applying the actual exchange rate on the date of each new issue.

e. exchange differences arising on the translation of Koligo’s operations are transferred directly to the Company’s foreign currency translation reserve in the Statement of Financial Position.

9.7 Reconciliation between US GAAP and AIFRS

The Directors have performed a review of the different recognition and measurement treatments between the application of US GAAP and AIFRS in the preparation of Koligo’s audited financial statements for the FY2018, which is also the basis of the Pro Forma Statement of Financial Position in section 9.4. Following this review the Directors have not identified any material differences in the value or presentation of assets and liabilities recognised in the Pro Forma Statement of Financial Position, nor in the value of the net profit disclosed for FY2017 and FY2018.

9.8 Liquidity and capital resources

Following the completion of the Offers, the Company’s principal source of funds will be cash flow from operations and proceeds from the Public Offer.
9.9 Dividend Policy

Depending on available profits and the financial position of the Company, it is not the current intention of the Board to declare dividends in respect of the year ending 31 December 2018. The payment of a dividend by the Company is at the discretion of the Directors and will depend on the availability of distributable earnings and operating results and financial condition of the Company, future capital requirements and general business and other factors considered relevant by the Directors.

No assurance in relation to the payment of dividends or franking credits attaching to dividends can be given by the Company.

Please read the risk factors set out in Sections 3.7 and 7.
7 February 2019

Board of Directors
Koligo Therapeutics Limited
Level 5, 126 Phillip Street
SYDNEY NSW 2000

Dear Sirs,

INDEPENDENT LIMITED ASSURANCE REPORT ON KOLIGO THERAPEUTICS LIMITED’S HISTORICAL AND PRO FORMA HISTORICAL FINANCIAL INFORMATION

Introduction

HLB Mann Judd Corporate (NSW) Pty Ltd (“HLBMJC”) has been engaged by Koligo Therapeutics Limited (“the “Company”) to prepare this report for inclusion in the prospectus to be dated on or around 6 February 2019 (“Prospectus”), and to be issued by the Company in respect of the initial public offering of shares in the Company (the “Public Offer”) and the listing on the Australian Securities Exchange.

It is proposed that the Company, will simultaneously acquire the issued shares in Koligo Therapeutics, Inc. (“Koligo”) upon completion of the Public Offer.

HLB Mann Judd Corporate (NSW) Pty Ltd holds the appropriate Australian Financial Services licence (AFSL: 253134) under the Corporations Act 2001 for the issue of this report.

Expressions defined in the Prospectus have the same meaning in this report.

Scope

Historical Financial Information

HLBMJC has been requested to review the following historical financial information of Koligo included in the Prospectus:

- Historical Statements of Comprehensive Income for the years ended 31 December 2017 and 2018;
- Historical Statements of Cash Flows for the years ended 31 December 2017 and 2018;
- Historical Statement of Financial Position as at 31 December 2017 and 31 December 2018;

Collectively the “Historical Financial Information”.

hlb.com.au

HLB Mann Judd Corporate (NSW) Pty Ltd ABN 94 003 918 125 AFSL 253134
Level 19, 207 Kent Street Sydney NSW 2000 Australia
T: +61 (0)2 9020 4000  F: +61 (0)2 9020 4950  E: mailbox@hlbnsw.com.au
The Historical Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in Generally Accepted Accounting Principles (United States) (“US GAAP”) and the Company’s adopted accounting policies.

The Historical Financial Information has been extracted from the financial report of Koligo for the years ended 31 December 2017 and 2018, which have been audited by CohnReznick LLP (“CohnReznick”) in accordance with US GAAP. CohnReznick issued an unqualified audit opinion on the financial report for the year ended 31 December 2017 and 31 December 2018.

Pro Forma Historical Financial Information

HLBMJC has been requested to perform limited assurance procedures in relation to the Pro Forma Historical Financial Information of the Company (the responsible party) included in the Prospectus.

The Pro Forma Historical Financial Information consists of the statement of financial position of Koligo as at 31 December 2018, adjusting for the impact of the Historical Statement of Financial Position of the Company, the Public Offer and other significant transactions and events, and related notes as set out in sections 9.4.3 of the Prospectus (collectively the “Pro Forma Historical Financial Information”).

The Pro Forma Historical Financial Information has been derived from the Historical Financial Information of Koligo, after adjusting for the effects of pro forma adjustments described in sections 9.4.3 of the Prospectus.

The stated basis of preparation is the recognition and measurement principles contained in Australian Accounting Standards applied to the historical financial information and the event(s) or transaction(s) to which the pro forma adjustments relate, as described in section 9.2 of the Prospectus. Due to its nature, the Pro Forma Historical Financial Information does not represent the Company’s actual or prospective financial position.

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 US GAAP or Australian Accounting Standards and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act 2001.

Our limited assurance engagement has not been carried out in accordance with auditing or other standards and practices generally accepted outside of Australia and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

Directors’ responsibilities

The directors of the Company and Koligo are responsible for:

- the preparation of the Historical Financial Information and Pro Forma Historical Financial Information, including the selection and determination of the pro forma transactions and/or adjustments made to the Historical Financial Information and included in the Pro Forma Historical Information; and
- the information contained in the Prospectus.

The directors’ responsibility includes establishing and maintaining such internal controls as the directors determine are necessary to enable the preparation of the Historical Financial Information and the Pro Forma Historical Financial Information that is free from material misstatement, whether due to fraud or error.
Our responsibility

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

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

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

Conclusions

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 section 9.3.1, section 9.5.1, and section 9.4.1 of the Prospectus, and comprising:

- The Historical Statements of Comprehensive Income of Koligo for the years ended 31 December 2017 and 2018;
- The Historical Statements of Cash Flows of Koligo for the years ended 31 December 2017 and 2018; and

are not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in section 9.2 of the Prospectus.

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 being the pro forma historical statement of financial position of the Company as at 31 December 2018 is not presented fairly in all material respects, in accordance with the stated basis of preparation as described in section 9.2 of the Prospectus.

Independence

HLBMJC does not have any interest in the outcome of the proposed initial public offering, other than in connection with the preparation of this report and participation in due diligence procedures for which normal professional fees will be received. From time to time, HLB Mann Judd also provides Koligo with certain other professional services for which normal professional fees are received.

General advice warning

This report has been prepared, and included in the Prospectus, to provide investors with general information only and does not take into account the objectives, financial situation or needs of any specific investor. It is not intended to take the place of professional advice and investors should not make specific investment decisions in reliance on the information contained in this report. Before acting or relying on any information, an investor should consider whether it is appropriate for their circumstances having regard to their objectives, financial situation or needs.
Restriction on use

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

Consent

HLBMJC has consented to the inclusion of this Independent Limited Assurance Report in the Prospectus in the form and context in which it is so included, but has not authorised the issue of the Prospectus. Accordingly, HLBMJC makes no representation regarding, and takes no responsibility for, any other statements, or material in, or omissions from, the Prospectus.

Yours faithfully

Nicholas Guest
Director and Authorised Representative
Financial Service Guide

Dated 7 February 2019

1. HLB Mann Judd Corporate (NSW) Pty Ltd
   HLB Mann Judd Corporate (NSW) Pty Ltd ABN 94 003 918 125 (“HMJC” or “we” or “us” or “our” as appropriate) has been engaged to issue general financial product advice in the form of a Report to be provided to you.

2. 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 a 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, No. 253134;
   - 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 complaints handling procedures and how you may access them.

3. Financial services we are licensed to provide
   We hold an Australian Financial Services Licence which authorises us to provide reports for the purposes of acting for and on behalf of clients in relation to proposed or actual mergers, acquisitions, takeovers, corporate restructures or share issues, securities valuations or reports and to provide general financial product advice for the following classes of financial products:
   (i) debentures, stocks or bonds issued or proposed to be issued by a government;
   (ii) interests in managed investment schemes excluding investor directed portfolio services;
   (iii) securities; and
   (iv) superannuation;
   to retail and wholesale clients
   We provide financial product advice by virtue of an engagement to issue a report in connection with a financial product of another person. Our report will include a description of the circumstances of our engagement and identify the person who has engaged us. You will not have engaged us directly but will be provided with a copy of the report as a retail client because of your connection to the matters in respect of which we have been engaged to report. Any report we provide is provided on our own behalf as a financial services licensee authorised to provide the financial product advice contained in the report.

4. General financial product advice
   In our report we provide general financial product advice, not personal financial product advice, because it has been prepared for the shareholder group as a whole without taking 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. Where the advice relates to the acquisition or possible acquisition of a financial product and there is no statutory exemption relating to the matter, you should also obtain a product disclosure statement relating to the product and consider that statement before making any decision about whether to acquire the product.
5. Benefits that we may receive
We charge fees for providing reports. These fees will be agreed with, and paid by, the person who engages us to provide the report. Fees will be agreed on either a fixed fee or time cost basis. Except for the fees referred to above, neither HMJC, 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.

6. Remuneration or other benefits received by us
HMJC has no employees. All personnel who complete reports for HMJC are either partners of, or personnel employed by, HLB Mann Judd’s New South Wales Partnership. None of those partners or personnel is eligible for bonuses directly in connection with any engagement for the provision of a report.

7. 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.

8. Associations and relationships
HMJC is wholly owned by HLB Mann Judd (NSW) Pty Limited. Also, all directors of HMJC are partners in HLB Mann Judd’s New South Wales Partnership. Ultimately the partners of HLB Mann Judd’s New South Wales Partnership own and control HMJC. From time to time HMJC, HLB Mann Judd (NSW) Pty Ltd or HLB Mann Judd’s New South Wales Partnership may provide professional services, including audit, tax and financial advisory services, to financial product issuers in the ordinary course of their business.

9. Complaints resolution
9.1. Internal complaints resolution process
As the holder of an Australian Financial Services Licence, we are required to have a system for handling complaints from persons to whom we provide financial product advice. Complaints must be in writing, addressed to The Complaints Officer, HLB Mann Judd Corporate (NSW) Pty Ltd, Level 19, 207 Kent Street NSW 2000. When we receive a written complaint we will record the complaint, acknowledge receipt of the complaint within 7 days and investigate the issues raised. As soon as practical, and not more than one month after receiving the written complaint, we will advise the complainant in writing of the determination.

9.2. Referral to external disputes 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 is an independent company that has been established to provide free advice and assistance to consumers to help in resolving complaints relating to the financial services industry. Further details about AFCA are available at the AFCA website www.afca.org.au or by contacting them directly via the details set out below.

Australian Financial Complaints Authority
GPO Box 3, Melbourne VIC 3001
Toll free: 1800 931 678
Facsimile: (03) 9613 6399

10. Contact details
You may contact us using the details at the foot of page 1 of this FSG.
February 20, 2019

The Board of Directors
Koligo Therapeutics Limited
Level 5
126 Phillip Street
Sydney, NSW 2000
Australia

Re: Koligo Therapeutics, Inc. Compliance with U.S. Food and Drug Administration Regulations for KYSLECEL™

This report regarding the compliance of KYSLECEL™ with regulations administered by the U.S. Food and Drug Administration (“USFDA”) (hereinafter “Report”) has been prepared at the request of the Directors of Koligo Therapeutics Limited (the “Company”), a public company registered in Australia which has agreed to acquire the entire stock in Koligo Therapeutics, Inc. (“Koligo”), located in Louisville, Kentucky. This Report summarizes the current USFDA compliance status of Koligo’s product KYSLECEL, consisting of autologous pancreatic islet cells. This Report is for inclusion in an IPO Prospectus (“Prospectus”) to be lodged by the Company at the Australian Securities & Investments Commission for the purpose of raising funds through the issue of securities and listing on the Australian Securities Exchange Limited.

Section I provides an overview of the regulatory framework for cell and tissue products in the U.S. It is meant to provide a high-level summary of the applicable U.S. regulatory framework, and should not be interpreted as providing a comprehensive description of USFDA law in general or the regulatory framework for products such as KYSLECEL in particular.

Section II provides responses to six specific questions posed by the Directors regarding regulation of KYSLECEL in the U.S.

Section III provides limitations and qualifications regarding the contents of, and conclusions reached in, this Report.

The information in this Report is considered current as of January 22, 2019.
I. REGULATION OF CELLS AND TISSUES IN THE U.S.

A. General Regulatory Framework

KYSLECEL is regulated in the U.S. as a “human cell, tissue, or cellular and tissue-based product” (“HCT/P”). HCT/Ps are defined as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.”¹ USFDA regulates these products under the authority of the Federal Food, Drug, and Cosmetic Act (“FFDCA”), the Public Health Service Act (“PHS Act”), and the implementing regulations at 21 C.F.R. Part 1271.²

USFDA regulates HCT/Ps using a risk-based framework that is focused on the likelihood that the HCT/P will transmit a communicable disease from one individual to another. Depending upon this communicable disease risk, HCT/Ps may (1) be exempt from USFDA oversight³ (“exempt HCT/Ps”); (2) be subject to limited regulation under PHS Act § 361 and specific HCT/P regulations⁴ (“361 HCT/Ps”); or (3) require USFDA pre-approval of a marketing application (typically a biologics license application (“BLA”)) and be subject to regulation under PHS Act § 351 and § 361, the FFDCA, and applicable regulations for HCT/Ps, biologics, and drugs⁵ (“351 HCT/Ps”).

In addition to these statutory and regulatory requirements, several other USFDA materials provide guidance regarding USFDA’s interpretation of the relevant HCT/P laws and how USFDA will apply those laws in certain situations. These include, but are not limited to, draft and final guidance documents, warning letters, and other enforcement actions undertaken by USFDA or another U.S. federal agency. State laws and regulations may apply as well.

B. Establishment Registration and HCT/P Product Listing

The sponsor of a 361 HCT/P or 351 HCT/P must register any establishment⁶ that manufactures⁷ an HCT/P. This registration must be accomplished within five days after

¹ 21 C.F.R. § 1271.3(d).
² Note that 21 C.F.R. Part 1270 (“Human Tissue Intended for Transplantation”) does not apply to autologous human tissue. 21 C.F.R. § 1270.1(c).
³ 21 C.F.R. § 1271.15. Note that, in one of these six exemptions, a company is subject to certain limited Part 1271 provisions. See 21 C.F.R. § 1271.15(f).
⁴ 21 C.F.R. § 1271.10.
⁵ 21 C.F.R. § 1271.20.
⁶ “Establishment” is a place of business under one management at one physical location that engages in HCT/P manufacture. It includes an individual, partnership, corporation, association, or other legal entity, as well as facilities that engage in contract manufacturing activities for an HCT/P manufacturer. 21 C.F.R. § 1271.3(b).
⁷ “Manufacture” includes (but is not limited to) any or all steps in recovering, processing, storing, labeling, packaging, or distributing an HCT/P, as well as the screening or testing of a cell or tissue donor. 21 C.F.R. § 1271.3(e).
⁸ “Recovery” is obtaining cells or tissues from a human donor intended for use in human implantation,
The Board of Directors
Koligo Therapeutics Limited
February 20, 2019
Page 3 of 11

beginning operations and must include the establishment’s legal name and physical location; the 
contact information for the reporting official at that establishment; and a dated signature of the 
reporting official affirming the truth and accuracy of the information in the establishment 
registration. If applicable, a foreign (ex-U.S.) establishment must also submit the contact 
information for each importer known to the establishment that imports or offers for import the 
HCT/P, and must include the name and relevant contact information for a U.S.-based agent.

Likewise, the sponsor of any 361 HCT/P or 351 HCT/P must submit a list of all HCT/Ps 
manufactured by the establishment within five days after beginning operations. The listing 
information must include all HCT/Ps (both established and proprietary names) that the sponsor 
reCOVERs, processes, stores, labels, packages, or distributes, and for which the sponsor performs 
donor screening and testing. The listing must also state whether the particular HCT/P(s) being 
listed meets the criteria set forth in 21 C.F.R. § 1271.10 (i.e., whether it is a 361 HCT/P).

USFDA will assign a permanent registration number to each establishment and will make 
this establishment registration information, along with the listing of the sponsor’s HCT/Ps, 
available on USFDA’s website.

Establishment registrations are required to be updated in December. If the 
establishment’s location or ownership changes, or if there is a change to the U.S. agent’s contact 
information, then a registration amendment must be submitted within thirty calendar days of the 
change.

If there are no changes to a sponsor’s HCT/P listings, then no listing update is required. If 
the list of HCT/Ps does change, then the list must be updated either at the time of the change, 
or each June or December (whichever month occurs first following the change). A listing

transplantation, infusion, or transfer. 21 C.F.R. § 1271.3(ii). “Processing” includes actions other than recovery, 
donor screening, donor testing, storage, labeling, packaging, or distribution. 21 C.F.R. § 1271.3(ff). “Storage” is 
the holding of HCT/Ps for future processing and/or distribution. 21 C.F.R. § 1271.3(jj). “Distribution” is any 
conveyance or shipment (including import/export) of an HCT/P that meets all release criteria; if the entity does not 
take physical possession of the HCT/P, then the entity is not a distributor. 21 C.F.R. § 1271.3(bb).

8 21 C.F.R. § 1271.21(a).
9 21 C.F.R. § 1271.25(a)(1)-(4).
10 21 C.F.R. § 1271.25(a)(5)-(6). A “U.S. agent” is a person who resides or maintains a place of business in the 
U.S. who is designated by a foreign establishment as its agent. It does not include mailboxes, answering machines 
or services, or other location where the agent is not physically present. 21 C.F.R. § 1271.3(nn).
11 21 C.F.R. § 1271.21(a).
12 21 C.F.R. § 1271.25(b).
13 21 C.F.R. §§ 1271.27, 1271.37.
14 21 C.F.R. § 1271.21(b).
16 21 C.F.R. § 1271.21(c)(i).
17 21 C.F.R. § 1271.21(c)(ii).
update for HCT/Ps must include (1) all HCT/Ps for which manufacturing, or donor screening or testing, has begun but that were not listed previously; (2) all HCT/Ps for which manufacturing, or donor screening or testing, has been discontinued; (3) all HCT/Ps for which manufacturing, or donor screening or testing, was once discontinued but has since been resumed; and (4) any material change in any information previously submitted.\textsuperscript{18} (The sponsor of a 351 HCT/P that requires USFDA pre-approval must also follow the drug establishment and listing requirements under 21 C.F.R. Part 207.\textsuperscript{19})

As discussed below, the regulation of KYSLECEL as a 361 HCT/P is consistent with FDA regulations and guidelines.

II. RESPONSES TO THE DIRECTORS’ QUESTIONS

This section contains the Directors’ six questions and our responses.

A. Question 1: How is KYSLECEL regulated in the U.S.?

We previously concluded that Koligo’s determination that KYSLECEL is regulated in the U.S. as a 361 HCT/P that does not require USFDA pre-approval for marketing is consistent with our interpretation of how the available FDA guidelines would be applied. This conclusion was reached during due diligence that we conducted from December 2017 to March 2018 for an investment involving Koligo (“Investment Project”). Our due diligence consisted of a review of documents provided by Koligo that would be customary for establishing the U.S. regulatory treatment of KYSLECEL, including information about KYSLECEL production; communications with vendors that supply Koligo with various items used during KYSLECEL production; and communications with individuals at Koligo. We reviewed the information gathered in due diligence and applied it to the HCT/P regulatory structure enforced by USFDA concluding, based upon our professional experience and judgment, that KYSLECEL’s regulation in the U.S. as a 361 HCT/P that does not require USFDA pre-approval for marketing—not an exempt HCT/P and not a 351 HCT/P—is consistent with our interpretation of how the available FDA guidelines would be applied.

Specifically, we reached that conclusion because the due diligence we reviewed regarding KYSLECEL was consistent with each of the four required criteria the USFDA has provided as necessary to be regulated as a 361 HCT/P. If, however, the USFDA would determine that any one of these criteria is not met, then the product would be deemed to be a 351 HCT/P that requires USFDA pre-approval. The four-pronged test which will be applied by the USFDA to determine if KYSLECEL is a 361 HCT/P is:

\textsuperscript{18} 21 C.F.R. § 1271.25(c)(1)-(4).
\textsuperscript{19} 21 C.F.R. § 1271.25(d).
The Board of Directors
Koligo Therapeutics Limited
February 20, 2019
Page 5 of 11

1. The HCT/P is “minimally manipulated”\(^\text{20}\);

2. The HCT/P is only intended for homologous use\(^\text{21}\) (as reflected by the manufacturer’s objective intent);

3. The manufacture does not involve combining the cells or tissues with another article (except for water; crystalloids;\(^\text{22}\) or a sterilizing, preserving, or storage agent—provided the addition does not raise new clinical safety concerns for the HCT/P); and

4. Either the HCT/P does not have a systemic effect and is not dependent on the metabolic activity of living cells for its primary function; or the HCT/P has a systemic effect or is dependent on the metabolic activity of living cells for its primary function, and (i) it is for autologous use;\(^\text{23}\) (ii) it is for allogeneic use in a first- or second-degree blood relative; or (iii) is for reproductive use.

Based upon our review of the due diligence we conducted during the Investment Project, we concluded that the information we gathered on KYSLECEL was consistent with all four of these criteria that the USFDA would apply to determine if KYSLECEL is to be regulated as a 361 HCT/P. Accordingly, we concluded for purposes of the Investment Project that Koligo must comply with certain regulations within 21 C.F.R. Part 1271, but that no USFDA pre-approval was required.

The conclusion in this Report that the USFDA would consider KYSLECEL a 361 HCT/P is based upon our due diligence conducted for the Investment Project and our professional judgment as to how the USFDA is likely to interpret its four pronged test. As conveyed to us on January 22, 2019 by Mr. Matt Lehman, Chief Executive Officer and Executive Director of Koligo, Koligo has confirmed that no changes to the KYSLECEL production process have been made since our analysis for the Investment Project. Based on this Koligo representation, we continue to conclude for purposes of this Report that regulation of KYSLECEL is consistent with the criteria for a 361 HCT/P.

\(^{20}\) In the case of structural tissue, “minimal manipulation” is processing that does not alter the original relevant characteristics of the tissue’s utility for reconstruction, repair, or replacement. For cells or non-structural tissue, “minimal manipulation” is processing that does not alter the relevant biological characteristics of the cells or tissue. 21 C.F.R. § 1271.3(f).

\(^{21}\) “Homologous use" is the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P performing the same basic function(s) in the recipient as it did in the donor. 21 C.F.R. § 1271.3(c).

\(^{22}\) “Crystalloid” is an isotonic salt and/or glucose solution for electrolyte replacement or to increase intravascular volume (e.g., saline solution; Ringer’s lactate solution; or 5% dextrose in water). 21 C.F.R. § 1271.3(k).

\(^{23}\) “Autologous use” is the implantation, transplantation, infusion, or transfer of human cells or tissues into the same individual from whom they were recovered. 21 C.F.R. § 1271.3(a). In this case, KYSLECEL has a systemic effect or is dependent on the metabolic activity of living cells for its primary function, and it is for autologous use.
Within 21 C.F.R. Part 1271, there are a number of specific regulations with which Koligo and KYSLECEL must comply, including the following:

- Subpart B—Procedures for Registration and Listing (21 C.F.R. § 1271.21-§ 1271.37)
- Subpart D—Current Good Tissue Practice (21 C.F.R. § 1271.145-§ 1271.320)
- Subpart E—Additional Requirements for Establishments Described in § 1271.10 (21 C.F.R. § 1271.330-§ 1271.370) (these additional requirements pertain to reporting adverse events and HCT/P deviations, as well as labeling)
- Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10 (21 C.F.R. § 1271.390-§ 1271.440)

These are operational requirements that Koligo management must ensure it follows. A USFDA inspection of Koligo’s facilities would, as noted below, assess Koligo and KYSLECEL compliance with these regulatory requirements.

B. **Question 2**: Is Koligo registered appropriately with USFDA?

Yes. Koligo is currently registered with USFDA. The screen shots below, taken from USFDA’s website on January 22, 2019, confirms this fact.
As seen above, Koligo has identified its establishment functions as packaging, processing, storing, labeling, and distributing autologous pancreatic islet cells.

Furthermore, as shown below, Koligo has listed its KYSLECEL product with USFDA as an HCT/P “Described in 21 CFR 1271.10.” As noted previously, 21 C.F.R. § 1271.10 describes 361 HCT/Ps. Therefore, this statement is accurate and is consistent with our conclusion that KYSLECEL is a 361 HCT/P that does not require USFDA pre-approval.
C. **Question 3:** What is the scope of the Koligo registration and what does that registration permit Koligo to do?

361 HCT/Ps are not pre-approved by USFDA prior to marketing. As a result, sponsors do not obtain an official USFDA determination in advance of marketing that the sponsor’s conclusion about the 361 HCT/P status of its product is correct. The sponsor also does not receive any notification from USFDA in advance of product production that the 361 HCT/P manufacturing facility is legally compliant.

The Koligo establishment registration permits Koligo to undertake those activities with its HCT/P that it identified on the registration form—namely, packaging, processing, storing, labeling, and distribution of KYSLECEL. Registration does not signify that USFDA has determined that the establishment is in compliance with the applicable laws and regulations, and does not denote that the HCT/P is licensed or approved by USFDA.24

Registration provides USFDA with the information needed to facilitate an establishment inspection after manufacturing has already begun. These inspections, which encompass the practices and procedures that an establishment follows to produce an HCT/P, are not scheduled at regular intervals. When USFDA does arrive for an inspection, the establishment must permit USFDA to enter the premises and inspect the activities that take place there and the conditions in which they take place.25 An establishment inspection may result in USFDA issuing a list of observations of company practices that violate the statutes and/or regulations and require correction. If such violations are not corrected, then USFDA may take further enforcement action against a company, including but not limited to issuing a publicly-available warning letter.

D. **Question 4:** What is required to maintain and renew such registration and what conditions attach to the registration?

As noted above, Koligo must take the following steps to maintain its establishment registration and HCT/P listing:

- **Establishment registration**
  - Update in December of each year.
  - If the location or ownership changes, then submit a registration amendment within thirty calendar days of the change.

- **HCT/P listing**
  - If no change, then no update is required.
  - If there is a change, then update the list at the time of the change, or each June or December (whichever month occurs first following the change).

---

24 21 C.F.R. § 1271.27(b).
25 21 C.F.R. § 1271.400.
A registration is unique to each “establishment,” which is a place of business under one management at one physical location that manufactures HCT/Ps. An establishment can be an individual, partnership, corporation, association, or other legal entity, including a contract manufacturing organization.

E. **Question 5:** Will the acquisition of Koligo by the Company and subsequent Company IPO have any adverse effect on the Koligo registration with USFDA?

There is no expected adverse effect on the Koligo establishment registration or HCT/P listing with USFDA. Koligo will be required to notify USFDA of the change in its ownership. After speaking with an individual from USFDA who is involved with 361 HCT/P establishment registration (but without revealing the identity of Koligo or the Company), we were instructed that Koligo must take the following steps.

- During the annual establishment registration renewal dates (November 15-December 31), Koligo U.S. should indicate on the electronic renewal form (in the field named “additional information”) that there has been a change in ownership. If the ownership change occurs outside of this annual establishment registration renewal period, then Koligo must still complete its annual registration renewal, followed later by an update to the “additional information” field, as noted above, that the ownership has changed. Koligo appears to have completed its most recent annual registration renewal, as evidenced by the fact that the “Last Annual Registration Year” is listed as “2019,” as reflected in the screen shot in Question 2, above.

- In addition to this annual establishment registration renewal, Koligo should send USFDA an email within thirty calendar days of the ownership change (to tissueereg@USFDA.hhs.gov) that identifies the establishment name (Koligo), establishment number, the name of the new owner (the Company), and the effective date of the ownership change.

We note that because the establishment producing KYSLECEL (Koligo) is based in the U.S., there is no need to identify and report a U.S. agent to USFDA even though a foreign entity (the Company) will own Koligo.

F. **Question 6:** Does Koligo hold all required permits, registrations, and/or approvals required to operate its current business in the U.S.?

As set forth in Section III below, this Report only addresses USFDA-related matters. As noted, Koligo is a USFDA-registered establishment and has listed KYSLECEL with USFDA. As set forth above, we have concluded that KYSLECEL does not require a USFDA-approved application.
On an ongoing basis, Koligo management must continue to ensure that it complies with applicable USFDA (and state) laws and regulations, including the requirements of 21 C.F.R. Part 1271 as listed above.

III. LIMITATIONS AND QUALIFICATIONS OF THIS REPORT

This Report is limited by, subject to, and based on the following:

1. This Report is limited in all respects to our interpretation and application of U.S. food and drug laws as set forth in the FFDCA, the PHS Act, and the implementing regulations at 21 C.F.R. Part 1271. This Report does not address other U.S. laws except those listed above. We have not reviewed whether KYSLECEL meets the requirements of any U.S. state law, and this Report does not address any state law requirements or compliance. This Report does not address the legality of marketing KYSLECEL in Australia or any other non-U.S. country, whether under Australian or any other non-U.S. law.

2. Koligo management is responsible for ensuring ongoing compliance of its establishment, and of KYSLECEL, with all applicable U.S. federal and state laws. Failure to ensure compliance could result in, among other things, USFDA issuance of a public warning letter or a finding that KYSLECEL is adulterated and/or misbranded under applicable U.S. laws.

3. This Report only addresses KYSLECEL does not address the USFDA regulatory status of any other products that Koligo is developing or contemplating developing, including but not limited to those specifically identified in the Prospectus.

4. Application of USFDA’s HCT/P regulatory framework is highly fact-specific. The framework is also subject to ongoing change, including but not limited to USFDA’s issuance of draft and final guidance documents providing USFDA’s interpretation of its HCT/P regulations. Future changes to the KYSLECEL production process may change our conclusion that KYSLECEL is a 361 HCT/P. Even absent changes in the KYSLECEL production process, a change to the HCT/P regulatory framework, or USFDA’s interpretation of those regulations, may materially impact the future USFDA regulation of KYSLECEL.

5. Our determination that regulation of KYSLECEL as a 361 HCT/P is consistent with FDA criteria is informed by the information provided to us by Koligo and by applying our professional experience and judgment. We express no opinion as to the effect on this Report of any documents which we did not review.
6. This Report is not a guarantee or prediction of what FDA or a U.S. court of law would conclude or hold with respect to KYSLECEL regulation. USFDA may in the future disagree with our application of the 361 HCT/P criteria and the conclusion that KYSLECEL is regulated as a 361 HCT/P. USFDA may, among other things, determine in the future that KYSLECEL is a 351 HCT/P that requires USFDA approval of an application. If an application is required, then clinical trials and other testing would be required before KYSLECEL could continue to be marketed in the U.S.

7. Buchanan Ingersoll & Rooney PC is a U.S. law firm of approximately 425 attorneys and government relations professionals based in Pittsburgh, Pennsylvania. Buchanan Ingersoll & Rooney PC has seventeen offices in nine U.S. states and the District of Columbia. Members of the FDA & Biotechnology practice group are responsible for the preparation of this Report. The FDA & Biotechnology practice group provides legal counsel to clients on the laws and regulations related to the U.S. approval and marketing of products regulated by USFDA, including but not limited to HCT/Ps.

8. Buchanan Ingersoll & Rooney PC has no interest in Koligo or the Company, other than the receipt of fees for professional work done. Buchanan Ingersoll & Rooney PC has or expects to receive approximately $35,000 USD based on time spent at normal professional rates for the preparation of this Report.

9. The information in this Report is current as of January 22, 2019. Buchanan Ingersoll & Rooney PC assumes no obligation to update this Report based on future developments of law or fact or information that may come to the attention of Buchanan Ingersoll & Rooney PC at a future date.

10. Buchanan Ingersoll & Rooney PC has no involvement in the preparation of this Company’s Prospectus, other than the preparation of this Report. Buchanan Ingersoll & Rooney PC gives its consent for inclusion of this Report in the Prospectus.
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koliko Therapeutics Limited (ACN 627 117 677).
11. BOARD, MANAGEMENT AND CORPORATE GOVERNANCE

11.1 Directors and key personnel

MATTHEW LEHMAN
Chief Executive Officer and Executive Director

Mr. Lehman is currently Koligo’s Chief Executive Officer, which he has served as since its inception. Mr. Lehman previously served as interim Chief Executive Officer of M Pharmaceutical, Inc. (now Callitas Health Inc.), where he revamped the company’s technology pipeline. Prior to that, he was the CEO (and prior to that COO) of Prima Biomed Ltd, a dual-listed public company (ASX:PRR (now IMM) and NASDAQ:PBMD (now IMMP)) developing cellular immunotherapies for cancer. Earlier in his career, he was Chief Operating Officer of SPRI Clinical Trials, a global contract research organisation that, among other things, conducts clinical trials in various fields. Mr. Lehman holds a Masters of Science from Columbia University and a Bachelor of Arts from the University of Louisville.

PETER JAMES
Non-Executive Chairman

Mr. James has over 30 years’ experience in industries with emerging technologies, and has extensive experience as Chair, Non-Executive Director and Chief Executive Officer across a range of publicly listed and private companies. He is currently Chair of ASX-listed companies Macquarie Telecom Ltd, nearmap Ltd, Dreamscape Networks Ltd, DroneShield Limited, Keytone Dairy Corporation Limited and UUV Aquabotix Limited. Mr. James has recently completed 12 years as a Non-Executive Director for ASX-listed iiNet, Australia’s second largest DSL Internet Services Provider, chairing iiNet’s Strategy and Innovation Committee. iiNet was recently acquired by TPG Telecom for $1,560,000,000. He travels extensively reviewing innovation and consumer trends primarily in the U.S. and also Asia and he is a successful investor in a number of digital media, e-commerce and technology businesses in Australia and the U.S.

Dr. Stuart Williams
Chief Technology Officer (Koligo Therapeutics, Inc.) and Executive Director

Dr. Williams is an internationally recognised expert in research and development in the field of regenerative medicine. He is a Professor in the Department of Physiology and Biophysics at the University of Louisville, and is the Director of the University of Louisville’s Bioficial Organs Program, a program that he established in 2014. At the University of Louisville, he has led research into 3D bioprinting technology of tissue and organs. Dr. Williams has also served in a number of executive roles, including as the Executive and Scientific Director of the Cardiovascular Innovation Institute between 2007 and 2013. Prior to joining the University of Louisville in 2007, Dr. Williams held faculty positions at the University of Arizona, including Chair of Biomedical Engineering Program, a program he founded. He held faculty appointments at Jefferson Medical College where he was Director of...
Research in the Department of Surgery. He is a Fellow of the American Heart Association and Fellow of the American Institute of Medical and Biological Engineering. Dr. Williams holds a Ph.D. in Cell Biology from the University of Delaware and conducted postdoctoral training in Pathology at the Yale School of Management.

Mr. Marks has over 18 years’ experience in marketing. He is the co-founder and, for the recent 15 years, has been the Chief Executive Officer, of The Nile, one of Australia’s most established online retailers, and Mercury Retail, a leading Australian eCommerce service provider. Mr. Marks holds a Bachelor of Commerce with Honours from University of Auckland.

Mr. Clisdell began his career at Ernst & Young where he qualified as a Chartered Accountant. Mr. Clisdell has a Bachelor of Commerce degree from the University of Sydney (majoring in Finance & Accounting) and a Graduate Diploma in Applied Finance & Investment from FINSIA.

Dr. Appakalai is an international pioneer in islet cell isolation and transplantation for the treatment of diabetes and chronic pancreatitis. Previously, Dr. Appakalai directed the clinical islet cGMP facility at the University of Louisville and Jewish Hospital Cardiovascular Innovation Institute. Dr. Appakalai was appointed as Associate professor of Surgery and the Director of Islet Cell Laboratory at the University of Louisville Department of Surgery in June 2014. Dr. Appakalai joined the University of Louisville to establish a clinical islet transplant program to treat patients with painful chronic pancreatitis (islet auto-transplantation) and severe type-1 diabetes (islet allo-transplantation). Before joining the University of Louisville, Dr. Appakalai served on the faculty of the Schulze Diabetes Institute of the University of Minnesota between 2007 to 2014, where he was also the Director of the Islet Processing Core Director. Dr. Appakalai also previously served on the faculty at the Thomas E. Starzl Transplantation Institute of the University of Pittsburgh, where he was an Assistant Professor of Surgery, holding leadership positions as Associate Director of the Islet Transplant Program and the Co-Director of Islet Processing Core. Dr. Appakalai holds a Masters of Science from Mardras University and a Ph.D. from Christian Medical College, and he conducted postdoctoral training in bio-artificial pancreas transplantation at Kyoto University.
Dr. Michael Hughes, MD
Chief Medical Officer (Koligo Therapeutics, Inc.)

Dr. Hughes is a transplant surgeon who started the clinical islet transplant program at Jewish Hospital in Louisville, Kentucky. He was awarded National Pancreas Foundation Center status for Chronic Pancreatitis on behalf of the Jewish Hospital. He is currently Director of the Pancreatic Disease Center at Jewish Hospital and Director of Pancreas and Islet Transplantation at the University of Louisville. Previously, Dr. Hughes was an Assistant Professor of Surgery at the Medical University of South Carolina, where he helped with the initiation of an islet auto transplant program. Dr. Hughes holds a Bachelors of Arts and a Medical Degree from Wake Forest University.

Dr. Hughes is a transplant surgeon who started the clinical islet transplant program at Jewish Hospital in Louisville, Kentucky. He was awarded National Pancreas Foundation Center status for Chronic Pancreatitis on behalf of the Jewish Hospital. He is currently Director of the Pancreatic Disease Center at Jewish Hospital and Director of Pancreas and Islet Transplantation at the University of Louisville. Previously, Dr. Hughes was an Assistant Professor of Surgery at the Medical University of South Carolina, where he helped with the initiation of an islet auto transplant program. Dr. Hughes holds a Bachelors of Arts and a Medical Degree from Wake Forest University.

David Blanford, CPA
Chief Operating Officer (Koligo Therapeutics, Inc.)

Mr. Blanford has over 25 years of finance and accounting experience. Prior to co-founding Koligo, Mr. Blanford served as Chief Financial Officer of The Geneva Foundation, a non-profit organisation that supports and advances innovative medical research and excellence in education within the U.S. military. He previously served as Chief Financial Officer of Logan’s Linens Holdings, Tacoma Electric Supply, and Connecticut Electric & Switch Mfg. Co. Mr. Blanford holds a Bachelors of Science in Accounting from Oral Roberts University and is a licensed Certified Public Accountant (CPA).

Ariel Sivikofsky, FCA
Chief Financial Officer

Mr. Sivikofsky has over 20 years’ industry experience in the biotech industry, financial services and accounting both in Australia and Europe. Mr. Sivikofsky is a seasoned finance executive, having been the Chief Financial Officer at Luoda Pharma and Bova UK, private biotech companies based in London, and Investor First Limited (now HUB24 Limited), an ASX-listed financial services company (ASX:INQ (now HUB)). Further, Mr. Sivikofsky previously served as a Director of Financial Advisory Services at Deloitte Australia, where he specialised in Chief Financial Officer secondments and technical accounting advisory engagements. Prior to that role, Mr. Sivikofsky was a financial controller at Babcock & Brown in both Sydney and London. Mr. Sivikofsky is a Chartered Accountant (FCA) and a graduate member of the Australian Institute of Company Directors (GAICD).

Andrew Bursill
Company Secretary

Mr. Bursill is a Chartered Accountant with more than 20 years of accounting experience. He is a Principal at Franks & Associates Pty Ltd, where he has assisted publicly listed and unlisted companies since 1998 with capital raising activities, financial management, investor relations and company secretarial services and compliance. Mr. Bursill is a Company Secretary of a number of publicly listed entities and several unlisted public and private companies.
MANAGEMENT AND CONSULTANTS

The Company is aware of the need to have sufficient management to properly supervise its operations, expansion and research and development, and the Board will continually monitor the management roles in the Company. As the Company’s operations require an increased level of involvement the Board will look to appoint additional management and/or consultants when and where appropriate to ensure proper management of the Company’s operations.

11.2 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 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 Corporate Governance Principles and Recommendations (3rd Edition) as published by ASX Corporate Governance Council (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 outlined below and the Company’s full Corporate Governance Plan is available in a dedicated corporate governance information section on the Company’s website www.koligo.net.

BOARD OF DIRECTORS

The Board is responsible for corporate governance of the Company. The Board develops strategies for the Company, reviews strategic objectives and monitors performance against those objectives. The goals of the corporate governance processes are to:

a. maintain and increase Shareholder value;

b. ensure a prudential and ethical basis for the Company’s conduct and activities; and

c. ensure compliance with the Company’s legal and regulatory objectives.

Consistent with these goals, the Board assumes the following responsibilities:

d. developing initiatives for profit and asset growth;

e. reviewing the corporate, commercial and financial performance of the Company on a regular basis;

f. acting on behalf of, and being accountable to, the Shareholders; and

g. identifying business risks and implementing actions to manage those risks and corporate systems to assure quality.

The Company is committed to the circulation of relevant materials to Directors in a timely manner to facilitate Directors’ participation in the Board discussions on a fully-informed basis.

COMPOSITION OF THE BOARD

Election of Board members is substantially the province of the Shareholders in general meeting.

IDENTIFICATION AND MANAGEMENT OF RISK

The Board’s collective experience will enable accurate 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.

ETHICAL STANDARDS

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

INDEPENDENT PROFESSIONAL ADVICE

Subject to the Chairman’s approval (not to be unreasonably withheld), the Directors, at the Company’s expense, may obtain independent professional advice on issues arising in the course of their duties.

REMUNERATION ARRANGEMENTS

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

In accordance with the Constitution, the total maximum remuneration of non-executive Directors is initially set by the Board and subsequent variation is by ordinary resolution of Shareholders in general meeting in accordance with the Constitution, the Corporations Act and the ASX Listing Rules, as applicable. The determination
of non-executive Directors’ remuneration within that maximum will be made by the Board having regard to the inputs and value to the Company of the respective contributions by each non-executive Director. The current amount has been set at an amount not to exceed $500,000 per annum.

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

Directors are also entitled to be paid reasonable travelling, hotel and other expenses incurred by them respectively in or about the performance of their duties as Directors.

The Board reviews and approves the remuneration policy to enable the Company to attract and retain executives and Directors who will create value for Shareholders having consideration to the amount considered to be commensurate for a company of its 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.

**TRADING POLICY**

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

**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.

**AUDIT COMMITTEE**

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

**DIVERSITY POLICY**

The Board has adopted a diversity policy which provides a framework for the Company to achieve, amongst other things, a diverse and skilled workforce, a workplace culture characterised by inclusive practices and behaviours for the benefit of all staff, improved employment and career development opportunities for women and a work environment that values and utilises the contributions of employees with diverse backgrounds, experiences and perspectives.
## 11.3 Departures from Recommendations

Following admission to the Official List of ASX, 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 set out on the following pages.

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>Due to the Company’s stage of development and number of employees, the Company may face particular issues in relation to setting, reviewing, assessing and reporting on certain diversity measures. Consequently, the Company will not comply with Recommendation 1.5 (diversity) in full.</td>
</tr>
<tr>
<td>2.1, 4.1, 7.1, 7.3 &amp; 8.1</td>
<td>Due to the size and nature of the existing Board and the magnitude of the Company’s current operations, the Board does not consider that the Company will gain any benefit from individual Board committees and that its resources would be better utilised in other areas. The Board is of the view that at this stage, the experience and skill set of the current Board is sufficient to perform these roles. As such, the Company does not currently have a Nomination Committee, an Audit and Risk Committee, an internal audit function or a Remuneration Committee as required by Recommendations 2.1, 4.1, 7.1, 7.3 and 8.1 respectively. Pursuant to the Company’s Board Charter, the full Board carries out the duties that would ordinarily be assigned to the Nomination, Audit and Risk and Remuneration Committees. The roles and responsibilities of these Committees are outlined in the relevant Committee Charters contained in the Company’s Corporate Governance Plan which is available on the Company’s website. The Board will devote time on an annual basis to discuss Board succession issues and to fulfil the roles and responsibilities associated with both maintaining the Company’s internal audit function and arrangements with external auditors and with setting the level and composition of remuneration for Directors and senior executives and ensuring that such remuneration is appropriate and not excessive. Further, all members of the Board are involved in the Company’s audit function to ensure the proper maintenance of the entity and the integrity of all financial reporting. The Company’s Board Charter also outlines the monitoring, review and assessment of a range of internal audit functions and procedures of the Company. The Company will establish separate Nomination, Audit and Risk and Remuneration Committees once the Company’s operations are considered to be of sufficient magnitude to warrant such Committees.</td>
</tr>
<tr>
<td>2.4</td>
<td>As at the date of this Prospectus, only two of the five Board members are independent Directors. Matthew Lehman and Stuart Williams are not considered to be independent directors due to their respective executive roles on the Board. Robert Clisdell is not considered to be an independent director due to his association with Brentridge Capital Pty Ltd (Corporate Adviser to the Public Offer) and with Long Hill Capital V, LLC, a substantial shareholder of the Company. Peter James and Jethro Marks are considered to be independent directors of the Company. The Board, having regard to the Company's stage of development and the collective experience and expertise of the Directors, considers the current composition of the Board is appropriate. The Board will also look to appoint additional independent Non-Executive Directors once the Company’s operations are considered to be of sufficient magnitude to warrant such appointments.</td>
</tr>
</tbody>
</table>
MATERIAL
CONTRACTS

Dr. Hughes performing TP-IAT in Louisville, Kentucky

This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
12. MATERIAL CONTRACTS

12.1 Exchange Agreement – Acquisition of Koligo

The Company, Koligo, the shareholders of Koligo (the Koligo Shareholders) and Matthew Lehman as the representative of the Koligo Shareholders are parties to an Exchange Agreement in respect of the acquisition by the Company of 100% of the issued share capital of Koligo (the Exchange) (the Exchange Agreement). Pursuant to the Exchange Agreement, the Koligo acquisition is to be effected by an issue by the Company of 75,000,000 Shares and 25,000,000 Performance Shares to be apportioned among the Koligo Shareholders pro rata to their respective shareholdings in Koligo. This issue will occur concurrently with the issue by the Company of the Shares under the Public Offer and in any event no later than 31 December 2019.

Completion of the Exchange Agreement is conditional upon the fulfilment of the following conditions precedent:

a. each of the representations and warranties made by each party under the Exchange Agreement being true and correct in all material respects on and as at the date of completion;

b. each party performing and complying with, in all material respects, each agreement, covenant and obligation required by the Exchange Agreement; and

c. the Company issuing the Shares the subject of the Public Offer to applicants under this Prospectus.

Under the Exchange Agreement, each Koligo Shareholder waives any and all pre-emptive (or similar) rights with regard to the shareholding interests in Koligo or the Company. Further, each Koligo Shareholder (and Koligo) authorises the use by the Company of Koligo’s corporate name and trademarks including its logo and domain name.

The Exchange Agreement also contains other representations, warranties and conditions considered standard for an agreement of this nature, including those related to U.S. securities law compliance.

12.2 Joint Lead Manager Mandates – Novus Capital Limited and APP Securities Pty Limited

The Company has entered into a mandate letter with each of APP Securities Pty Limited (APP) and Novus Capital Limited (Novus) pursuant to which APP and Novus (together, the Joint Lead Managers) have agreed to act as joint lead managers to the Public Offer (JLM Mandates).

The Company has agreed to pay the Joint Lead Managers and Brentridge (refer to Section 12.3 below) the following fees to be shared by the Joint Lead Managers and Brentridge on an equal basis (unless agreed otherwise):

a. a management fee equal to 1% of the amount raised under the Public Offer (Management Fee); and

b. a success fee equal to $200,000 (Success Fee).

In addition, the Company has agreed to pay each Lead Manager the following fee and issue each Lead Manager the following Options:

c. a selling fee equal to 5% of the amount raised by that Lead Manager under the Public Offer (excluding GST); and

d. such number of Options which equals 2.5% of the number of Shares on issue after completion of the Offers (Joint Lead Manager Options) on the terms and conditions set out in Section 13.4.

The Joint Lead Managers are also entitled to reimbursement of their reasonable expenses incurred in respect of the Public Offer.

The Novus JLM Mandate may be terminated:

e. by the Company:

i. at any time on the occurrence of a breach by Novus;

ii. at any time after 12 June 2019 by giving 60 days’ notice and paying all fees and expenses accrued; or

iii. at any time before 12 June 2019 by giving 30 days’ notice and paying all fees and expenses accrued; and

f. by Novus at any time by giving 30 days’ notice or on the occurrence of a number of standard termination events.

The APP JLM Mandate may be terminated by the Company in the event APP commits a material breach that remains unremedied for a period of five business days after notification. APP may terminate the APP JLM Mandate by written notice at any time.

Under the APP JLM Mandate, the Company has also agreed to appoint APP as lead manager in any further equity capital raising undertaken by the Company within 12 months of the date the Company is admitted to the Official List, subject to reasonable terms.
The JLM Mandates contain other standard indemnities, terms and conditions expected to be included in mandates of this nature.

12.3 Corporate Advisory Mandate – Brentridge Capital Pty Ltd

The Company has signed a corporate advisory mandate dated 7 February 2019 (Commencement Date) with Brentridge Capital Pty Ltd (Brentridge) to act as corporate adviser in respect of the Public Offer (Brentridge Mandate). Brentridge is a related party of Long Hill Capital V, LLC, the Company’s sole shareholder at the date of this Prospectus.

The Company has agreed to pay Brentridge an equal share of the Management Fee and Success Fee described in Section 12.2. Further, the Company has agreed to pay Brentridge a selling fee equal to 5% of the amount raised by the Company under the Public Offer less the selling fees paid to the Joint Lead Managers described in Section 12.2.

The Brentridge Mandate may be terminated:

a. by the Company in the event Brentridge commits a material breach that remains unremedied for a period of ten business days after notification or without cause on 7 November 2019; and

b. by Brentridge at any time on the occurrence of a number of standard termination events.

The Company has also agreed to offer Brentridge the role of corporate adviser in any further equity capital raising undertaken by the Company within 18 months of the date the Company is admitted to the Official List, subject to competitive terms in respect of pricing, fees and timing relative to market practices at the relevant time.

12.4 Knowledge Licence Agreement – University of Louisville Research Foundation, Inc.

Koligo and the University of Louisville Research Foundation Inc. (the Foundation) (as agent for the University of Louisville (UofL)) entered into an agreement dated 20 November 2017 (as varied), pursuant to which the Foundation agreed to grant Koligo a license to use non-patented intellectual property in technical information developed during research undertaken at UofL related to Kyslecel™ (Technical Knowledge) related to the preparation and isolation of human islets for autologous transplantation (Invention) (Knowledge Licence Agreement). A summary of the material terms of the Knowledge Licence Agreement is set out below:

a. (Licence) Koligo has been granted a worldwide licence to manufacture, import and sell isolated human islets for autologous transplantation into a human patient which utilise any of the Technical Knowledge (Licensed Products) and provide services that use the Licensed Products (Licensed Services) (Licence);

b. (Term and Exclusivity) the Licence is exclusive until 20 November 2019 (Exclusivity End Date) during which time the Foundation cannot licence the Technical Knowledge to any competitor of Koligo. On the Exclusivity End Date, provided Koligo has complied with all material terms and conditions of the Knowledge Licence Agreement, the Licence will become a perpetual, non-exclusive, irrevocable, sub-licensable, royalty-free license. On the Exclusivity End Date, the Foundation will retain all rights to practice the Technical Knowledge. Refer to Section 7.2(d) for further details;

c. (Retained Rights) the Foundation retains ownership of the right, title and interest in and to the Technical Knowledge. The Foundation also reserves the right to (i) publish information resulting from research relating to the Invention, (ii) practice the Technical Knowledge for any not-for-profit educational, research, teaching and/or public service purpose, (iii) practice the Technical Knowledge for clinical use (only in the event Koligo is unable or unwilling to make a Licensed Product for clinical use) or (iv) allow other non-profit academic research institutions to do any one or more of the activities described in paragraphs (i) to (iii) above provided such institution does not compete with Koligo;

d. (U.S. Federal Government Rights) the Government of the United States of America is entitled as a legal right under U.S. federal law to a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced any inventions the subject of the Knowledge License Agreement for governmental purposes but only to the extent it has funded research, during the course of or under which any of the inventions were conceived or made;

e. (Koligo Ownership) Koligo owns all right, title and interest in and to all intellectual property made or developed at any time after Koligo’s formation entirely by (i) employees or contractors of Koligo, (ii) persons providing services to Koligo (including employees of the Foundation and UofL) or (iii) Koligo itself or its affiliates in connection with its business;

f. (Joint Ownership) Koligo and the Foundation jointly own all right, title and interest in and to all intellectual property made or developed jointly by them with the inventorship of the relevant intellectual property.
being determined by U.S. patent and other applicable intellectual property law;

g. (Sub-licensing) Koligo may sub-licence the Technical Knowledge to third parties in all fields of use. If Koligo is unable or unwilling to develop potential Licensed Products or Licensed Services or to serve a market territory for which there is an organisation willing to be a sub-licensee, Koligo will (at the Foundation’s request) negotiate in good faith a sub-licence with such organisation;

h. (Fees) in consideration for the grant of the Licence, Koligo has agreed to pay the Foundation a licence fee, performance milestone payments (in respect of the sale of Licensed Products and Licensed Services) and a percentage of revenue derived from any sub-licences of the Licence on market terms;

i. (Shares) as part consideration for the grant of the Knowledge Licence Agreement, the Foundation was originally entitled to receive equity in Koligo. However, in satisfaction of this obligation, (and in lieu of the Foundation’s right to receive equity in Koligo) the Company has undertaken to issue 1,041,903 Shares to the Foundation on the date which is two years from the date the Company is admitted to the Official List;

j. (Indemnity and Insurance) Koligo has agreed to indemnify the Foundation and the UofL against all claims, damages and losses arising out of the exercise of the Licence, including product liability. Koligo is also required to obtain and maintain various insurance policies in relation to its activities; and

k. (Early Termination) Koligo may terminate the Knowledge Licence Agreement for any reason prior to the Exclusivity End Date by providing 90 days’ written notice. The Foundation may terminate the Knowledge Licence Agreement by providing 60 days’ written notice. The Foundation may terminate the agreement with immediate effect in the event Koligo suffers an insolvency event. Upon early termination of the Knowledge Licence Agreement, Koligo will cease all use of the Technical Knowledge.

The Knowledge Licence Agreement otherwise contains terms which are customary for an agreement of its nature.

12.5 Facilities Licence Agreement – University of Louisville

Koligo entered into a limited licence agreement with the University of Louisville and Jewish Heritage Fund for Excellence Cardiovascular Innovation Institute (CII), dated 20 November 2017 (as varied) pursuant to which Koligo was granted an exclusive right to access and use certain premises and equipment for the manufacture of auto-islets (Facilities Licence Agreement).

a. (Term and Termination): The term of the Facilities Licence Agreement ends on 20 May 2019. Either party may terminate the Facilities Licence Agreement for any reason by providing 60 days’ written notice to the other party. In addition, CII may terminate immediately in the event of the following conduct on the part of Koligo:

i. material non-compliance with any regulations related to the manufacture, distribution or sale of the auto-islets;

ii. the provision of research islets for purposes other than non-clinical research applications;

iii. a material breach that is not cured within thirty business days of notification;

b. (Fees): Koligo has agreed to pay CII a monthly licence fee and a share of the cost of utilities and services on market terms; and

c. (Indemnity): Koligo has agreed to indemnify CII against all claims, damages and liabilities arising out of Koligo’s acts or omissions.

12.6 Exclusive License Agreement - University of Louisville Research Foundation, Inc.

Koligo and the University of Louisville Research Foundation, Inc. (Foundation) (as the agent of the University of Louisville (UofL)) entered into an agreement (Exclusive Licence Agreement), pursuant to which the Foundation agreed to grant Koligo an exclusive worldwide license to use intellectual property developed during research conducted at the UofL relating to Koligo’s 3D-V technology platform (Inventions) (Licensed Patents). A summary of the material terms of the Exclusive Licence Agreement is set out below:

a. (Licence): Koligo has been granted a worldwide licence to make, use, sell, offer for sale, and import products, methods, and services which utilise the Inventions (Licensed Products) and provide ser-
vices that use the Licensed Products (Licensed Services) (Licence);

b. (Term): the Licence is exclusive until the expiration of the last to expire of the Licensed Patents which is approximately August 2034, subject to any patent term adjustment in the United States (Termination Date);

c. (Retained Rights): the Foundation reserves the right to (i) publish any information resulting from research relating to the Invention; (ii) practice the Licensed Patents for any not-for-profit education, research, teaching and/or public service purpose, (iii) make, use and import the Invention and associated technology for educational and research purposes; and (iv) allow other non-profit academic research institutions to do any one or more of the activities described in paragraphs (i) to (iii) above;

d. (U.S. Federal Government Rights): the Government of the United States of America is entitled as a legal right under U.S. federal law to a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced any inventions the subject of the Exclusive License Agreement for governmental purposes but only to the extent it has funded research, during the course of or under which any of the inventions were conceived or made.

e. (Koligo Ownership): Koligo owns all right, title and interest in all intellectual property created, developed and produced outside of the scope of the faculty or staff member’s employment or research with UofL or the Foundation provided the use of certain specialised resources of the Foundation is not significant;

f. (Joint Ownership): Koligo and the Foundation jointly own all right, title and interest in and to all intellectual property made or developed jointly by them with the inventorship of the relevant intellectual property being determined by U.S. patent and other applicable intellectual property law;

g. (Sub-licensing): Koligo may sub-licence the Licensed Patents to third parties in all fields of use. If Koligo is unable or unwilling to develop potential Licensed Products or Licensed Services or to serve a market territory for which there is an organisation willing to be a sub-licensee, Koligo will (at the Foundation’s request) negotiate in good faith a sub-licence with such organisation;

h. (Fees): in consideration for the grant of the Licence, Koligo has agreed to pay the Foundation a licence fee, royalties (in respect of the sale of Licensed Products and Licensed Services sold during the Term) and a percentage of revenue derived from any sublicences of the Licence and in the event that the total amount of fees paid in accordance with these terms does not meet a set threshold for the relevant year Koligo will pay the Foundation any shortfall. In addition, on and from 1 January 2020, Koligo will pay the Foundation an annual licence maintenance fee. Koligo also agreed to pay the Foundation performance milestone payments in respect of each Licensed Product, for FDA approval of each Licensed Product and in respect of net sales of Licensed Products. All fees are considered by Koligo to be on market terms;

i. (Indemnity and Insurance): Koligo has agreed to indemnify the Foundation and UofL against all claims, suits, losses, fellows, officers, employees, students, and agents from and against any and all claims, suits, losses, damage, costs, fees and expenses arising out of the exercise of the Licence, including product liability. Koligo is also required to obtain and maintain various insurance policies in relation to its activities; and

j. (Early Termination): Koligo may terminate the Exclusive License Agreement for any reason prior to the Termination Date by providing 90 days’ written notice. The Foundation may terminate the Exclusive Licence Agreement by written notice in the event of a breach that is not remedied within 30 days of notice of such breach and may also terminate the agreement with immediate effect in the event Koligo suffers an insolvency event.

The Exclusive Licence Agreement otherwise contains terms which are customary for an agreement of its nature.

12.7 Exclusive License Agreement – Arizona Board of Regents on behalf of the University of Arizona

Koligo and the Arizona Board of Regents (on behalf of the University of Arizona) (UA), entered into an agreement dated 15 October 2018 (UA Licence Agreement), pursuant to which UA agreed to grant Koligo an exclusive worldwide license to use of the rights and technology set out in the US Provisional Patent Application (US Patent Application) filed on 2 June 2006, titled “Prevascularised Devices and Related Methods” and any foreign patents derived from the US Patent Application (the Patents). A summary of the material terms of the UA Licence Agreement is set out below.

a. (UA Licence): Koligo has been granted an exclusive, worldwide licence to make, use, sell, offer for sale, and import products, methods, and services which utilise the rights and technology of the US Patent Application (Licensed Products) and provide services that use the Licensed Products (Licensed Services) (UA Licence);
b. **(Term):** the UA Licence is in force until the expiration of the Licensed Patents, which is approximately June 2026, subject to any patent term adjustment in the United States (Termination Date);

c. **(Retained Rights):** UA retains its rights in and to the Patents for research and education purposes;

d. **(U.S. Federal Government Rights):** the Government of the United States of America is entitled as a legal right under U.S. federal law to a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced any inventions the subject of the UA License Agreement for governmental purposes but only to the extent it has funded research, during the course of or under which any of the inventions were conceived or made;

e. **(Koligo Ownership):** Koligo owns all right, title and interest in any its improvements to the technology. If such improvements are provided jointly by the parties, they shall negotiate their respective part in the ownership of these improvements according to their respective contribution;

f. **(Sub-licensing):** Koligo may sub-license all or any portion of its rights under the Licence to third parties in all fields of use. If Koligo is unable or unwilling to develop potential Licensed Products or Licensed Services or to serve a market territory for which there is an organisation willing to be a sub-licensee, Koligo will (at UA's request) negotiate in good faith a sub-license with such organisation;

g. **(Fees):** in consideration of the grant of the UA Licence, Koligo agrees to pay UA licence fees and royalties (in respect of sales of Licensed Products) on market terms;

h. **(Indemnity and Insurance):** Koligo has agreed to indemnify UA against all claims, suits, losses, fellows, officers, employees, students, and agents from and against any and all claims, suits, losses, damage, costs, fees and expenses arising out of the exercise of the UA Licence. Koligo is also required to obtain and maintain various insurance policies in relation to its activities; and

i. **(Early Termination):** Koligo may terminate the UA Licence Agreement for any reason prior to the Termination Date by providing 90 days' written notice. UA may terminate the UA Licence Agreement by written notice in the event of a breach that is not remedied within 30 days of notice of such breach and may also terminate the agreement with immediate effect in the event Koligo suffers an insolvency event.

### 12.8 Research Agreement

On 20 February 2018, Koligo entered into a research agreement with Vanderbilt University Medical Centre (Vanderbilt) whereby Koligo agreed to assist Vanderbilt in conducting research into improving isolation of pancreatic islets in Type 1 diabetes to assess alpha cell function and gene expression (Project) (**Research Agreement**). The Research Agreement commenced on 1 November 2018 and will terminate on 30 April 2019 unless otherwise agreed between the parties (**Term**). Koligo will be reimbursed for research conducted on the Project during the Term on market terms. The Research Agreement otherwise contains terms and conditions typical for an agreement of this nature.

### 12.9 Master Supply Agreements

Koligo generally enters into master supply agreements (**Supply Agreements**) with each of its health provider customers pursuant to which Koligo agrees to manufacture and supply Kyslecel to the health provider, on standard terms and conditions determined by Koligo. Each of the Supply Agreements is generally on substantially the same or similar terms as follows.

Each Supply Agreement commences on its effective date and continues in full force and effect until terminated in accordance with its terms.

In general, the Supply Agreements each terminate:

a. in the event the parties to the relevant Supply Agreement do not enter into a purchase order for Kyslecel for a period of 12 consecutive calendar months; or

b. on the provision of 30 calendar days’ written notice by either party to the relevant Supply Agreement.

The Supply Agreements generally provide for payment of Kyslecel™ in advance prior to the processing of a patient's pancreas for Kyslecel™.

The Supply Agreements typically provide that Koligo is required to maintain certain levels of insurance, including for bodily injury claims and professional liability.

Koligo is generally required to indemnify the health provider customer for certain gross negligence and other wilful acts or omissions; however, Koligo’s liability is capped at the amount of its insurance coverage it is required to maintain under the applicable Supply Agreement. Koligo is also entitled to indemnification by the health provider customer for certain personal injury claims relating to the use of Kyslecel™.

The Supply Agreements contain other standard terms and conditions expected to be included in contracts of
this nature. Koligo may enter into Supply Agreements that do not contain its standard terms and conditions.

As of the date of this Prospectus, Koligo has entered into master supply agreements with Jewish Hospital & St. Mary’s Healthcare, Inc. d/b/a Jewish Hospital and State University of New York.

12.10 Employment Agreements

Koligo has entered into employment agreements (Employment Agreements) with each of Matthew Lehman (a Director of the Company), Dr Balamurugan Appakalai and David Blanford (together, the Executives), pursuant to which Koligo has engaged Matthew Lehman as President and Chief Executive Officer, Dr Balamurugan Appakalai as Vice President, Chief of Manufacturing and Mr Blanford as Secretary, Treasurer and Chief Operating Officer. The Employment Agreements superseded prior employment agreements with the Executives that were on substantially the same terms. Employment under the Employment Agreements commenced on 1 March 2018 for Messrs Lehman and Appakalai and on 16 June 2018 for Mr Blanford and continue until terminated in accordance with their terms.

a. Remuneration:

Mr Lehman, Dr Appakalai and Mr Blanford will receive salaries of approximately US$265,000 (approximately $376,000) (to be increased to US$300,000 (approximately $426,000) on the date the Company is admitted to the Official List), US$250,000 (approximately $355,000) and US$200,000 per annum (approximately $284,000), respectively.

b. Bonus:

i. the Executives may be considered for an annual incentive bonus with a target equal to 33%, 25% and 25%, respectively, of Mr Lehman’s, Dr Appakalai’s and Mr Blanford’s annual base salary, upon attainment of certain performance objectives with the potential to increase above the respective targets, as applicable, in the event the relevant Executive exceeds their performance objectives, as applicable and, in relation to Mr Lehman and Dr Appakalai, subject to paragraph (b)(ii) below.

ii. the bonus in respect of Koligo’s 2018 fiscal year will be US$85,000 (approximately $121,000) and US$50,000 (approximately $71,000) for Mr Lehman and Dr Appakalai, respectively.
c. **Termination:**

Koligo may immediately terminate the employment of the Executives by written notice for a number of standard events including, but not limited to, if at any time, such Executive:

i. breaches any of the material provisions of the Employment Agreement which are not cured within thirty (30) days of Koligo providing the Executive with written notice of such breach;

ii. intentionally or recklessly commits any act which materially impacts on the business, business relationships, reputation or trade secrets or other material intellectual property of Koligo or its affiliates; or

iii. intentionally or recklessly engages in any activity that is in conflict with or adverse to the interests of Koligo or its affiliates, including without limitation violation of foreign or domestic anti-corruption laws, rules and regulations.

An Executive may terminate an Employment Agreement immediately by written notice for a number of standard events including, but not limited to, where Koligo breaches any of the material provisions of the Employment Agreement which are not cured within thirty (30) days of the Employee providing Koligo with written notice of such breach. Further, either party may terminate an Employment Agreement for any reason by giving 30 days’ written notice. Where Koligo terminates an Employment Agreement without cause or where the Executive has terminated an Employment Agreement for cause, Koligo has agreed to pay the relevant Executive 6 months’ base salary. Further, where a change of control occurs in respect of Koligo and within 12 months of such event, an Executive’s employment is terminated without cause or an Executive has terminated an Employment Agreement for cause, Koligo has agreed to pay the relevant Executive 12 months’ base salary.

d. **Intellectual Property Rights**

Any intellectual property arising out of or produced during the Executives’ employment remains the sole and exclusive property of Koligo and the Executives agree to assign ownership of all right, title and interest in any such intellectual property to Koligo.

e. **Non-compete**

The Executives must not compete directly or indirectly with Koligo’s business during their employment or for a period of 1 year after termination of such employment, subject to Koligo agreeing to continue to pay the Executives their base salary for this 1 year period.

f. **Indemnity**

Koligo agrees to indemnify the Executives to the maximum extent permitted by law from and against any liabilities and costs in the event the Executives are made a party to any action or proceeding by reason of the fact they were an officer of Koligo.

The Employment Agreements contain other standard terms and conditions expected to be included in contracts of this nature.

12.11 **Consultancy Agreements**

Koligo has entered into consultancy agreements (Consultancy Agreements) with each of Dr Michael Hughes and Dr Stuart Williams (a Director of the Company) (Consultants) dated 6 March 2018, as varied, pursuant to which Koligo has engaged Dr Hughes as Vice President, Chief Medical Officer and Dr Williams as Vice President, Chief Technology Officer. The Consultancy Agreements commenced on 6 March 2018 and continue until terminated in accordance with their terms. The material terms and conditions of the Consultancy Agreements are summarised below:

a. **(Fees)** Dr Hughes and Dr Williams will each receive fees of approximately US$60,000 per annum (approximately $85,000).

b. **(Bonus)** The Consultants may also each be paid a cash bonus of up to US$60,000 per annum (approximately $85,000) upon the satisfaction of set sales goals and quality goals.

c. **(Termination)** Koligo may terminate the Consultancy Agreements at any time by written notice, for a number of standard events including, but not limited to, if at any time, the Consultant:

i. breaches any of the material provisions of the Consultancy Agreement which are not cured within thirty (30) days of Koligo providing the Consultant with written notice of such breach;

ii. intentionally or recklessly commits any act, which materially detrimentally impacts on Koligo;

iii. commits an act that amounts to wilful misconduct, wanton misconduct or gross negligence; or

iv. intentionally or recklessly engages in any activity that is in conflict with or adverse to the interests of Koligo.
A Consultant may terminate his Consultancy Agreement immediately by written notice for a number of standard events including, but not limited to, where Koligo breaches any of the material provisions of the Consultancy Agreement which are not cured within thirty (30) days of the Consultant providing Koligo with written notice of such breach.

Either party may terminate the Consultancy Agreement at any time, without reason, by providing thirty (30) days written notice to the other party. Where Koligo terminates a Consultancy Agreement without cause or where the Consultant has terminated a Consultancy Agreement for cause, Koligo has agreed to pay the relevant Consultant 6 months’ base fees. Further, where a change of control occurs in respect of Koligo and within 12 months of such event, a Consultant’s engagement is terminated without cause or a Consultant has terminated a Consultancy Agreement for cause, Koligo has agreed to pay the relevant Consultant 12 months’ base salary.

d. Intellectual Property Rights

Any intellectual property arising out of or produced during the Consultant’s engagement remains the sole and exclusive property of Koligo and the Consultants agree to assign ownership of all right, title and interest in any such intellectual property to Koligo.

e. Indemnity

Koligo agrees to indemnify the Consultants to the maximum extent permitted by law from and against any liabilities and costs in the event the Consultants are made a party to any action or proceeding by reason of the fact they were an officer of Koligo.

The Consultancy Agreements otherwise contain terms and conditions considered standard for agreements of this nature.

12.12 Executive Employment Agreement – Ariel Sivikofsky

The Company has entered into an executive employment agreement with Ariel Sivikofsky (CFO Employment Agreement), pursuant to which the Company has engaged Mr. Sivikofsky as Chief Financial Officer of the Company. The material terms and conditions of the CFO Employment Agreement are summarised below:

a. Term:

Mr. Sivikofsky’s employment commenced on 3 September 2018 (Commencement Date) and will continue until the CFO Employment Agreement is terminated.

b. Remuneration:

Mr. Sivikofsky will receive a salary of $200,000 per annum plus superannuation from the Commencement Date until the date the Company is admitted to the Official List (Listing Date) at which time his salary will increase to $250,000 per annum plus superannuation.

c. Incentive Programs:

Mr. Sivikofsky is eligible to participate in any incentive plan that the Company may introduce.

i Short Term Incentive Program: Mr. Sivikofsky may be awarded a bonus in the form of cash or equity at the discretion of the Board.

ii Long Term Incentive Program: Upon (or prior to) the Listing Date, Mr. Sivikofsky will be issued 2,000,000 Options on the terms and conditions set out in Section 13.3, 1,000,000 of which will vest on the Listing Date (or earlier at the discretion of the Company), 500,000 of which will vest 12 months after the Listing Date and 500,000 of which will vest 24 months after the Listing Date (Secondary Anniversary Date).

d. Termination:

The Company may immediately terminate the CFO Employment Agreement by written notice if, among other termination events, Mr. Sivikofsky commits a material breach of the agreement or engages in conduct that constitutes intentional disobedience, dishonesty or serious or persistent neglect or acts in a manner which, in the reasonable opinion of the Company will detrimentally affect the Company or its reputation.

The Company may at any time and for any reason terminate the CFO Employment Agreement by giving Mr. Sivikofsky eight weeks’ notice (prior to the Second Anniversary Date) or twelve weeks’ notice (after the Second Anniversary Date) and Mr. Sivikofsky can terminate the CFO Employment Agreement by giving the Company four weeks’ notice.

The CFO Employment Agreement otherwise contains standard terms and conditions expected to be included in a contract of this nature.
12.13 Loan Agreement – Long Hill Capital V, LLC

The Company has entered into a loan agreement with Long Hill Capital V, LLC (the sole Shareholder of the Company at the date of this Prospectus) (Lender) pursuant to which the Lender has agreed to lend up to $300,000 to the Company (Long Hill Loan). The material terms of the Long Hill Loan are as follows:

a. **Loan Amount:** the maximum amount which can be borrowed under the Long Hill Loan is $300,000;

b. **Purpose:** the Long Hill Loan is to be used by the Company toward paying the expenses of the Offers and for payment of employees' salaries;

c. **Security:** the Long Hill Loan is unsecured;

d. **Interest:** no interest is payable on the Long Hill Loan; and

e. **Repayment:** the Long Hill Loan is repayable in cash upon the earlier of:

   i. the date which is 14 days after the date the Company is admitted to the Official List of ASX (from the proceeds of the Public Offer);

   ii. the date which is 14 days after 1 May 2019, in the event the Company is not admitted to the Official List of ASX by that date; or

   iii. immediately in the event that a standard event of default has occurred.

12.14 Line of Credit Agreement – Koligo and Stuart Williams

Koligo has entered into a line of credit agreement with Stuart Williams (a Director of the Company) dated 11 January 2019 pursuant to which Mr Williams has agreed to lend up to US$50,000 (being approximately $71,000) to Koligo (Williams Loan). The material terms of the Williams Loan are as follows:

a. **Loan Amount:** the maximum amount which can be borrowed under the Williams Loans is US$50,000 (approximately $71,000);

b. **Purpose:** the Williams Loan is to be used by Koligo toward paying its operating expenses;

c. **Security:** the Williams Loan is unsecured;

d. **Interest:** interest is payable on the Williams Loan at a rate of 3% per annum on any amount drawn down (Advance) from the date of the Advance;

e. **Repayment:** the Williams Loan is repayable in cash by:

   i. 31 May 2019; or

   ii. immediately in the event that a standard event of default has occurred.
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
13. ADDITIONAL INFORMATION

13.1 Litigation

As at the date of this Prospectus, neither the Company nor Koligo is involved in any legal proceedings nor are the Directors aware of any legal proceedings pending or threatened against the Company or Koligo.

13.2 Rights attaching to Shares

The following is a summary of the more significant rights attaching to Shares. This summary is not exhaustive and does not constitute a definitive statement of the rights and liabilities of Shareholders. To obtain such a statement, persons should seek independent legal advice.

Full details of the rights attaching to Shares are set out in the Constitution, a copy of which is available for inspection at the Company’s registered office during normal business hours.

a. General meetings

Shareholders are entitled to be present in person, or by proxy, attorney or representative to attend and vote at general meetings of the Company.

Shareholders may requisition meetings in accordance with section 249D of the Corporations Act and the Constitution.

b. Voting rights

Subject to any rights or restrictions for the time being attached to any class or classes of Shares, at general meetings of Shareholders or classes of Shareholders:

i. each Shareholder entitled to vote may vote in person or by proxy, attorney or representative;

ii. on a show of hands, every person present who is a Shareholder or a proxy, attorney or representative of a Shareholder has one vote; and

iii. on a poll, every person present who is a Shareholder or a proxy, attorney or representative of a Shareholder shall, in respect of each fully paid Share held by him, or in respect of which he is appointed a proxy, attorney or representative, have one vote for the Share, but in respect of partly paid Shares shall have such number of votes as bears the same proportion to the total of such Shares registered in the Shareholder’s name as the amount paid (not credited) bears to the total amounts paid and payable (excluding amounts credited).

c. Dividend rights

Subject to the rights of any preference Shareholders and to the rights of the holders of any shares created or raised under any special arrangement as to dividend, the Directors may from time to time declare a dividend to be paid to the Shareholders entitled to the dividend which shall be payable on all Shares according to the proportion that the amount paid or credited as paid is of the total amounts paid and payable in respect of such Shares.

The Directors may from time to time pay to the Shareholders any interim dividends as they believe to be justified subject to the requirements of the Corporations Act. No dividend shall carry interest as against the Company. The Directors may set aside out of the profits of the Company any amounts that they may determine as reserves, to be applied at the discretion of the Directors, for any purpose for which the profits of the Company may be properly applied.

Subject to the ASX Listing Rules and the Corporations Act, the Company may, by resolution of the Directors, grant shareholders or a class of shareholders the right to elect to reinvest cash dividends paid by the Company by subscribing for Shares on the terms determined by the Board.

d. Winding-up

If the Company is wound up, the assets of the Company must be applied in repayment to the Shareholders in proportion to their respective holdings.

e. Shareholder liability

As the Shares under the Prospectus are fully paid shares, they are not subject to any calls for money by the Directors and will therefore not become liable for forfeiture.

f. Transfer of Shares

Generally, Shares are freely transferable, subject to formal requirements, the registration of the transfer not resulting in a contravention of or failure to observe the provisions of a law of Australia and the transfer not being in breach of the Corporations Act or the ASX Listing Rules.

g. Variation of rights

Pursuant to section 246B of the Corporations Act, the Company may, with the sanction of a special resolution passed at a meeting of Shareholders vary or abrogate the rights attaching to Shares.
If at any time the share capital is divided into different classes of Shares, the rights attached to any class (unless otherwise provided by the terms of issue of the shares of that class), whether or not the Company is being wound up, may be varied or abrogated with the consent in writing of the holders of three-quarters of the issued shares of that class, or if authorised by a special resolution passed at a separate meeting of the holders of the shares of that class.

h. Alteration of Constitution

The Constitution can only be amended by a special resolution passed by at least three quarters of Shareholders present and voting at the general meeting. In addition, at least 28 days written notice specifying the intention to propose the resolution as a special resolution must be given.

13.3 Options to be issued to Directors, Management and Medical Advisory Consultant

a. Entitlement

Each Option entitles the holder to subscribe for one Share upon exercise of the Option.

b. Exercise Price

Subject to paragraph (j), the amount payable upon exercise of each Option will be $0.30 (Exercise Price).

c. Expiry Date

Each Option will expire at 5:00 pm (WST) on the third anniversary of the date of their vesting (Expiry Date). An Option not exercised before the Expiry Date will automatically lapse on the Expiry Date.

d. Exercise Period

The Options are exercisable at any time on or prior to the Expiry Date (Exercise Period).

e. Notice of Exercise

The Options may be exercised during the Exercise Period 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.

f. Exercise Date

A Notice of Exercise is only effective on and from the later of the date of receipt of the Notice of Exercise and the date of receipt of the payment of the Exercise Price for each Option being exercised in cleared funds (Exercise Date).

g. Timing of issue of Shares on exercise

Within 15 Business Days after the Exercise Date, the Company will:

i. issue the number of Shares required under these terms and conditions in respect of the number of Options specified in the Notice of Exercise and for which cleared funds have been received by the Company;

ii. if required, give ASX a notice that complies with section 708A(5)(e) of the Corporations Act, or, if the Company is unable to issue such a notice, lodge with ASIC a prospectus prepared in accordance with the Corporations Act and do all such things necessary to satisfy section 708A(11) of the Corporations Act to ensure that an offer for sale of the Shares does not require disclosure to investors; and

iii. if admitted to the official list of ASX at the time, apply for official quotation on ASX of Shares issued pursuant to the exercise of the Options.

If a notice delivered under (g)(ii) for any reason is not effective to ensure that an offer for sale of the Shares does not require disclosure to investors, the Company must, no later than 20 Business Days after becoming aware of such notice being ineffective, lodge with ASIC a prospectus prepared in accordance with the Corporations Act and do all such things necessary to satisfy section 708A(11) of the Corporations Act to ensure that an offer for sale of the Shares does not require disclosure to investors.

h. Shares issued on exercise

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

i. Quotation of Shares issued on exercise

If admitted to the official list of ASX at the time, application will be made by the Company to ASX for quotation of the Shares issued upon the exercise of the Options.
Reconstruction of capital

If at any time the issued capital of the Company is reconstructed, all rights of an Optionholder are to be changed in a manner consistent with the Corporations Act and the ASX Listing Rules at the time of the reconstruction.

Participation in new issues

There are no participation rights or entitlements inherent in the Options and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Options without exercising the Options.

Change in exercise price

An Option does not confer the right to a change in Exercise Price or a change in the number of underlying securities over which the Option can be exercised.

Unquoted

The Company will not apply for quotation of the Options on ASX.

Transferability

The Options are transferable subject to any restriction or escrow arrangements imposed by ASX or under applicable Australian securities laws.

13.4 Options to be issued to the Joint Lead Managers

The Options to be issued to the Joint Lead Managers (or their nominees) will be issued on the same terms and conditions set out in Section 13.3 above, except the expiry date will be the third anniversary of their date of issue.

13.5 Performance Shares

The terms and conditions of the Performance Shares to be issued to the current shareholders of Koligo pursuant to the Exchange are summarised below.

Performance Shares

Each Class A Performance Share and Class B Performance Share (together and each being a Performance Share) is a share in the capital of the Company.

General meetings

Each Performance Share confers on the holder (Holder) the right to receive notices of general meetings and financial reports and accounts of the Company that are circulated to Shareholders. Holders have the right to attend general meetings of Shareholders.

No voting rights

A Performance Share does not entitle the Holder to vote on any resolutions proposed by the Company except as otherwise required by law.

No dividend rights

A Performance Share does not entitle the Holder to any dividends.

No rights to return of capital

A Performance Share does not entitle the Holder to a return of capital, whether in a winding up, upon a reduction of capital or otherwise.

Rights on winding up

A Performance Share does not entitle the Holder to participate in the surplus profits or assets of the Company upon winding up.

Not transferable

A Performance Share is not transferable.

Reorganisation of capital

If at any time the issued capital of the Company is reconstructed, all rights of a Holder will be changed to the extent necessary to comply with the applicable ASX Listing Rules at the time of reorganisation.

Application to ASX

The Performance Shares will not be quoted on ASX. However, if the Company is listed on ASX at the time of conversion of the Performance Shares into Shares, the Company must within 10 Business Days apply for the official quotation of the Shares arising from the conversion on ASX.

Participation in entitlements and bonus issues

A Performance Share does not entitle a Holder (in their capacity as a holder of a Performance Share) to participate in new issues of capital offered to holders of Shares such as bonus issues and entitlement issues.
k. No other rights

A Performance Share gives the Holder no rights other than those expressly provided by their terms and those provided at law where such rights at law cannot be excluded by these terms.

l. Conversion on achievement of milestone

Subject to paragraph (n), a Performance Share in the relevant class will convert into one Share upon achievement of:

i. **Class A Performance Share**: each Class A Performance Share will convert into one Share upon the Company achieving, in relation to Koligo, sales of $5,000,000 in the financial year in which the Company is admitted to the Official List, or in any of the first three complete financial years following the financial year in which the Company is admitted to the Official List (Class A Milestone); and

ii. **Class B Performance Share**: each Class B Performance Share will convert into one Share upon the Company achieving, in relation to Koligo, sales of $10,000,000 in the financial year in which the Company is admitted to the Official List, or in any of the first three complete financial years following the financial year in which the Company is admitted to the Official List (Class B Milestone).

m. Conversion on change of control

Subject to paragraph (n) and notwithstanding the relevant milestone has not been satisfied, upon the occurrence of either:

i. a takeover bid under Chapter 6 of the Corporations Act having been made in respect of the Company having received acceptances for more than 50% of the Company’s Shares on issue and being declared unconditional by the bidder; or

ii. a Court granting orders approving a compromise or arrangement for the purposes of or in connection with a scheme of arrangement for the reconstruction of the Company or its amalgamation with any other company or companies,

the Performance Shares shall automatically convert into Shares, provided that if the number of Shares that would be issued upon such conversion is greater than 10% of the Company’s Shares on issue as at the date of conversion, then that number of Performance Shares that is equal to 10% of the Company’s Shares on issue as at the date of conversion under this paragraph will automatically convert into an equivalent number of Shares. The conversion will be completed on a pro rata basis for each Holder. Performance Shares that are not converted into Shares under this paragraph will continue to be held by the Holders on the same terms and conditions.

n. (Deferral of conversion if resulting in a prohibited acquisition of Shares) If the conversion of a Performance Share under paragraph (l) or (m) would result in any person being in contravention of section 606(1) of the Corporations Act (General Prohibition) then the conversion of that Performance Share shall be deferred until such later time or times that the conversion would not result in a contravention of the General Prohibition. In assessing whether a conversion of a Performance Share would result in a contravention of the General Prohibition:

i. Holders may give written notification to the Company if they consider that the conversion of a Performance Share may result in the contravention of the General Prohibition. The absence of such written notification from the Holder will entitle the Company to assume the conversion of a Performance Share will not result in any person being in contravention of the General Prohibition;

ii. The Company may (but is not obliged to) by written notice to a Holder request a Holder to provide the written notice referred to in paragraph (n)(i) within seven days if the Company considers that the conversion of a Performance Share may result in a contravention of the General Prohibition. The absence of such written notification from the Holder will entitle the Company to assume the conversion of a Performance Share will not result in any person being in contravention of the General Prohibition.

o. (Lapse of Performance Share) each Performance Share shall expire on the date that is four months after the after the third anniversary of the last day of the financial year in which the Company is admitted to the Official List (Expiry Date) if the relevant milestone attached to that Performance Share has not been achieved, at which time the Company will redeem the relevant Performance Shares in accordance with paragraph (p) below. For the avoidance of doubt, a Performance Share will not lapse in the event the relevant milestone is met before the Expiry Date and the Shares the subject of a conversion are...
deferred in accordance with paragraph (n) above.

p. (Redemption if Milestone not achieved) If the relevant milestone is not achieved by the relevant Expiry Date, then each Performance Share in the relevant class will be automatically redeemed by the Company for the sum of $0.00001 within 10 Business Days of that Expiry Date.

q. (Conversion procedure) The Company will issue the Holder with a new holding statement for any Share issued upon conversion of a Performance Share within 10 Business Days following the conversion.

r. (Ranking upon conversion) The Share into which a Performance Share may convert will rank pari passu in all respects with existing Shares.

13.6 Employee Share Option Plans

The Company has adopted two separate Incentive Option Plans to allow eligible participants to be granted Options to acquire Shares in the Company and to accommodate the differing taxation treatment of incentives issued to Australian resident Directors and employees to that of incentives issued to non-Australian resident Directors and employees. These are the Koligo Incentive Option Plan and the Koligo Concessional Incentive Option Plan. The principal terms of the Plans are summarised below.

13.6.1 Koligo Incentive Option Plan

a. Eligibility and Grant of Options: The Board may grant Options to any Director, full or part time employee, or casual employee or contractor who falls within ASIC Class Order 14/1000, or the Company or an associated body corporate (Eligible Participant). The Board may also offer Options (Options Offer) to a prospective Eligible Participant provided the Options Offer can only be accepted if they become an Eligible Participant. Options may be granted by the Board at any time.

b. Consideration: Each Option granted under the Plan will be granted for no more than nominal cash consideration.

c. Conversion: Each Option is exercisable into one Share in the Company ranking equally in all respect with the existing issued Shares in the Company.

d. Exercise Price and Expiry Date: The exercise price and expiry date for Options granted under the Plan will be determined by the Board prior to the grant of the Options.

e. Exercise Restrictions: The Options granted under the Plan may be subject to conditions on exercise as may be fixed by the Directors prior to grant of the Options (Vesting Conditions). Any restrictions imposed by the Directors must be set out in the offer for the Options.

f. Lapsing of Options: An unexercised Option will lapse:

i. on its Expiry Date;

ii. if any Vesting Condition is unable to be met and is not waived, as determined by the Board; or

iii. subject to certain good leaver exceptions or a determination by the Board, where the Eligible Participant ceases to be an Eligible Participant.

g. Disposal of Options: Options will not be transferable except to the extent the Plan or any offer provides otherwise.

h. Quotation of Options: Options will not be quoted on the ASX, except to the extent provided for by the Plan or unless an offer provides otherwise.

i. Trigger Events: The Company may permit Options to be exercised in certain circumstances where there is a change in control of the Company (including by takeover) or entry into a scheme of arrangement.

j. Participation generally: There are no participating rights or entitlements inherent in the Options and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Options without exercising the Options.

k. Reorganisation: The terms upon which Options will be granted will not prevent the Options being re-organised as required by the Listing Rules on the re-organisation of the capital of the Company.

l. Limitations on Offers: The Company must have reasonable grounds to believe, when making an Options Offer, that the number of Shares to be received on exercise of Options offered under an Options Offer, when aggregated with the number of Shares issued or that may be issued as a result of offers made in reliance on the Class Order at any time during the previous 3 year period under an employee incentive scheme covered by the Class Order or an ASIC exempt arrangement of a similar kind to an employee incentive scheme, will not exceed 5% of the total number of Shares on issue at the date of the Options Offer.
13.6.2 Koligo Concessional Incentive Option Plan

The Koligo Concessional Incentive Option Plan contains standard terms to those set out in the Koligo Incentive Option Plan along with the following additional terms:

a. **Leaver Provisions:** where an Eligible Participant ceases to be employed or contracted by the Company or an associated body corporate (Leaver), the Board may, in its absolute discretion:
   i. serve a notice on the Leaver advising that some or all the Leaver’s unvested Options have lapsed;
   ii. serve a notice on the Leaver requiring the Leaver to sell some or all of the Leaver’s vested Options for fair market value to any person nominated by the Board; or
   iii. allow the Leaver to retain some or all the Leaver’s Options.

b. **Cashless Exercise:** The Plan also allows Eligible Participants to exercise vested Options by way of a ‘cashless exercise’. Where an Eligible Participant makes such an election, rather than the participant being required to pay the exercise price of each Option to be exercised, the Company will issue the Eligible Participant with a smaller number of Shares on the exercise of the Options representing the difference between the value of the Shares to be issued and the exercise price of the Option. Where the Options are exercised by a ‘cashless exercise’, the Company will only issue such number of Shares as is equivalent to the number of Options being exercised multiplied by the excess of the average Share price over the exercise price of the Options divided by the average Share price and then rounded down to a whole number of Shares.

c. **Loan:** An Eligible Participant who is to be granted Options may request the Company to grant a loan up to the total amount payable in respect of the exercise price of the Options granted to the Eligible Participant (Loan), on the following terms:
   i. the Loan will be interest free;
   ii. the Loan will be deemed to have been made at the time the Company issues the Shares on exercise of the Options to the Eligible Participant;
   iii. the Loan shall be applied by the Company directly toward payment of the exercise price of the Options on exercise of such Options by the Eligible Participant;
   iv. the Company will apply any cash dividends in respect of Shares issued on exercise of the Options to repayment of any outstanding Loan amount;
   v. the Loan repayment date and the manner for making such payments shall be determined by the Board and set out in the offer of Options;
   vi. an Eligible Participant must repay the Loan in full by the Loan repayment date but may elect to repay the Loan amount in respect of any or all of the exercised Options at any time prior to the Loan repayment date;
   vii. the Company shall have a lien over the Shares issued on exercise of the Options and in respect of which a Loan is outstanding and the Company shall be entitled to sell those Shares in the event the Eligible Participant does not repay the Loan by the repayment date;
   viii. the Loan is repayable in full where the Eligible Participant suffers an insolvency event or breaches any condition of the Loan or the Plan;
   ix. an Eligible Participant must not transfer, assign, encumber or otherwise deal with the Shares issued on exercise of the Options until the Loan has been fully repaid;
   x. a Loan will be non-recourse except against the Shares issued on exercise of Options issued under the Plan and which are held by the Eligible Participant to which the Loan relates; and
   xi. the Board may, in its absolute discretion, agree to forgive a Loan made to an Eligible Participant.

13.7 Interests of Directors

Other than as set out in this Prospectus, no Director or proposed Director holds, or has held within the 2 years preceding lodgement of this Prospectus with the ASIC, any interest in:

a. the formation or promotion of the Company;

b. any property acquired or proposed to be acquired by the Company in connection with:
   i. its formation or promotion; or
   ii. the Offers; or
13.8 Interests of Experts and Advisers

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

a. person 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;

b. promoter of the Company; or

c. underwriter (but not a sub-underwriter) to the issue or a financial services licensee named in this Prospectus as a financial services licensee involved in the issue, holds, or has held within the 2 years preceding lodgement of this Prospectus with the ASIC, any interest in:

d. the formation or promotion of the Company;

e. any property acquired or proposed to be acquired by the Company in connection with:

   i. its formation or promotion; or
   
   ii. the Offers; or

f. the Offers,

and no amounts have been paid or agreed to be paid and no benefits have been given or agreed to be given to any of these persons for services provided in connection with:

g. the formation or promotion of the Company; or

h. the Offers.

HLB Mann Judd Corporate (NSW) Pty Ltd has acted as Investigating Accountant and has prepared the Independent Limited Assurance Report which is included in Section 9 of this Prospectus. The Company estimates it will pay HLB Mann Judd Corporate (NSW) Pty Ltd a total of $25,000 (excluding GST) for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, HLB Mann Judd Corporate (NSW) Pty Ltd has not received fees from the Company.

K&L Gates LLP has acted as Intellectual Property Counsel in relation to the Public Offer and has prepared the Intellectual Property Report which is included in Section 8 of this Prospectus. The Company estimates it will pay K&L Gates LLP a total of approximately $25,000 (excluding GST) for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, K&L Gates LLP has not received fees from the Company.

Steinepreis Paganin has acted as the solicitors to the Company in Australia in relation to the Offers. The Company estimates it will pay Steinepreis Paganin $150,000 (excluding GST) for these services. Subsequently, fees will be charged in accordance with normal charge out rates. During the 24 months preceding lodgement of this Prospectus with the ASIC, Steinepreis Paganin has not received fees from the Company.

Moses & Singer LLP has acted as the solicitors to the Company in the United States in relation to the Offers. The Company estimates it will pay Moses & Singer LLP approximately $125,000 (excluding GST) for these services. Subsequently, fees will be charged in accordance with normal charge out rates. During the 24 months preceding lodgement of this Prospectus with the ASIC, Moses & Singer LLP has not received fees from the Company.

APP Securities Pty Ltd has acted as Joint Lead Manager in relation to the Public Offer. The Company estimates it will pay APP Securities Pty Ltd the fees set out in Section 12.2 for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, APP Securities Pty Ltd has not received fees from the Company.

Novus Capital Limited has acted as Joint Lead Manager in relation to the Public Offer. The Company estimates it will pay Novus Capital Limited the fees set out in Section 12.2 for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, Novus Capital Limited has not received fees from the Company.

Brentridge Capital Pty Ltd has acted as Corporate Advisor in relation to the Public Offer. The Company estimates it will pay Brentridge Capital Pty Ltd the fees set out in Section 12.3 for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, Brentridge Capital Pty Ltd has not received fees from the Company.

Buchanan Ingersoll & Rooney PC has acted as U.S Legal Counsel in respect of FDA matters in relation to the Public Offer. The Company estimates it will pay Buchanan
Ingersoll & Rooney PC approximately $47,000 for these services. During the 24 months preceding lodgement of this Prospectus with the ASIC, Buchanan Ingersoll & Rooney PC has not received fees from the Company.

13.9 Consents

Each of the parties referred to in this Section:

a. does not make, or purport to make, any statement in this Prospectus other than those referred to in this Section; and

b. to the maximum extent permitted by law, expressly disclaim and take no responsibility for any part of this Prospectus other than a reference to its name and a statement included in this Prospectus with the consent of that party as specified in this Section.

HLB Mann Judd Corporate (NSW) Pty Ltd has given its written consent to being named as Investigating Accountant of the Company in this Prospectus and to the inclusion of the Independent Limited Assurance Report in Section 9 of this Prospectus in the form and context in which the information and report is included. HLB Mann Judd Corporate (NSW) Pty Ltd has not withdrawn its consent prior to lodgement of this Prospectus with the ASIC.

K&L Gates has given its written consent to being named as the Intellectual Property Counsel of the Company in this Prospectus and to the inclusion of the Intellectual Property Report in Section 8 of this Prospectus in the form and context in which the report is included. K&L Gates has not withdrawn its consent prior to lodgement of this Prospectus with the ASIC.

Steinepreis Paganin has given its written consent to being named as the Australian solicitors to the Company in this Prospectus. Steinepreis Paganin has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.

Moses & Singer LLP has given its written consent to being named as the United States solicitors to the Company in this Prospectus. Moses & Singer LLP has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.

APP Securities Pty Ltd has given its written consent to being named as Joint Lead Manager to the Public Offer. APP Securities Pty Ltd has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.

Novus Capital Limited has given its written consent to being named as Joint Lead Manager to the Public Offer. Novus Capital Limited has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.

Brentridge Capital Pty Ltd has given its written consent to being named as Corporate Advisor to the Public Offer. Brentridge Capital Pty Ltd has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.

CohnReznick LLP has given its written consent to being named in this Prospectus as the auditor of Koligo and to the inclusion of the audited financial statements for Koligo for the period from inception (7 March 2016) to 31 December 2016 and for the 12 months ended 31 December 2017 and 31 December 2018 (which financial statements have been incorporated by reference into this Prospectus as described in Section 3.15) and has not withdrawn its consent prior to lodgement of this Prospectus with the ASIC.

Buchanan Ingersoll & Rooney PC has given its written consent to being named as U.S Legal Counsel in respect of FDA matters to the Public Offer. Buchanan Ingersoll & Rooney PC has not withdrawn its consent prior to the lodgement of this Prospectus with the ASIC.
13.10 Expenses of the Offers

The total expenses of the Offers (excluding GST) are estimated to be approximately $1,194,536 for minimum subscription or $1,255,909 for full oversubscriptions and are expected to be applied towards the items set out in the table below:

<table>
<thead>
<tr>
<th>ITEM OF EXPENDITURE</th>
<th>MINIMUM SUBSCRIPTION ($)</th>
<th>FULL OVERSUBSCRIPTION NUMBER ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASIC fees</td>
<td>3,206</td>
<td>3,206</td>
</tr>
<tr>
<td>ASX fees</td>
<td>116,659</td>
<td>118,032</td>
</tr>
<tr>
<td>Commissions</td>
<td>360,000</td>
<td>420,000</td>
</tr>
<tr>
<td>Joint Lead Manager Fee</td>
<td>200,000</td>
<td>200,000</td>
</tr>
<tr>
<td>Legal Fees</td>
<td>322,000</td>
<td>322,000</td>
</tr>
<tr>
<td>Intellectual Property Counsel’s Fees</td>
<td>23,676</td>
<td>23,676</td>
</tr>
<tr>
<td>Investigating Accountant’s Fees</td>
<td>25,000</td>
<td>25,000</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>143,995</td>
<td>143,995</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,194,536</strong></td>
<td><strong>1,255,909</strong></td>
</tr>
</tbody>
</table>

13.11 Continuous disclosure obligations

Following admission of the Company to the Official List, 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 Company’s securities.

Price sensitive information will be publicly released through ASX before it is disclosed to shareholders and market participants. Distribution of other information to shareholders and market participants will also be managed through disclosure to the ASX. In addition, the Company will post this information on its website after the ASX confirms an announcement has been made, with the aim of making the information readily accessible to the widest audience.

13.12 Electronic Prospectus

If you have received this Prospectus as an electronic Prospectus, please ensure that you have received the entire Prospectus accompanied by the Application Form. If you have not, please contact the Company and the Company will send you, for free, either a hard copy or a further electronic copy of this Prospectus or both. Alternatively, you may obtain a copy of this Prospectus from the website of the Company at www.koligo.net.

The Company reserves the right not to accept an Application Form from a person if it has reason to believe that when that person was given access to the electronic Application Form, it was not provided together with the electronic Prospectus and any relevant supplementary or replacement prospectus or any of those documents were incomplete or altered.
13.13 Clearing House Electronic Sub-Register System (CHESS) and Issuer Sponsorship

The Company will apply to participate in CHESS, for those investors who have, or wish to have, a sponsoring stockbroker. Investors who do not wish to participate through CHESS will be issuer sponsored by the Company.

Electronic sub-registers mean that the Company will not be issuing certificates to investors. Instead, investors will be provided with statements (similar to a bank account statement) that set out the number of Shares issued to them under this Prospectus. The notice will also advise holders of their Holder Identification Number or Security Holder Reference Number and explain, for future reference, the sale and purchase procedures under CHESS and issuer sponsorship.

Electronic sub-registers also mean ownership of securities can be transferred without having to rely upon paper documentation. Further monthly statements will be provided to holders if there have been any changes in their security holding in the Company during the preceding month.

13.14 Privacy Statement

If you complete an Application Form, you will be providing personal information to the Company. The Company collects, holds and will use that information to assess your application, service your needs as a Shareholder and to facilitate distribution payments and corporate communications to you as a Shareholder.

The information may also be used from time to time and disclosed to persons inspecting the register, including bidders for your securities in the context of takeovers, regulatory bodies including the Australian Taxation Office, authorised securities brokers, print service providers, mail houses and the share registry.

You can access, correct and update the personal information that the Company holds about you. If you wish to do so, please contact the share registry at the relevant contact number set out in this Prospectus.

Collection, maintenance and disclosure of certain personal information is governed by legislation including the Privacy Act 1988 (as amended), the Corporations Act and certain rules such as the ASX Settlement Operating Rules. You should note that if you do not provide the information required on the application for Shares, the Company may not be able to accept or process your application.
14. DIRECTORS’ AUTHORITY

This 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 the ASIC.

_______________________________
PETER JAMES
Chairman

For and on behalf of
KOLIGO THERAPEUTICS LIMITED
15. GLOSSARY

Where the following terms are used in this Prospectus they have the following meanings:

$ means an Australian dollar.

Application Form means the application form attached to or accompanying this Prospectus relating to the Public Offer, the Consideration Offer or the Joint Lead Manager Offer.

ASIC means Australian Securities & Investments Commission.

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

ASX Listing Rules means the official listing rules of ASX.

Board means the board of Directors as constituted from time to time.

Closing Date means the closing date of the Offers as set out in the indicative timetable in the Investment Overview in Section 3.9 of this Prospectus (subject to the Company reserving the right to extend the Closing Date or close the Offers early).

Company means Koligo Therapeutics Limited (ACN 627 117 677).

Consideration Offer means the offer of the Shares and Performance Shares in accordance with the Exchange Agreement.

Constitution means the constitution of the Company.

Corporations Act means the Corporations Act 2001 (Cth).

Directors means the directors of the Company at the date of this Prospectus.

Exchange has the meaning set out in Section 12.1.

Exchange Agreement has the meaning set out in Section 12.1.

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.

Included Documents has the meaning set out in Section 3.15.

Joint Lead Manager Application Form means the application form attached to or accompanying this Prospectus relating to the Joint Lead Manager Offer.

Joint Lead Manager Mandates means the mandates between the Company and the Joint Lead Managers summarised in Section 12.2.

Joint Lead Manager Offer means the Offer of Options to the Joint Lead Managers as set out at Section 5.2 of this Prospectus.

Koligo means Koligo Therapeutics Inc, a company incorporated in the Commonwealth of Kentucky, in the United States, on 7 March 2016 and having a place of business at 204 South Floyd Street, Louisville, Kentucky, United States of America.

Listing Approval means ASX granting conditional approval for the Company to be admitted to the Official List and for Official Quotation of the Shares.

Listing Date means the date that the Company is admitted to the Official List.

Long Hill Loan has the meaning set out in Section 12.13.

Offers means the Public Offer, the Consideration Offer and the Joint Lead Manager Offer.

Official List means the official list of ASX.

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

Option means an option to acquire a Share.

Optionholder means a holder of an Option.

Performance Share means a performance share in the Company with the terms and conditions set out in Section 13.5.

Prospectus means this prospectus.

Public Offer means the public offer of Shares pursuant to this Prospectus as set out in Section 5 of this Prospectus.

Recommendations has the meaning set out in Section 11.2.

Regulation S has the meaning set out in Section 5.7.1.

Section means a section of this Prospectus.

Securities means Shares, Options and Performance Shares.
Securities Act has the meaning set out in Section 5.7.1.

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

Shareholder means a holder of Shares.

US$ means a U.S. dollar.

Williams Loan has the meaning set out in Section 12.14
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus dated 8 February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).
KOLIGO THERAPEUTICS LIMITED
ACN 627 117 677

Application Form

This is an Application Form for Ordinary Fully Paid Shares ('Shares') in Koligo Therapeutics Limited (ACN 627 117 677) ('Company'), made under the terms set out in the Replacement Prospectus dated 25 February 2019 ('Replacement Prospectus'). This Application Form and payment of your application monies must be received by the registry, Automic Registry Services, by the closing date. The expiry date of the Replacement Prospectus is the date which is 13 months after the Original Prospectus dated 8 February 2019.

To make payment of your application monies by BPAY®: Apply online by following the instructions at https://automic.com.au/koligotherapeutics.html and completing a BPAY® payment. Your online Application Form and BPAY® payment must be completed and received by no later than 5.00pm (AEDT) on the Closing Date.

To make payment of your application monies by Electronic Funds Transfer (EFT): Please email your completed Application Form to koligo@automicgroup.com.au. The registry will then contact you with your unique payment reference number and will outline the procedure for making payment by EFT. All EFT payments and the associated completed Application Form must be received by the registry by 5.00pm (AEDT) on the Closing Date. Applicants should be aware of their financial institution's cut-off time. It is the Applicant's responsibility to ensure funds are submitted correctly by the Closing Date and time.

To make payment of your application monies by Cheque: If you wish to make payment by cheque, your completed Application Form and your cheque must be received by the Company's registry, Automic Registry Services, by 5.00pm (AEDT) on the Closing Date.

The Replacement Prospectus contains important information relevant to your decision to invest and you should read the entire Replacement Prospectus before applying for Shares. If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser.

1. Number of Shares applied for
   Application payment (multiply box 1 by A$0.20 per share)
   Applications must be for a minimum of 10,000 Shares (A$2,000), and thereafter in multiples of 500 Shares (A$100)

2. Applicant name(s) and postal address: refer to naming standards for correct form of registrable title(s) overleaf
   Name of Applicant 1
   Name of Applicant 2 or <Account Designation>
   Name of Applicant 3 or <Account Designation>
   Postal address
   Unit / Street Number / Street name or PO Box
   Suburb/Town
   State
   Postcode
   Non-Australian Residents – additional information required
   Country
   Country Code
   Postcode

3. Contact details
   Telephone Number
   Email Address
   By providing your email address, you elect to receive all communications despatched by the Company electronically (where legally permissible).

4. CHESS Holders Only – Holder Identification Number (HIN)
   X

5. TFN/ABN/Exemption Code
   Applicant 1
   Applicant #2
   Applicant #3
   Note: if the name and address details in sections 2 do not match exactly with your registration details held at CHESS, any Shares issued as a result of your Application will be held on the Issuer Sponsored subregister.

If NOT an individual TFN/ABN, please note the type in the box
C = Company; P = Partnership; T = Trust; S = Super Fund
INSTRUCTIONS FOR COMPLETING THE FORM

YOU SHOULD READ THE REPLACEMENT PROSPECTUS CAREFULLY BEFORE COMPLETING THIS APPLICATION FORM.

Please complete all relevant sections of this Application Form using BLOCK LETTERS.

The Replacement Prospectus contains important information relevant to your decision to invest and you should read the entire Replacement Prospectus before applying for Shares.

If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser. To meet the requirements of this Corporations Act, this Application Form must not be distributed unless included in, or accompanied by, the Replacement Prospectus and any supplementary prospectus (if applicable).

While the Replacement Prospectus is current, the Company will send paper copies of the Replacement Prospectus, and any supplementary prospectus (if applicable) and an Application Form, on request and without charge.

1. Shares applied for & payment amount - Enter the number of Shares you wish to apply for. Your Application must be for a minimum of 10,000 Shares ($A2,000). Applications for greater than 10,000 shares must be in multiples of 500 Shares ($A100). Next, enter the amount of the Application Monies payable. To calculate this amount, multiply the number of Shares applied for by the offer price, which is $A2.00 per share.

2. Applicant name(s) and postal address - Note that ONLY legal entities can hold Shares. The application must be in the name of a natural person(s), companies or other legal entities acceptable by the Company. At least one full given name and surname is required for each natural person. You should refer to the table above for the correct forms of registrable title(s). Applicants using the wrong form of names may be rejected. Next, enter your postal address for the registration of your holding and all correspondence. Only one address can be recorded against a holding.

3. Contact Details - Please provide your contact details for us to contact you between 9:00am AEDT and 5:00pm AEDT should we need to speak to you about your application. In providing your email address you accept to receive electronic communications. You can change your communication preferences at any time by logging in to the Investor Portal accessible at https://investor.automic.com.au/#/home

4. CHESS Holders - If you are sponsored by a stockbroker or other participant and you wish to hold shares allotted to you under this Application on the CHESS sub-register, enter your CHESS HIN. Otherwise leave the section blank and on allotment you will be sponsored by the Company and a “Securityholder Reference Number” (SRN) will be allocated to you.

5. TFN/ABN/Exemption - If you wish to have your Tax File Number, ABN or Exemption registered against your holding, please enter the details. Collection of TFN’s is authorised by taxation laws but quotation is not compulsory and it will not affect your Application.

6. Payment - To make payment via BPAY®: Please apply online using an online Application Form at https://automic.com.au/koligotherapeutics.html and you will be given a BPAY® biller code and unique customer reference number for your Application once you have completed your online Application Form.

To make payment by EFT: Please email your completed Application Form to koligo@automicgroup.com.au. The registry will then contact you with your unique payment reference number and will outline the procedure for making payment by EFT. Applicants should be aware of their financial institution’s cut-off time. It is the Applicant’s responsibility to ensure funds are submitted correctly by the Closing Date and time.

To make payment via cheque: Cheques must be drawn on an Australian branch of a financial institution in Australian currency, made payable to “Koligo Therapeutics Limited” and crossed “Not Negotiable”. Sufficient cleared funds should be held in your account as your acceptance may be rejected if your cheque is dishonoured.

**CORRECT FORMS OF REGISTRABLE TITLE**

Note that ONLY legal entities can hold Shares. The application must be in the name of a natural person(s), companies or other legal entities acceptable by the Company. At least one full given name and surname is required for each natural person.

<table>
<thead>
<tr>
<th>Type of Investor</th>
<th>Correct Form of Registration</th>
<th>Incorrect Form of Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>Mr John Richard Sample</td>
<td>J R Sample</td>
</tr>
<tr>
<td>Joint Holdings</td>
<td>Mr John Richard Sample &amp; Mrs Anne Sample</td>
<td>John Richard &amp; Anne Sample</td>
</tr>
<tr>
<td>Company</td>
<td>ABC Pty Ltd</td>
<td>ABC P/L or ABC Co</td>
</tr>
<tr>
<td>Trusts</td>
<td>Mr John Richard Sample</td>
<td>John Sample Family Trust</td>
</tr>
<tr>
<td>Superannuation Funds</td>
<td>Mr John Sample &amp; Mrs Anne Sample</td>
<td>John &amp; Anne Superannuation Fund</td>
</tr>
<tr>
<td>Partnerships</td>
<td>Mr John Sample &amp; Mrs Anne Sample</td>
<td>John Sample &amp; Son</td>
</tr>
<tr>
<td>Clubs/Unincorporated Bodies</td>
<td>Mr John &amp; Annie Superannuation Fund</td>
<td>Food Health Club</td>
</tr>
<tr>
<td>Deceased Estates</td>
<td>Mr John Sample</td>
<td>Estate Lat &amp; Anne Sample A/C</td>
</tr>
</tbody>
</table>

**DECLARATIONS**

BY SUBMITTING THIS APPLICATION FORM WITH THE APPLICATION MONIES, YOU DECLARE THAT:

- you have received a paper or electronic copy of the Replacement Prospectus that accompanies this Application Form and have read the Replacement Prospectus in full and agree to be bound by the terms and conditions of the Public Offer as declared in the Replacement Prospectus;
- all details and statements made on the form are complete and accurate;
- where information has been provided about another individual, that individual’s consent has been obtained to transfer the information to the Company;
- the Company and their respective officers and agents are authorised to do anything on your behalf (including the completion and execution of documents) to enable the Shares to be allocated to you;
- you agree to be bound by the constitution of the Company;
- neither the Company nor any person or entity guarantees any particular rate of return on the Shares, nor do they guarantee the repayment of capital.

**LODGEMENT INSTRUCTIONS**

The Public Offer opens at 9.00am (AEDT) on 25 February 2019 and is expected to close at 5.00pm (AEDT) on 22 March 2019. The Company may elect to extend the Public Offer or close it (after the Public Offer is open) at any earlier date and time, without further notice. Applicants are therefore encouraged to submit their Applications as early as possible.

Completed Application Forms and cheques must be:

<table>
<thead>
<tr>
<th>POSTED TO:</th>
<th>DELIVERED TO (during business hours only - 9am to 5pm (AEDT)):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Koligo Therapeutics Limited</td>
<td>Koligo Therapeutics Limited</td>
</tr>
<tr>
<td>C/- Automic Pty Ltd</td>
<td>C/- Automic Pty Ltd</td>
</tr>
<tr>
<td>GPO Box 5233</td>
<td>Level 5, 126 Phillip Street</td>
</tr>
<tr>
<td>SYDNEY NSW 2001</td>
<td>SYDNEY NSW 2000</td>
</tr>
</tbody>
</table>

Your Application Form must be received by Automic no later than 5.00pm (AEDT) 22 March 2019

If you have any enquiries in respect of this Application, please contact Automic by either phone on 1300 288 664 (within Australia), +61 2 9698 5414 or at koligo@automicgroup.com.au.

**YOUR PRIVACY**

Automic Pty Ltd (ACN 152 260 814) trading as Automic advises that Chapter 2C of the Corporation Act 2001 requires information about you as a securityholder (including your name, address and details of the securities you hold) to be included in the public register of the entity in which you hold securities. Primarily, your personal information is used in order to provide a service to you. We may also disclose the information that is related to the primary purpose and it is reasonable for you to expect the information to be disclosed. You have a right to access your personal information, subject to certain exceptions allowed by law and we ask that you provide your request for access in writing (for security reasons). Our privacy policy is available on our website – www.automic.com.au
This is a Replacement Prospectus dated 25 February 2019. It replaces a prospectus issued in February 2019, relating to the Shares of Koligo Therapeutics Limited (ACN 627 117 677).