

# QBiotics Group PROSPECTUS

QBiotics Group Limited ACN 617 596 139

Offer of 11,111,111 fully paid ordinary shares at \$0.90 to raise \$10 million, with a minimum raising of \$5 million and a provision of oversubscriptions of up to \$2.5 million, from Existing Shareholders (shareholders who held Shares as at 5:00pm on the date of this Prospectus).

The minimum Application amount under the Offer is \$9,000 or 10.000 Shares.

This offer is not underwritten.

Investment in the Shares of QBiotics Group Limited should be considered speculative. This is an important document that should be read in its entirety. If you do not understand any part of this Prospectus, or any of its content, we recommend that you consult with your professional adviser.



### **Important Notice**

### **PUBLIC OFFER**

The Offer contained in this Prospectus is an invitation to apply for fully paid ordinary shares (Shares) in QBiotics Group Limited ACN 617 596 139 (QBiotics or Company). This Prospectus is issued by the Company.

The Company is not applying for listing on the Australian Securities Exchange (ASX) or any other securities exchange in connection with this Prospectus.

### **LODGEMENT**

This Prospectus is dated 17 May 2021 and a copy of this Prospectus was lodged with Australian Securities and Investments Commission (ASIC) on that date.

Neither ASIC nor its officers take any responsibility for the contents of this Prospectus or for the merits of the investment to which this Prospectus relates.

### **EXPIRY DATE**

No Shares will be allotted or issued on the basis of this Prospectus later than 13 months after the date of this Prospectus. Shares offered pursuant to this Prospectus will be issued on the terms and conditions set out in this Prospectus.

### **NOTE TO APPLICANTS**

The information in this Prospectus is not financial product advice and does not take into account your investment objectives, financial situation or particular needs. This Prospectus should not be construed as financial, taxation, legal or other advice.

This Prospectus is important and should be read in its entirety prior to deciding whether to invest in the Company's Shares. There are risks associated with an investment in the Shares and the Shares offered under this Prospectus must be regarded as a speculative investment. Some of the risks that should be considered are set out in Section 6 of this Prospectus. You should carefully consider these risks in light of your personal circumstances (including financial and tax issues). There may also be risks in addition to these that should be considered in light of your personal circumstances.

If you do not fully understand this Prospectus or are in doubt as to how to deal with it, you should seek professional guidance from your stockbroker, lawyer, accountant or other independent

professional adviser before deciding whether to invest in the Shares.

No person named in this Prospectus guarantees the Company's performance or the repayment of capital or any return on investment made pursuant to this Prospectus.

# NO OFFER WHERE OFFER WOULD BE ILLEGAL

This Prospectus does not constitute an offer or invitation in any place in which, or to any person to whom, it would not be lawful to make such an offer or invitation. No action has been taken to register or qualify the Shares in any jurisdiction outside Australia and New Zealand. Except as permitted in the jurisdictions set out below, the distribution of this Prospectus outside Australia and New Zealand may be restricted by law and persons who come into possession of this Prospectus outside Australia should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

### **New Zealand**

This offer to New Zealand investors is a regulated offer made under Australian and New Zealand law. In Australia, this is Chapter 8 of the Corporations Act 2001(Aust) and regulations made under that Act. In New Zealand, this is subpart 6 of Part 9 of the Financial Markets Conduct Act 2013 and Part 9 of the Financial Markets Conduct Regulations 2014.

This offer and the content of the offer document are principally governed by Australian rather than New Zealand law. In the main, the Corporations Act 2001 (Aust) and the regulations made under that Act set out how the offer must be made.

There are differences in how financial products are regulated under Australian law. For example, the disclosure of fees for managed investment schemes is different under the Australian regime. The rights, remedies, and compensation arrangements available to New Zealand investors in Australian financial products may differ from the rights, remedies, and compensation arrangements for New Zealand financial products.

Both the Australian and New Zealand financial markets regulators have enforcement responsibilities in relation to this offer. If you need to make a complaint about this offer, please contact the Financial Markets Authority, New

Zealand (http://www.fma.govt.nz). The Australian and New Zealand regulators will work together to settle your complaint.

The taxation treatment of Australian financial products is not the same as for New Zealand financial products.

If you are uncertain about whether this investment is appropriate for you, you should seek the advice of an appropriately qualified financial adviser.

The offer may involve a currency exchange risk. The currency for the financial products is not New Zealand dollars. The value of the financial products will go up or down according to changes in the exchange rate between that currency and New Zealand dollars. These changes may be significant.

If you expect the financial products to pay any amounts in a currency that is not New Zealand dollars, you may incur significant fees in having the funds credited to a bank account in New Zealand in New Zealand dollars.

If the financial products are able to be traded on a financial product market and you wish to trade the financial products through that market, you will have to make arrangements for a participant in that market to sell the financial products on your behalf. If the financial product market does not operate in New Zealand, the way in which the market operates, the regulation of participants in that market, and the information available to you about the financial products and trading may differ from financial product markets that operate in New Zealand.

### **European Union**

This Prospectus has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this Prospectus may not be made available, nor may Shares be offered for sale, in any member state of the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the "Prospectus Regulation").

In accordance with Article 1(4) of the Prospectus Regulation, an offer of Shares in each member state of the European Union is limited:

> to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation);

- to fewer than 150 natural or legal persons (other than qualified investors); or
- in any other circumstance falling within Article 1(4) of the Prospectus Regulation.

### Jersey (Channel Islands)

No offer or invitation to subscribe for shares may be made to the public in Jersey. Shares will be offered in Jersey only to existing shareholders of the Company and to the extent they constitute less than 50 persons.

### **Mauritius**

In accordance with The Securities Act 2005 of Mauritius, no offer of Shares may be made to the public in Mauritius without the prior approval of the Financial Services Commission. Mauritius Accordingly, this Offer is being made on a private placement basis only and does not constitute a public offering. As such, this document has not been approved or registered by the Mauritius Financial Services Commission and is for the exclusive use of the person to whom it is addressed. The Prospectus is confidential and should not be disclosed or distributed in any way without the express written permission of the Company.

### **United Kingdom**

Neither 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 New Shares.

Shares may not be offered or sold in the United Kingdom by means of this Prospectus or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This Prospectus is issued on a confidential basis in the United Kingdom to fewer than 150 persons who are Existing Shareholders of the Company. This document may not be distributed 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 Shares has only been

### **Important Notice**

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 document is being distributed only to, and is directed at, persons (i) 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"), (ii) 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 (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.

# FINANCIAL INFORMATION AND AMOUNTS

Section 7 sets out in detail the financial information referred to in this Prospectus and the basis of preparation for the financial information. The financial information has been prepared in accordance with the recognition and measurement principles prescribed by the Australian Accounting Standards issued by the Australian Accounting Standards Board, which are consistent with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board.

Given the fact that the Company is in an early stage of development, there are significant uncertainties associated with forecasting the future development and expenses of the Company. As such, the Directors believe that the Company is not in a position to forecast any future earnings for the Company. To date, the Company has not made a profit. Save as set out above, the financial amounts referred to in this Prospectus are expressed in Australian dollars unless stated otherwise.

### **DISCLAIMER**

Investors should not rely on any information which is not contained in this Prospectus in making a decision as to whether to acquire securities in the Company under the Offer. No person is authorised by the Company to give any information or make any representation in connection with the Offer that is not contained in the Prospectus. Any information

or representation not contained in this Prospectus may not be relied on as having been authorised by the Company, its Directors or any other person in connection with the Offer. The Company's business, financial condition, results of operations and prospects may have changed since the date of this Prospectus.

Except as required by law, and only to the extent so required, no person named in this Prospectus, nor any other person, guarantees the performance of the Company, the repayment of capital by the Company or the payment of a return on the Shares.

### FORWARD LOOKING STATEMENTS

Prospectus contains forward-looking statements concerning the Company's business, operations, financial performance and condition as well as the Company's plans, objectives and expectations for its business, operations, financial performance and condition. Any statements contained in this Prospectus that are not of historical facts may be deemed to be forwardlooking statements. You can identify these statements by words such as "aim", "anticipate", "assume", "believe", "could", "due", "estimate", "expect", "goal", "intend", "may", objective", "predict", "potential", "positioned", "should", "target", "will", "would" and other similar expressions that are predictions of or indicate future events and future trends.

These forward-looking statements are based on current expectations, estimates, forecasts and projections about the Company's business and the industry in which the Company operates and management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties. assumptions and other factors that are in some cases beyond the Company's control. As a result, any or all of the Company's forward-looking statements in this Prospectus may turn out to be Factors that may cause such inaccurate. differences include, but are not limited to, the risks described in Section 6.

Potential investors and other readers are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. These forward-looking statements speak only as at the date of this Prospectus. Unless required by law, the Company does not intend to publicly update or revise any forward-looking

statements to reflect new information or future events or otherwise. You should, however, review the factors and risks the Company describes in the reports after the date of this Prospectus.

This Prospectus contains market data and industry forecasts that were obtained from industry publications, third-party market research and publicly available information. These publications generally state that the information contained in them has been obtained from sources believed to be reliable, but the Company has not independently verified the accuracy and completeness of such information.

Some numerical figures included in this Prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in certain tables may not be an arithmetic aggregation of the figures that preceded them.

### **EXPOSURE PERIOD**

The Corporations Act prohibits the Company from processing Applications under the Offer in the seven day period after the date of lodgement of the Prospectus with ASIC (Exposure Period).

This period may be extended by ASIC for a further period of up to seven days. The purpose of the Exposure Period is to enable this Prospectus to be examined by market participants prior to the raising of funds under the Offer. That examination may result in the identification of deficiencies in this Prospectus, in which case any Application received may need to be dealt with in accordance with section 724 of the Corporations Act.

This Prospectus will be made generally available to during the Exposure Period, without the Application Form, by being posted on the QBiotics' website at the following address: <a href="https://www.qbiotics.com/prospectus">www.qbiotics.com/prospectus</a>. Applications received during the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on any Applications received during the Exposure Period.

### **ELECTRONIC PROSPECTUS**

This Prospectus will be made available in electronic form on QBiotics' website at the following address: <a href="https://www.qbiotics.com/prospectus">www.qbiotics.com/prospectus</a>. The information on <a href="https://www.qbiotics.com/prospectus">www.qbiotics.com/prospectus</a> does not form part of the Prospectus and is not to be interpreted as part of, nor incorporated into, this Prospectus.

The distribution of this Prospectus in electronic form outside Australia and New Zealand may be restricted by law. Persons who access the electronic version of this Prospectus should ensure that they download and read the entire Prospectus. If unsure about the completeness of the Prospectus received electronically, or a printed version, you should contact the Company for a paper copy of the Prospectus, which will be supplied free of charge.

Applications for Shares under this Prospectus may only be made via the Application Form attached to or accompanying this Prospectus. By making an Application, you declare that you were given access to the Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing the Application Form on to another person unless it is attached to a hard copy of the Prospectus or the complete and unaltered electronic version of the Prospectus. If this Prospectus is found to be deficient, any Applications may need to be dealt with in accordance with section 724 of the Corporations Act.

### **PRIVACY**

By completing an Application Form, you are providing personal information to the Company and Link Market Services Limited as the Share Registry, which is contracted by the Company to manage Applications, and consenting to the collection and use of that personal information in accordance with these terms. The personal information will be collected, held, and used both in and outside of Australia by the Company, and the Share Registry on its behalf, to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration of your investment. If you do not wish to provide this information, the Company may not be able to process your Application.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included in the Company's public share register. This information must continue to be included in the Company's public share register if you cease to be a Shareholder.

The Company and the Share Registry on its behalf, may disclose your personal information for purposes related to your investment to their agents and service providers (which may be located

### **Important Notice**

outside of Australia) including those listed below or as otherwise authorised under the Privacy Act:

- the Share Registry for ongoing administration of the Shareholder register;
- printers and other companies for the purposes of preparation and distribution of documents and for handling mail;
- market research companies for the purpose of analysing the Company's Shareholder base and for product development and planning; and
- legal and accounting firms, auditors, management consultants and other advisers for the purpose of administering and advising on the Shares and for associated actions.

The Company's agents and service providers may be located outside Australia where your personal information may not receive the same level of protection as that afforded under Australian law.

Under the Privacy Act, you may request access to your personal information held by, or on behalf of, the Company. You may obtain further information about the Company's privacy practices by contacting the Company or the Share Registry, details of which are set out elsewhere in this Prospectus. You may be required to pay a reasonable charge to the Share Registry in order to access your personal information.

For further information about the Company's privacy policy, please also refer to www.gbiotics.com/privacy.

The Company aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact the Company or the Share Registry if any of the details you have provided change.

### **DEFINITIONS AND ABBREVIATIONS**

Defined terms and abbreviations used in this Prospectus are explained in Section 11.

### **TIME**

Defined terms and abbreviations used in this Prospectus, unless specified otherwise, have the meaning given in the glossary in Section 11. Unless otherwise stated or implied, reference to times in this Prospectus are to AEST. Unless otherwise stated or implied, references to dates or years are to a calendar year.

### **COMPANY'S WEBSITE**

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

### **PHOTOGRAPHS AND DIAGRAMS**

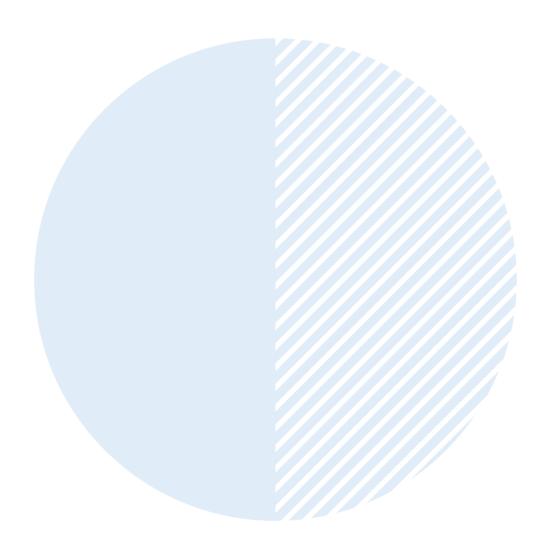
Photographs used in this Prospectus which do not have any descriptions are for illustration only and should not be interpreted to mean that any person shown endorses this Prospectus or its contents or that the assets shown in them are owned by the Company.

Diagrams used in the Prospectus are illustrative only and may not be drawn to scale. Unless otherwise stated, all data contained in charts, graphs and tables is based on information available as at the date of this Prospectus.

### **QUESTIONS**

If you have any questions in relation to the Offer or the Company, contact QBiotics by emailing <a href="mailto:investors@qbiotics.com">investors@qbiotics.com</a> or phoning (07) 3870 8933 between 9.00am and 5.00pm AEST, Monday to Friday.

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





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Key Offer Information

# **Key Offer Information**

This Prospectus provides investors with information on an opportunity to purchase Shares in QBiotics Group Limited.

### 1.1 Key dates

Prospectus Date	17 May 2021
Opening Date for Applications (9.00am)	25 May 2021
Closing Date for Applications (5.00pm)	21 June 2021
Issue and allotment of Shares (completion of Offer)	25 June 2021
Expected dispatch of Holding Statements	30 June 2021

The above key dates are indicative only. All times are AEST. The Company reserves the right to vary the dates and times set out above subject to the Corporations Act and other applicable laws. In particular, the Company reserves the right to extend the Closing Date or accept late Applications without notifying any recipients of this Prospectus or any Applicants. Investors who wish to submit an Application are encouraged to do so as soon as practicable after the Opening Date.

### 1.2 Key offer details

Offer Price per Share	\$0.90
Total number of Shares on issue as at the date of this Prospectus	470,358,228
Minimum investment application amount	\$9,000

	Based on Minimum Subscription of \$5 million	Based on Maximum Subscription of \$10 million	Based on Oversubscription of \$12.5 million
Total number of Shares to be issued under the Offer	5,555,556	11,111,111	13,888,889
Total number of Shares on issue at completion of the Offer (note 1)	475,913,784	481,469,339	484,247,117
Gross cash proceeds from the Offer (note 2)	\$5,000,000	\$10,000,000	\$12,500,000

Note 1 - Includes the maximum number of Shares available under this Offer plus Shares retained by the Existing Shareholders. Note 2 - Equal to the Shares issued under the Offer multiplied by the Offer Price.

### 1.3 How to invest

Applications for Shares can only be made by completing and lodging an Application Form. Instructions on how to apply for Shares are set out in Section 8.5.

### 1.4 Questions

If you have any questions about the Offer or the Company, please contact QBiotics by emailing <a href="mailto:investors@qbiotics.com">investors@qbiotics.com</a> or phoning (07) 3870 8933, if calling within Australia, or +61 7 3870 8933, if calling from outside Australia, from 9.00am to 5.00pm (AEST) Monday to Friday.

If you are in any doubt as to what to do in relation to the Offer, you should seek professional advice from a licensed financial adviser, accountant, stockbroker, lawyer or other professional adviser before deciding whether to invest in the Company.





Chairman's and CEO's Letter

### Chairman's & CEO's Letter



17 May 2021

Dear fellow shareholders,

We are writing to you at what is a pivotal time in the history of our Company.

Since addressing shareholders at our Annual General Meeting last November, QBiotics has continued to consolidate its position by progressing product development, strengthening our pipeline and implementing a strategy to underpin strong and continuous advancement of the company towards our eventual goal of an Australian based pharmaceutical company.

Following its earlier registration in Europe via the European Medicines Agency, the UK via the UK Veterinary Medicines Directorate and Switzerland's Swissmedic, our lead veterinary drug, STELFONTA® achieved marketing authorisation from the US Food and Drug Administration late 2020. STELFONTA® is now marketed in all of these major regions which is a major achievement for the Company. Our application for registration in Australia is progressing and we hope to have STELFONTA® also marketed here in the coming months.

The above milestones occurred in parallel with progress in diversifying our human pharmaceutical product pipeline. We now have four human clinical trials either in place, or in planning, where our drug candidate, tigilanol tiglate, will be investigated for its potential across a range of cancer types, including Head and Neck Squamous Cell Carcinoma, Melanoma and Soft Tissue Sarcoma.

In addition to our own development of tigilanol tiglate's use as a monotherapy, QBiotics negotiated a collaboration with MSD (tradename of Merck & Co., Inc., Kenilworth, NJ, USA), to evaluate the use of tigilanol tiglate in combination with MSD's anti-PD-1 therapy, Keytruda® (pembrolizumab) in melanoma patients.

Wound healing is our next focus area. Our first in class wound healing drug candidate EBC-1013, which is demonstrating potential to address a range of problem wounds, is progressing steadily through preclinical and veterinary clinical development.

In March this year, we welcomed Australian institutional investor, TDM Growth Partners (TDM) to our share register with an investment in QBiotics of \$50 million. TDM is an excellent match for QBiotics with ethics and vision for the future of QBiotics much aligned with our own. TDM is a global investment firm that invests in fast growing companies run by passionate management teams. Their fund operates on long-term time horizons with a commitment to help scale investee businesses.

www.qbiotics.com

Subsequent to the cornerstone investment by TDM, we accepted a further \$22.55 million placement from existing sophisticated shareholders. Pursuant to this Prospectus, we are offering our retail shareholders the opportunity to participate at the same price as the TDM and existing sophisticated investor placements.

The funds raised from these initial rounds of investment will be directed to further human clinical development of tigilanol tiglate, progress marketing of STELFONTA® and build the QBiotics team.

Funds raised under this Prospectus will be specifically directed towards human and veterinary clinical development of our wound healing drug candidate EBC-1013.

We encourage you to read this document carefully and in its entirety before making an investment decision. In particular, you should consider the investment risks outlined in Section 6 before deciding whether or not to participate

We invite you to consider the Offer contained within this Prospectus, and as always, invite you to make contact with any questions you may have.

We thank you for your support.

Yours sincerely,

Rick Holliday Smith

Chairman

Dr Victoria Gordon

**CEO & Managing Director** 

If you are in any doubt as to what to do in relation to the Offer, you should seek professional advice from a licensed financial adviser, accountant, stockbroker, lawyer or other professional adviser before deciding whether to invest in the Company.

www.qbiotics.com



The following table sets out common questions and corresponding answers in relation to the Offer, and where to find more information within this Prospectus. You should read this section in conjunction with the remainder of the information contained in this Prospectus, including the Risk Factors in Section 6. If you are in doubt as to the course you should follow, please consult your professional adviser.

### 3.1 Business overview

Question	Answer	Where to find more information
Who is the issuer of this Prospectus?	QBiotics Group Limited ACN 617 596 139 (QBiotics or the Company).	Section 5
What does the Company do?	QBiotics is in the business of discovery, development and commercialisation of new pharmaceuticals. The Company specialises in plant derived small molecules that function by cell signalling to address challenging medical conditions in humans and companion animals (dogs, cats and horses). QBiotics has a pipeline of products, with current development focus on solid tumour anticancer and wound healing. The human and veterinary pharmaceutical programs are structured to be mutually supportive. Early veterinary clinical data has the potential to provide initial proof of concept of our drugs to inform the human program. In return, the scientific rigor of the human program potentially supports our veterinary program. In addition, veterinary products can be quicker to market, potentially creating early revenue streams. QBiotics lead oncology pharmaceutical tigilanol tiglate (previously known as EBC-46), is an intratumoural treatment with the potential to treat a range of solid tumours in humans and initially dogs (with horses and cats possibly to follow).  A Human Clinical Phase I/IIA safety trial has been completed. There are currently four tigilanol tiglate human oncology clinical trials in progress or planning including for head and neck squamous cell carcinoma (HNSCC), melanoma (as a monotherapy and in combination with the anti PD1 blocker Keytruda®), and soft tissue sarcoma (STS). QBiotics has registered tigilanol tiglate, under the brand name STELFONTA® as a veterinary pharmaceutical to treat mast cell tumours (MCT) in dogs under the US Food and Drug Administration – Center for Veterinary Medicines (FDA-CVM), the European Medicines Agency (EMA), Switzerland's Swissmedic, and the UK Veterinary Medicines Directorate (VMD). We are currently awaiting registration approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Marketing of the drug in Europe, the UK and the USA has commenced.  QBiotics' lead wound healing drug candidate is EBC-1013 (previously known as WH-1). EBC-1013 is a semi-synt	Section 4

Question	Answer	Where to find more information
	Intellectual Property (IP) and technology relating to these QBiotics products are fully owned by QBiotics Pty Ltd (previously QBiotics Limited), a subsidiary of QBiotics.  As at 31 December 2020, QBiotics has invested approximately \$89.7 million into the development of IP and technology since 2010.	
Does the Company generate revenue?	QBiotics currently generates revenue from sales of STELFONTA® in the USA, European and UK markets, having received marketing authorisation from the US FDA-CVM, EMA, Swissmedic and the UK VMD for treating canine MCT. QBiotics has applied for registration of STELFONTA® under the APVMA and, if granted, expects to generate revenue from the Australian veterinary market approximately from late 2021.	Section 4
What is the Company's business model and business plan?	For veterinary pharmaceuticals, QBiotics business model is to develop products to registration with major regulatory authorities, and then attempt to partner with global veterinary pharmaceutical companies for marketing and distribution of products. QBiotics has partnered with the global veterinary health company Virbac for marketing and distribution of STELFONTA® in the USA, Europe, UK and Australia. Further information about the Virbac agreement is contained in Section 10. For human pharmaceuticals, QBiotics plans to develop products to 'proof of concept' stage Human Clinical Phase IIA/B where the products safety and efficacy is defined, before attempting to license on to pharmaceutical companies for final development and marketing in return for one or a combination of upfront fees, milestone payments, and/or royalties on sales.  QBiotics has a clinical collaboration deal with MSD (Merck Sharp & Dohme, tradename of Merck & Co., USA) for a trial combining MSDs immune checkpoint inhibitor pharmaceutical Keytruda with tigilanol tiglate for the treatment of melanoma. Further information about the MSD agreement is contained in Section 10.  The Company's current business plans are as follows:  Tigilanol tiglate oncology veterinary product:  In conjunction with our marketing and distribution partner Virbac, grow the market share for STELFONTA® as a veterinary pharmaceutical for canine MCT in Australia and other relevant veterinary markets, and market the drug in these regions.  Tigilanol tiglate oncology human product:  Continue to develop tigilanol tiglate for a range of indications for the human market potentially through to Phase IIA/B and then attempt to partner with a pharmaceutical company for possible completion of development, registration, marketing and distribution. We currently believe it is too early to estimate when such a partnership might be identified.	Section 4

Question	Answer	Where to find more information
	Complete all necessary preclinical testing, and appropriate levels of product manufacturing, and then move into clinical trials for human markets. QBiotics plans to develop EBC-1013 through to at least Human Clinical Phase IIA, then attempt to partner with a global pharmaceutical company for final development, registration, marketing and distribution. We currently believe it is too early to estimate when such a partnership might be identified.  For the veterinary market, attempt to develop EBC-1013 through to registration under the regulatory authorities in the USA, EU, UK and Australia. Marketing and distribution is planned to be via partnering with a global veterinary pharmaceutical company.	
What Intellectual Property does QBiotics own?	QBiotics has full ownership of all Patents relating to both tigilanol tiglate and EBC-1013. Both tigilanol tiglate and EBC-1013 are novel molecules.	Section 9
How will the Company generate income?	For veterinary products, revenue may be generated through marketing and distribution deals. Revenue for the STELFONTA® marketing and distribution deal QBiotics has with Virbac is already being generated through USA, European and UK sales, with revenue from the Australian market expected from late 2021 if registration is achieved in Australia. For human products, if partnering at Clinical Phase IIA/B with a large human pharmaceutical company is successful, revenue may be derived from one or a combination of upfront licensing fees, milestone payments and/or royalties on sales following marketing of products.	Section 4
How does the Company expect to fund its operations?	<ul> <li>QBiotics expects to fund its operations by utilising a combination of:</li> <li>Capital raised under this Offer;</li> <li>Existing capital and future capital raises where necessary;</li> <li>Organic operating revenue generated from the ongoing sale of STELFONTA® in the USA, Europe and UK veterinary markets, and the Australian veterinary markets expected late 2021 if registration is successful;</li> <li>Organic operating revenue generated from sales of future veterinary products such as the wound healing drug candidate if development and registration is successful; and</li> <li>Potential sign on fees, milestone payments and/or royalties on sales for human products if development and partnering is successful.</li> </ul>	Section 4
Does the Company have any debt facilities?	The Company does not have any debt facilities.	Section 7

Question	Answer	Where to find more information
What are the Company's key relationships?	The Company's key relationships are with veterinary and human pharmaceutical companies, suppliers of services including product research and development, product manufacture, professional advisory services such as clinical development, regulatory, marketing, business development, and distribution and marketing services.	Section 10
Who does QBiotics compete with?	QBiotics competes with a very wide range of other small to medium sized life science companies as well as pharmaceutical companies globally. For the human markets, our competition is primarily other life sciences companies as our target clients are the large pharmaceutical companies who are looking to licence new products in mid development from companies such as QBiotics. For the veterinary markets our competition is the veterinary pharmaceutical companies.	Section 4
What is QBiotics' competitive position?	QBiotics' competitive position depends on a wide range of factors, including primarily the therapeutic advantages derived by medical practitioners from use of our products, which is essentially a function of the safety and efficacy profile of the products and the strength of the clinical data supporting those profiles. The competitive position also depends on external factors, including the existence and strength of an incumbent standard of care which our products may replace, disrupt or change, and therefore whether medical practitioners are willing (and able) to change their practice away from the existing defensible standard of care. The Company's competitive position also depends on the actions and reactions of competing pharmaceutical companies, some of which may lose revenue if our products are widely adopted. QBiotics' discovery technology, which underpins new and novel small molecule discovery, is a unique approach and this is considered to be a competitive advantage. However, development of a product from discovery point to the market is a high risk, expensive and long term undertaking.	Section 4

# 3.2 Summary of the Offer

Question	Answer	Where to find more information
What is the Offer?	This Prospectus relates to an offering of 11,111,111 Shares at a price of \$0.90 per Share to raise \$10 million (Maximum Subscription) from Existing Shareholders (holders of Shares as at 5:00pm on the Prospectus Date).  The Offer is conditional on the Company raising at least \$5 million (Minimum Subscription). If the Company fails to raise the Minimum Subscription within 3 months after the Prospectus Date, all Application Monies received by the Company will be refunded to Applicants (without interest) in accordance with the Corporations Act.	Section 8

Question	Answer				Where to find more information
	The Company may acci 2,777,778 Shares at an further \$2.5 million (Ove may be raised under the Oversubscriptions). The Shares being offere the total Shares on issu whether the Minimum S Oversubscription, respec	issue price of \$ersubscription). e Offers is there ed will represent e on completion tubscription, Ma	0.90 per Share The maximum a fore \$12.5 millio 1.17%, 2.31%, of the Offer dep ximum Subscrip	to raise up to a amount which in (including the and 2.87% of bending on	
What is the purpose of the Offer?	QBiotics raised \$72.55 fund human clinical devitigilanol tiglate, expand pharmaceutical STELFC capabilities for tigilanol.  Funds raised under this veterinary clinical devel	elopment of the the market for the DNTA, expand the tiglate and EBC- Offer are plann	anticancer drug ne anticancer ve ne raw material 1013 and streng ed to support hu	candidate sterinary supply gthen the team. Iman and	Section 8
	candidate EBC-1013.				
How will the proceeds of the Offer be used?	LDO 1010 Haman Ollinical Frida Civil Coalicty that treating				Section 8.3
	\$'000 Wound Healing EBC-VLU PI/IIA safety Wound Healing EBC-Dose determination study Pivotal field trial Target animal safety study Other approximate coworking capital Expenses of the Offer* Total	4,800 1013 veterinary - - -	4,800	4,800	

Question	Answer	Where to find more information
	associated with the Offer, depending on the level of subscription (refer to Table 10.2 in Section 10.13 for details about the Offer expenses). In the opinion of the Directors, on completion of the Offer, the Company will have sufficient working capital to carry out the activities described above. The Directors also believe that QBiotics' current financial position is sufficient to fund the Company's activities for at least the coming 2 years.	
Is the Offer underwritten?	No.	Section 8.4
Is there any brokerage, commission or stamp duty payable by Applicants?	No brokerage, commission or stamp duty is payable by Applicants on the acquisition of Shares under the Offer.	Section 8
What are the tax implications of investing in the Shares?	The tax consequences of any investment in Shares will depend on your personal circumstances. Prospective investors should obtain their own tax advice before deciding to invest.	Section 10
Can the Offer be withdrawn?	The Company reserves the right not to proceed with the Offer at any time before the issue of Shares to successful Applicants. If the Offer does not proceed, the Share Registry or the Company will refund all Application Monies.  No interest will be paid on any Application Monies refunded as a result of the withdrawal of the Offer.	Section 8
Who can apply for Shares under the Offer?	The Offer is open to retail and other Existing Shareholders who reside in Australia, New Zealand, the European Union, Jersey (Channel Islands), Mauritius, the United Kingdom and certain other jurisdictions determined by the Company in which it is lawful for the Company to make the Offer.	Section 8
What are the rights and liabilities attached to the security being offered?	All Shares issued under this Prospectus are ordinary shares and will rank equally in all respects with existing Shares on issue. A description of the Shares, including the rights and liabilities attaching to them, is set out in Section 10.4.	Section 10
What is the Offer period?	The key dates, including details of the Offer period, are set out in Sections 1 and 8.  No Shares will be issued on the basis of this Prospectus later than the Expiry Date of 13 months after the Prospectus Date.	Sections 1 and 8
What is the minimum Application	The minimum Application amount under the Offer is \$9,000 or 10,000 Shares.	Section 8

Question	Answer	Where to find more information
amount under the Offer?		
Over- subscriptions	The Company may accept oversubscriptions of up to \$2.5 million, as determined by the Directors.	Section 8
How do I apply for shares?	If you wish to apply for Shares under the Offer, the preferred method is via the Company's online Offer website.  Online Application Form: Applicants can apply for Shares via the online Offer website located at <a href="www.qbiotics.com/prospectus">www.qbiotics.com/prospectus</a> which is the preferred method.  Application Form: Applicants can also apply for Shares by completing the Application Form accompanying or attached to the back of this Prospectus.  Instructions on how to apply are set out in Section 8 and on the Application Form.  To the extent permitted by law, an application under the Offer is irrevocable.	Section 8
How do I pay?	Application Monies should be paid using the following methods:  By BPAY®: by following the instructions on the Application Form.  BPAY® is the preferred payment method.  By Cheque: Cheques should be crossed "Not Negotiable" and made out to "QBiotics Group Limited" and posted, together with the Application Form, to the address shown on the Application Form.	Section 8
What is the allocation policy and what happens if there are over-subscriptions?	The Board has absolute discretion regarding the basis for allocation of Shares, and there is no assurance that any Applicant will be allocated any Shares, or the number of Shares for which they have applied.	Section 8
Who should you contact if you have an enquiry?	For enquiries regarding the Offer or the Company, please contact QBiotics by emailing <a href="mailto:investors@qbiotics.com">investors@qbiotics.com</a> or phoning (07) 3870 8933 from 9.00am until 5.00pm (AEST) Monday to Friday. If you are unclear in relation to any matter or are uncertain as to whether the Company is a suitable investment for you, you should seek professional guidance from your solicitor, stockbroker, accountant or other independent and qualified professional adviser before deciding whether to invest.	Section 8

# 3.3 Board & Management and significant interests

Question	Answer			Where to find more information
Who are the Directors of QBiotics?	<ul> <li>Dr Victoria G</li> <li>Dr Paul Redd</li> <li>Nicholas Mod</li> <li>Dr Susan Fod</li> <li>Andrew Denv</li> <li>Professor Bru</li> <li>Associate Profesion</li> <li>Neville Mitch</li> </ul>	tors consists of: -Smith – Non-Executive Chordon - Managing Director - Core – Non-Executive Director – Core – Non-Executive Director – Non-Executive – Non-Executive Director – Non-Executive Director – Non-Executive – Non-Executi	Section 5.1	
Who are the key Executives of QBiotics?	<ul><li>Dr Victoria G</li><li>Dr Paul Redd</li><li>Michael Wen</li><li>Dr Peter Sch</li></ul>	agement consists of: ordon – Managing Director ell – Executive Director - C zel – Chief Financial Office midt - Chief Operating Offi - Chief Marketing Officer	Chief Scientific Officer and Company Secretary	Section 5.3
How are the Directors remunerated?	Details on the remusummarised below.	neration of the Directors a	nd senior executives is  Benefits	Section 5.2
	Rick Holliday- Smith	\$100,000 per annum, payable in Options	Superannuation contributions at the applicable statutory percentage	
	Dr Victoria Gordon	\$239,700 gross salary per annum plus Short Term Incentive (STI) of up to 20% of gross salary (≥50% to be taken as shares)	As above	
	Dr Paul Reddell	\$239,700 gross salary per annum plus Short Term Incentive (STI) of up to 20% of gross salary (≥50% to be taken as shares)	As above	
	Nicholas Moore	\$75,000 per annum, payable in Options	As above	
	Dr Susan Foden	\$75,000 per annum, payable in cash and shares	As above	
	Andrew Denver	\$75,000 per annum, payable in Options	As above	

Question	Answer				Where to find more information
	Professor Bruce Robinson AC	\$75,000 per annum, payable in Options	As above	9	
	Associate Professor Steven Ogbourne	\$75,000 per annum, payable in cash and shares	As above	<b>)</b>	
	Neville Mitchell	\$75,000 per annum, payable in Options	As above	e	
	Hamish Corlett	\$75,000 per annum, payable in Options	As above	<u> </u>	
What are the Directors'	At the date of the Plant the following Shares	rospectus, the Directors and Options.			Section 5.2
interests in Shares and Options?	Name	Shares	Options granted and vested	Options granted and not vested	
What related	Hamish Corlett is a The Directors may 6 Other than the com	on 32,831,975 29,933,696 12,309,523 80,162 250,000 350,000 350,000 55,555,556* eld by TDM Growth Podirector of TDM. elect to apply for Shard	3,510,917 Nil Nil 250,000 361,186 1,867,491 1,867,491 361,186 1,750,820 Nil artners Pty Ltd es under the O	901,363 Nil Nil 482,334 Nil 676,022 676,022 Nil 599,503 482,334 (TDM). Mr	Section 10.8
party transactions exist?	there are two relate premises occupied and (ii) a lease of la	which are described in d party agreements in by QBiotics and owne nd and service agreer mmary of the terms of	place, being (indexided by Drs Gordonnermont with an en	) a lease of a on and Reddell, atity related to	
Who are the substantial Shareholders and what will their interests be at completion of the Offer?	Managed Investmer 11.81%, Dr Victoria 6.36% of the shares Prospectus. Mr Ha	estantial shareholders int Funds Limited as cu Gordon holds 6.98% is on issue in the Comp mish Corlett is a direc and Mr Corletts holdi	ustodian for TD , and Dr Paul R pany at the date tor of TDM. De	M holds leddell holds e of this etails of Dr	Section 8.8

### 3.4 Financial information

Question	Answer					Where to find more information
What is the	Historical statement	of profit and	loss and oth	ner comprehe	ensive income	Section 7
historical financial performance of the Company?	The table below represents the summary audited historical statement of profit and loss and other comprehensive income for FY2019 and FY2020 and the six month ended 31 December 2020 (1HFY2021). Further discussion regarding the summarised historical statement of operations are set out in Section 7.					
			FY2019	FY2020	1HFY2021	
	<b>A</b> 1000		Audited	Audited	Reviewed	
	\$'000		\$	\$	\$	
	Total income		4,776	6,651	3,037	
	Total expenses Results from opera	itina	(17,951)	(18,576)	(9,790)	
	activities	itirig	(13,175)	(11,925)	(6,753)	
	Loss for the period		(12,796)	(11,809)	(6,627)	
	Total comprehensi	ve				
	income for the peri	od	(12,796)	(11,809)	(6,627)	
	of the pro-forma star adjustments are set		n 7.	a 31 Dec 202	·	
	Reviewed gross proceeds of					
		31 Dec	\$5	\$10	\$12.5	
		2020	million	million	million	
	\$'000	\$	\$	\$	\$	
	Total current assets	31,237	109,128	114,128	116,628	
	Total non current					
	assets	6,899	6,899	6,899	6,899	
	Total assets Total current	38,136	116,027	121,027	123,527	
	liabilities	4,835	4,593	4, 593	4, 593	
	Total non current					
	liabilities	1,671	1,671	1,671	1,671	
	Total liabilities	6,506	6,264	6,264	6,264	
	Net assets Total shareholder's equity	31,630 31,630	109,763	114,763	117,263 117,263	
What is QBiotics dividend policy?	The Directors may p as they see fit. The and the method of p The Directors may e plan or a dividend el the Company.	pay to Shareh Directors ma ayment. establish and	y fix the amo	ount, the time for a dividenc	e for payment I reinvestment	Section 10.4.5

Question	Answer	Where to find more information
	Note, the Directors do not foresee any payments of dividends in the near future.	

# 3.5 Summary of key risks

Risk	Answer	Where to find more information
Risks associate		
Failure of current clinical trials	The Company cannot guarantee that the current human clinical trials of tigilanol tiglate will be successful or produce the desired evidentiary endpoints, or with statistical probative value, or that there will be no significant adverse events in the human patients.	Section 6.1.1
Failure of future clinical trials	The Company cannot guarantee that future follow-up human clinical trial of tigilanol tiglate, or human clinical trials of EBC-1013 will be successful or produce the desired evidentiary endpoints, or with statistical probative value, or that there will be no significant adverse events in the human patients	Section 6.1.2
Competitive reactions	There are many large and specialist established anticancer and wound healing pharmaceutical companies who may attempt to compete with, delay or prevent the launch of tigilanol tiglate and EBC-1013, and we cannot control or anticipate their actions. Similarly, there are established standard treatment protocols accepted by medical specialists, their professional colleges, and their insurers, as the standard of care in the treatment of certain cancers and wounds, which the Company's products may need to disrupt.	Section 6.1.3
Commerciali- sation	The Company's ability to earn revenue from the commercialisation of tigilanol tiglate for treatment of human cancers, or EBC-1013 for the treatment of wounds may be delayed or prevented by failure to successfully develop the drugs or secure regulatory approval for them.	Section 6.1.4
Partnering to complete human clinical development and to commercialise	The Company cannot guarantee the successful negotiation or completion of sufficient, or appropriately remunerative, or any, human licensing or co-development contracts that would lead to the approval and commercialisation of our products in anticancer or wound healing.	Section 6.1.5
Health care insurers and reimbursement	There is no assurance that reimbursements for any products or services developed and commercialised by QBiotics or our pharmaceutical partners will be available to patients at all or without substantial delay, in any country. Even if such reimbursement is provided, the approved reimbursement amounts may not be sufficient to incent patients and	Section 6.1.6

Risk	Answer	Where to find more information		
	medical practitioners to adopt and use the Company's products in numbers sufficient to drive profitability for the Company.			
Risks associate	d with QBiotics' animal health pharmaceutical products			
Reliance on Virbac	All of the Company's revenues is reliant on its sales and distribution partner, Virbac. Refer to Section 10.7.2 for a summary of the agreement. Virbac is a French corporation listed on the Paris stock exchange, whose business focuses on the sale, distribution and marketing of medicines and vaccines for companion and food-producing animals. QBiotics depends on the ability of Virbac to build the requisite sales, marketing and distribution capabilities to successfully promote, market and sell STELFONTA® and gain market share in the licensed territories to help grow QBiotics' revenues derived from STELFONTA®. Being a publicly listed company, Virbac's interests to grow revenue are aligned with those of QBiotics in this regard. However, a slowdown, decrease in demand or failure to grow demand from Virbac, including as a consequence of COVID-19, could adversely impact QBiotics' operating and financial performance.	Section 6.2.1		
Regulatory approval is delayed	The commercialisation of the Company's products is subject to regulatory approvals. Delays or failure in obtaining regulatory approvals could result in failure to launch or delays in launching products and thus have an adverse effect on the value of the Company and consequently impact the financial performance of the Company.	Section 6.2.2		
Slower than anticipated market adoption and ongoing acceptance	The Company's commercialisation strategy relies on medical specialists, human and veterinary medical facilities, human and companion animal patients and pet owners accepting the Company's products for routine use. Medical specialists are historically slow to adopt new technologies, regardless of perceived merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires significant marketing expenditure or definitive product performance and/or pricing superiority. Market acceptance of a new technology such as QBiotics' can be difficult to obtain and may involve time consuming clinical studies to providefurther evidence of the medical benefits of the Company's products in order to overcome any inertia.	Section 6.2.3		
Risks specific to an investment in the Company				
Coronavirus (COVID-19)	COVID-19 has impacted the marketing and sales of STELFONTA® in most European countries as many veterinary practices were subject to operating restrictions. In addition, the recruitment of patients for the Group's human clinical trial QB46C-H03 treating head and neck squamous cell carcinoma was halted from February to mid July 2020 in Australia and India. Human clinical trials continue to be affected by COVID-19 restrictions world-wide. Consequently, the implementation of QBiotics' planned clinical trials may also be negatively impacted by	Section 6.3.1		

Risk	Answer	Where to find more information
	ongoing effects of COVID-19. QBiotics has received COVID-19 related incentives from the Australian Federal Government. The incentives have been used to help fund ongoing employee costs which allow continued work on human clinical trials and marketing initiatives. The duration and impact of the COVID-19 pandemic, as well as the effectiveness of government and central bank responses, remains unclear at this time. It is not possible to reliably estimate the duration and severity of these consequences, as well as their impact on the financial position and results of the Group for future periods. The Group's ability to recruit patients for its planned human clinical trials may also be negatively impacted.	
The regulatory environment changes adversely	The Company's operations are also subject to laws, regulatory restrictions and certain government directives, recommendations and guidelines relating to, amongst other things, occupational safety, laboratory practice, the use and handling of hazardous materials, prevention of illness and injury and environmental protection. There can be no assurance that future legislation will not impose further government regulation, which may adversely affect the business or financial condition of the Company.	Section 6.3.2
Product Liability	The testing, marketing and sale of the Company's products, whether directly or through licensees, involves a risk of product liability claims being brought against the Company. QBiotics seeks to limit its liability for such claims in its agreements with medical specialists and veterinarians and is also entitled to be indemnified by them in various circumstances.  However, limitations of liability are not necessarily effective at law and indemnification may not always be available. The Company maintains product liability insurance in respect of its products, however, if the Company is unable to continue to obtain sufficient product liability insurance at an acceptable cost, it could prevent or inhibit the commercialisation of our products.	Section 6.3.3
Intellectual property	One of the Company's assets is its Intellectual Property (IP) and patent rights that support its technology and other future products. The commercial value of the IP is dependent on certain legal protections, including patent rights. The grant of patent rights does not inevitably follow after making an application for such rights. Examination of patents, for example, may be expensive and time consuming with no guarantee that patent rights will be secured. Further, the grant of patent rights does not guarantee that such rights are valid or that they do not infringe another party's patent rights and no assurance can be given that others will not challenge the Company's IP rights in its technology.	Section 6.3.4
Future product development	There are many risks inherent in the development and use of new products for the human and veterinary markets. Products may fail during clinical trials or may fail to gain regulatory approval if required. The Company cannot guarantee that the development work being	Section 6.3.5

Risk	Answer	Where to find more information	
	undertaken will result in the successful development of any products, or even if they do, that the products will be registered, marketed or commercially successful.  The time required to develop and obtain regulatory approval for marketable products can be uncertain and in some cases very long.		
Raw material	Adverse weather conditions and other unpredictable factors may adversely affect the availability of the Fontainea shrub, which is the source of tigilanol tiglate and EBC-1013, and therefore QBiotics' operations. However, the Company has undertaken extensive domestication research and development for the grow out of Fontainea over the past 9 years. These activities have culminated in established plantations of Fontainea for supply of raw material. The Company will continue to cultivate Fontainea by expanding the number of trees under plantation, which will add scale to raw material production.	Section 6.3.7	
Clinical validation	A core component of the Company's strategy is the commercialisation and registration of its products. For the registration process, successful clinical trials will be necessary for the Company to obtain regulatory approval for its products. Such trials are expensive, time consuming, complicated, may be delayed or may fail. This could delay or restrict the Company's ability to commercialise some or all of its products.	Section 6.3.8	
Reputational Damage	<ul> <li>The reputation of the Company and its individual brands is important in attracting both human and veterinary medical specialists, hospitals and patients and key employees. Reputational damage could arise due to a number of circumstances, including: <ul> <li>Inadequate services or unsatisfactory clinical outcomes for patients;</li> <li>Error, malpractice or negligence of the Company's employees; or</li> <li>Error, malpractice or negligence of the medical specialists performing the treatments.</li> </ul> </li> <li>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 or medical specialists willing to provide them, and may lead to difficulties securing ongoing future revenue and/or shareholder funding to supplement any eventual revenue earned by the Company.</li> </ul>	Section 6.3.9	
Technological development and competitors	Currently there are many competing drugs either in the market or being developed by other companies that aim to address the same indications as tigilanol tiglate and EBC-1013 are focusing on. Due to the time it may take for QBiotics to commercialise its products, there is a risk that other competing or superior products may enter the market.	Section 6.3.10	
Manufacturing and product quality	QBiotics currently contracts out all Good Manufacturing Practice (GMP) manufacturing activities for tigilanol tiglate and EBC-1013, and as such the Company is reliant on contract providers adhering to regulatory requirements for production of human and veterinary	Section 6.3.11	

Risk	Answer	Where to find more information
	pharmaceuticals. Manufacturing batches may fail to meet the specific regulatory requirements and as such negatively impact development and marketing through lack of supply.	
Dependencies on service providers	The Company is dependent on service providers to perform many activities such as toxicology studies, implementation of clinical trials and manufacturing of products. While these service providers are replaceable, the sourcing of effective replacements in a timely manner may have an adverse effect on the future financial performance of the business.	Section 6.3.12
Reliance on key personnel	The Company's success depends to a significant extent on key personnel and the senior management team. QBiotics may not be able to attract and retain key staff or be able to find effective replacements in a timely manner. The loss of key personnel may have an adverse effect on the future financial performance of the business.	Section 6.3.13
Sufficiency of funding	The Directors believe that, on completion of the Offer, the Company will have sufficient working capital to carry out its stated objectives. Nevertheless, there can be no assurance that such objectives can be met or that no further funding will be required. Additional funds may be difficult to raise and will dilute existing shareholders.	Section 6.3.14
Speculative nature of investment	The Shares to be issued pursuant to the Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares.  The success of the Company is largely dependent on the results of its technology development, revenue from sales of STELFONTA®, the outcome of its proposed human clinical trials and obtaining regulatory approvals. An investment in its Shares should therefore be considered very speculative.	Section 6.3.15
General risks ro	elated to an investment in QBiotics	
Liquidity	QBiotics Shares are not listed on any stock exchange and there is no liquid market for the trading of Shares. Therefore, an investment in QBiotics should be considered a long term, high risk, illiquid investment. The Company's current intention is to eventually pursue a listing of its Shares on an appropriate stock market, provided favourable market conditions exist at the time and it is in the best interest of the Company and shareholders to do so. Listing of the Company's shares on a securities exchange will result in public market where shares in the Company may be sold or transferred. However, there can be no guarantee that the proposed capital raising or a listing on the ASX or any other securities exchange will occur or will be successful.	Section 6.4.1

Risk	Answer	Where to find more information
Other risks	A number of other risks are included in Section 6, and investors should review those risks and consider their own personal circumstances, investment objectives, financial situation and particular needs carefully and seek professional advice before making an investment decision.	Section 6





04

Industry & Business Overview

### 4.1 Business overview

QBiotics has a 21-year history specialising in plant derived small molecules that function by cell signalling, to address challenging medical conditions in humans and companion animals (dogs, cats and horses). The Company is built on a foundation of scientific excellence, innovative business thinking and strong ethical values.

QBiotics has a product platform, with a current focus in oncology, with tigilanol tiglate, and wound healing, with EBC-1013. Oncology is our most advanced program with human development entering Clinical Phase II for a range of solid tumours, with tigilanol tiglate both as a monotherapy, and in combination with the immune checkpoint inhibitor pharmaceutical pembrolizumab (Keytruda®). QBiotics has secured a clinical collaboration deal with the global pharmaceutical company MSD (Merck Sharp & Dohme, tradename of Merck & Co., USA) for the Keytruda® combination trial.

Our veterinary oncology pharmaceutical, STELFONTA®, has gained approval by the US FDA-CVM, EMA, Swissmedic and the UK VMD. STELFONTA® is being marketed and generating revenue in the USA, Europe, and the UK. QBiotics has a distribution and marketing deal for STELFONTA® with the global animal health company Virbac.

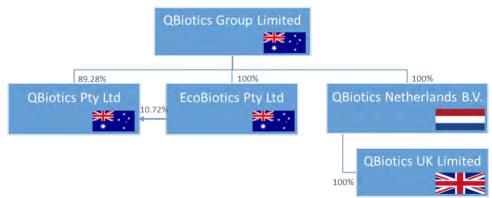
Our wound healing product EBC-1013 has a multifaceted mode of action that potentially addresses a range of wound types including acute and chronic wounds and burns. Human development is in preclinical stage, whereas veterinary development has reached clinical trials.

QBiotics drug candidates and products have intellectual property protection with composition of matter and use base patents, and extension patents are in process.

QBiotics has an experienced board and management team. They provide a skill set of scientific expertise complemented by corporate, finance and business experience.

The QBiotics Group is made up of 5 companies, structure of which can be seen in Figure 4.1.

Figure 4.1: Company structure of the QBiotics Group



Entity	Incorporation	Purpose
QBiotics Group Limited	24 February 2017	Parent entity and day-to-day operations
QBiotics Pty Ltd (previously QBiotics Limited)	26 July 2004	Owner of intellectual property QBiotics development entity 2009
EcoBiotics Pty Ltd (previously EcoBiotics Limited)	15 March 2000	Owner of intellectual property EcoBiotics discovery entity 2000
QBiotics Netherlands B.V.	15 June 2018	Holder of marketing authorisations granted in Europe
QBiotics UK Limited	3 July 2020	Support UK based research & development

QBiotics has funded operations to date primarily through equity investment. The Company has attracted Australian and overseas Government grants, as well as R&D tax incentive refunds as non-dilutive funding. Future funding of operations is proposed to be by a combination of the capital raised under this Offer, existing capital and repeatable revenue generated from our veterinary oncology product STELFONTA®. As human products reach suitable stages of development, there may be funding through licencing deals with pharmaceutical companies, but this is not guaranteed.

#### 4.1.1 Business model overview

QBiotics leverages benefits from co-development of our human and veterinary products. Early veterinary clinical data has the potential to provide proof of concept of our drug candidates, potentially informing the human development program. Veterinary development has the potential to provide a greater understanding of the biological activity of our drugs in complex animal patients with "real" disease that may be more predictive of the human response. In return, the stringent regulatory requirements of the human program has the potential to support a quality veterinary regulatory submissions.

Veterinary products may be quicker to market, potentially creating early non-dilutive revenue streams that could be reinvested into potentially higher value human programs. In contrast with human drug candidates, those for animals have the potential to go immediately from laboratory data to being tested in the target species and clinical trials often require fewer patients compared to human development.

The pharmaceutical industry is highly competitive and mature, characterised by a small number of very large global, regional and specialist established companies, plus a host of life sciences companies developing one or more products. The current structure of the industry is largely based on complimentary models with the large pharmaceutical companies concentrating on late stage development and marketing.<sup>1</sup> While the smaller more agile companies address high-risk early stage discovery and development, and then partner with larger companies for the complex and costly final stage development and marketing.<sup>1</sup>

#### For veterinary products commercialisation we attempt to:

 Develop to pharmaceutical registration with major regulatory authorities, and then partner with global veterinary pharmaceutical companies for marketing and distribution of products, with deals based on sales profit sharing.

#### For human products commercialisation we attempt to:

Develop to 'proof of concept' stage human clinical Phase IIA/B where the drug candidates safety and
efficacy is clearly defined, before licensing on to global pharmaceutical companies for final
development and marketing in return for one or more of upfront fees, milestone payments, and royalties
on sales.

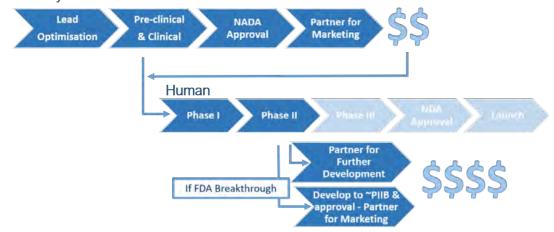
Refer to Figure 4.2 for the proposed QBiotics business model.

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<sup>&</sup>lt;sup>1</sup> Tralau-Stewart, C.J., Wyatt, C.A., Kleyn, D.E. and Ayad, A., 2009. Drug discovery: new models for industry–academic partnerships. *Drug discovery today*, *14*(1-2), pp.95-101.

Figure 4.2: QBiotics proposed business model





### 4.1.2 Human and veterinary drug registration pathways

QBiotics' registration pathway for both human and veterinary pharmaceuticals is focused initially on the large markets of the USA and Europe, followed by other regions of significance including the UK and Australia.

The US FDA is a regulatory body whose pharmaceutical development guidelines are generally accepted by other regions worldwide. Consequently, QBiotics' pharmaceuticals for the human markets are developed under FDA guidelines. QBiotics remains mindful of the various facilitated regulatory pathways the FDA offers (such as Fast Track, Breakthrough Therapy and Accelerated Approval) when selecting specific indications for development of our products.

QBiotics closely interacts with regulatory bodies other than the FDA in regions where human clinical studies are, and will be, undertaken such as the Therapeutic Goods Administration (TGA) in Australia, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the EMA, and the Drug Controller General of India (DCGI).

Veterinary products are also initially developed under the FDA-CVM guidelines, and registration submissions for other regions is based on data developed for the FDA-CVM submissions. As veterinary products are developed through to registration, QBiotics also interacts with a range of other regulatory bodies, including the EMA, the UK VMD, Swissmedic and the APVMA.

## 4.2 Product development

### 4.2.1 QBiotics' approach to product development

QBiotics specialises in plant derived cell signalling small molecules. Nature can be a source of new biologically active small molecule chemistry. The pharmaceutical industry was founded on small molecule discovery (biodiscovery) from plants, and biodiscovery still has a strong influence with currently approximately 45% of all marketed drugs having a basis in this approach.<sup>2</sup>

At QBiotics we saw the potential in using an ecology based approach to biodiscovery to elevate the success rate. This led to the development of our discovery platform EcoLogic™ and thus access to a potential source of new pharmaceuticals.

QBiotics' strategy is to leverage EcoLogic™, to discover novel bioactive molecules. The discovery success rate of EcoLogic™ enables hard cull of possible drug candidates at an early stage, selecting for development only those with the potential for eventual registration as novel pharmaceutical. This approach has the potential for savings in both costs and time of development.

<sup>&</sup>lt;sup>2</sup> Newman and Cragg (2020). Journal of Natural Products. 83(3): 770-803. doi: 10.1021/acs.jnatprod.9b01285.

The Company takes a different approach to the development of pharmaceuticals, combining novel technology with very early stage proof of concept testing of products including:

Selection of drug candidates that act as messengers and signalling agents in targeting and disrupting
disease processes with modes of action that stimulate and enhance the body's ability to address the
problem, thus increasing potential for efficacy while reducing the potential for negative side effects.

Early stage data from 'real world' veterinary studies may:

- Support the possibility of swifter progression from laboratory animal models that provide limited information about drug efficacy and safety to complex disease models in animal patients that are potentially more predictive of the human response;
- Inform toxicology and product manufacture, underpinning the development of potentially more robust programs that help to avoid late stage clinical failure due to incomplete and poor programs; and
- Inform safety aspects and dosing/treatment regimens of first-in-human clinical studies, thus potentially
  increasing the likelihood of data produced in these early human trials being predictive of proof of
  concept of the drug and underpinning efficient late stage development, with the possibility of reduced
  risk and costs.

### 4.2.2 Product pipeline

QBiotics has a pipeline of products. Our current focus is the treatment of solid tumours and chronic wounds, with earlier programs in antibiotics and anti-inflammatories. Refer to Figure 4.3 for QBiotics' current product development pipeline.

Figure 4.3 QBiotics' pipeline of products

Area	Molecule	Target	Stage of development						
HUMAN			Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/ marketing	Sponsor/collaborator
		Head and neck squamous cell carcinoma	Phase IB/I	IIA monotherap	ру				QBiotics Group
Oncology	Tigilanol	Melanoma (stage IIIB-IV M1c)	Phase IB/I	IIA Keytruda + <sup>-</sup>	тт				MSD MSD
0,	tiglate	Melanoma (stage IIIB in transit)	Phase IIA	/B monotherap	у				QBiotics Group
		Soft tissue sarcoma	Phase IIA	monotherapy					QBiotics Group
Wound	EBC-1013	Venus leg ulcers	CMC & to	xicology					QBiotics Group
healing	LBO-1013	Burns/blast wounds	Veterinary	/ models					QBiotics Group
VETERINA	RY		Discovery		Clin	ical		Registration/ marketing	
	Tigilanol	Canine - Mast cell tumour	STELFON	ITA® - markete	ed EU, UK, Sw	itzerland; laun	ch in US in Q1	2021	Virbac
Oncology	tiglate	Canine – Soft tissue sarcoma Equine - Sarcoids	STELFON	ITA® - label ex	tensions				QBiotics Group
Wound healing	EBC-1013	Equine – Acute/ chronic wounds	Veterinary	/ clinical case					QBiotics Group
NEW PROG	RAMS DISCOV	ERY	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/ marketing	
Antibiotics	Lead molecules	Multiple resistant bacteria	Screening						QBiotics Group
Anti- inflamma- tories	Lead molecules	Alzheimer's; inflammatory disease	Screening						QBiotics Group

### 4.3 Oncology

### 4.3.1 Tigilanol tiglate overview

QBiotics' lead anticancer drug candidate, tigilanol tiglate (EBC-46), is a novel small molecule epoxytigliane in development as a local treatment for a range of solid tumours. Tigilanol tiglate is being investigated as a single agent treatment (monotherapy) as well as in combination with MSD's (Merck Sharp & Dohme, tradename of Merck & Co., USA) immune check point inhibitor pharmaceutical pembrolizumab (Keytruda®).

Tigilanol tiglate is delivered as a simple injection directly into the tumour mass, usually without the need for general anaesthetics or sedation. Direct intratumoural treatment delivers the drug right where it is needed, thus reducing the potential of off-target toxicity. Destruction of the injected tumour is rapid, usually within 5-7 days, and the deficit or 'wound' remaining is stimulated to heal usually without the need for intervention.

Tigilanol tiglate has a multimodal action, initiated by Protein Kinase C (PKC)-activation dependent and PKC independent cell signalling mechanisms, which usually results in rapid tumour destruction and good healing of the site.<sup>3</sup>

Externally accessible cutaneous and subcutaneous tumours (i.e. tumours that can be reached from the outside) have been the focus of treatment to date. The drug also has potential to treat a range of internally situated tumours where injection can be guided by imaging, however this is yet to be examined.

In addition to local treatment, there are indications that tigilanol tiglate may stimulate the immune system resulting in (i) an anenestic/abscopal response where tumours distal to the injected tumour also respond, and (ii) synergistic effect when combined with the immune check point inhibitor anti-PD-1 drugs such as Keytruda.

Tigilanol tiglate's potential has been validated as a veterinary product. The US FDA-CVM, EMA, Swissmedic and UK VMD have approved tigilanol tiglate as a veterinary oncology pharmaceutical, commercialised as STELFONTA® with our partners Virbac, a global animal health company. STELFONTA® is also under late stage review by the Australian APVMA.

In a veterinary fully blinded and controlled pivotal field efficacy registration study (Phase III human equivalent) a single injection with STELFONTA® resulted in 75% complete destruction (Complete Response) of the tumour with p<0.001 versus the control. A second injection for partial responders resulted in 88% Complete Response (refer to Section 4.3.8 for more detail).

Tigilanol tiglate is not synthetically tractable and is isolated from the seed of the Australian rainforest native tree *Fontainea picrosperma* (Fontainea). QBiotics has undertaken domestication of Fontainea and established commercial plantations of the plant (refer to Section 4.5 for details).

The Current Good Manufacturing Practice (cGMP) manufacturing program for tigilanol tiglate drug substance (the active ingredient being tigilanol tiglate) and drug product (drug substance in a carrier for injection) for the human programs suitable for FDA-CVM, EMA etc submission is advanced for a drug at its current development stage. Both tigilanol tiglate cGMP veterinary drug substance and drug product have been approved by the FDA-CVM, EMA, Swissmedic and the UK VMD and we are currently awaiting approval by the Australia's APVMA.

<sup>&</sup>lt;sup>3</sup> Boyle GM *et al.* (2014). PLoS ONE 9(10): e108887. oi:10.1371/journal.pone.0108887

#### 4.3.2 Mode of action

#### How tigilanol tiglate works

Tigilanol tiglate's mode of action (the way the drug works) is a combination of protein kinase C (PKC) activation and other factors. <sup>4</sup> Tigilanol tiglate is a potent activator of PKC, which comprises a family of enzymes that induce changes in signal transduction pathways modulating diverse cellular responses. <sup>5,6,7,8</sup> Recent clinical data support a tumour suppressive effect for PKC. <sup>9,10</sup>

Tigilanol tiglate has a multi-modal action: targeting and activation of specific isoforms of PKC creates a cascade of intracellular signals which generate host responses against the tumour.<sup>3</sup> Tigilanol tiglate (*i*) induces a rapid, but highly localized, inflammatory response, (*ii*) increases permeability of the tumour vascular endothelium, and (*iii*) causes tumour cell death by oncosis, with no viable tumour cells evident four hours after injection by *ex vivo* culture from a melanoma mouse model. These effects result in tumour destruction and subsequent slough of the treated tumour usually within 5-7 days.<sup>3,11</sup>

Tigilanol tiglate also induces changes in cytokine signalling and gene expression in both blood derived cells and the surrounding normal tissue (both keratinocytes and fibroblasts) at the tumour deficit site that promote a wound healing response usually without requiring other interventions. Following tumour destruction, healing of the site is also initiated with full healing usually within approximately 4 weeks. Animal studies have established that tigilanol tiglate produces greater local responses following intratumoural injection compared with injection into normal tissue.

Preliminary evidence, from laboratory *in vivo* studies <sup>13,17</sup> and from clinical observation of anenestic/abscopal responses (where tumours distal to the injected tumour also respond) in two human patients <sup>14</sup>, is showing signs of an induction of an antigen specific immune response (Refer to Figure 4.4).

Systemic exposure of tigilanol tiglate is low and clearance of the drug is rapid, with  $T_{max}$  (the time the maximum amount of drug in the body is detected) at 15 minutes, plasma concentrations rapidly decline 2-4 hours post treatment with negligible plasma concentration by 24 hours. <sup>14</sup>

Human and animal patients generally tolerate the drug well with adverse events (side effects) largely reported to be moderate to mild and generally related to the drug mechanism e.g. injection site pain and swelling around

<sup>&</sup>lt;sup>4</sup> Boyle, G., D'Souza, M., Pierce, C., Adams, R., Cantor, A., Johns, J., Maslovskaya, L., Gordon, V., Reddell, R., and Parsons, P. 2014. Intra-lesional injection of the novel PKC activator EBC-46 rapidly ablates tumors in mouse models. *PLoS One.* 9(10):e108887.

<sup>&</sup>lt;sup>5</sup> Cooke, M, Magimaidas A, Cesado-Medrano V, Kazanietz M. 2017. Protein kinase C in cancer: the top five unanswered questions. *Molecular Carcinogenesis*. 56:1531-1542.

<sup>&</sup>lt;sup>6</sup> Drummond, M., Prehoda, K. 2016. Molecular control of atypical Protein Kinase C: tipping the balance between self-renewal and differentiation. *Journal of Molecular Biology*. 428:1455-1464.

 $<sup>^{7}</sup>$  Harrington, E., Löffler, J., Nelson, P., Kent, C., Simons, M., and Ware, J. 1997. Enhancement of migration by protein kinase Cα and inhibition of proliferation and cell cycle progression by protein kinase Cδ in capillary endothelial cells. *Journal of Biological Chemistry*. 272:7390-7397.

<sup>&</sup>lt;sup>8</sup> Newton A.1995. Protein kinase C: structure, function and regulation. *Journal of Biological Chemistry*. 270:28495-28498.

<sup>&</sup>lt;sup>9</sup> Newton, A., Brognard, J. 2017. Reversing the paradigm: protein kinase C as a tumor suppressor. *Trends in Pharmacological Sciences*. 38:438-447.

<sup>&</sup>lt;sup>10</sup> Dowling, C.M., Phelan, J., Callender, J.A., Cathcart, M.C., Mehigan, B., McCormick, P., Dalton, T., Coffey, J.C., Newton, A.C., O'sullivan, J. and Kiely, P.A. 2016. Protein kinase C beta II suppresses colorectal cancer by regulating IGF-1 mediated cell survival. *Oncotarget*. 7:20919-20933.

<sup>&</sup>lt;sup>11</sup> Barnett, C.M., Broit, N., Yap, P.Y., Cullen, J.K., Parsons, P.G., Panizza, B.J. and Boyle, G.M., 2019. Optimising intratumoral treatment of head and neck squamous cell carcinoma models with the diterpene ester Tigilanol tiglate. *Investigational new drugs*, *37*(1), pp.1-8.

<sup>&</sup>lt;sup>12</sup> Moses et al. (2020). Biochemical Pharmacology. 178: 114048

<sup>13</sup> Cullen et al. 2018. Immunogenic effects of tigilanol tiglate. Poster. World Congress of Cancer of the Skin.

<sup>&</sup>lt;sup>14</sup> Panizza, B.J. *et al.* 2019. Phase I dose escalation study to determine the safety, tolerability, preliminary efficacy and pharmacokinetics of an intratumoural injection of tiglanol tiglate (EBC-46). *EBioMedicine*, 50: 433-441.

the tumour.<sup>14,15</sup> These effects are transient and usually resolve within a few days. However, occasionally more serious side effects can be experienced.<sup>14</sup> The deficit or 'wound' remaining after tumour destruction usually heals without any intervention (e.g. no requirement for bandaging, antibiotics, antiseptic creams etc.) and with minimal to no scarring.<sup>16</sup>

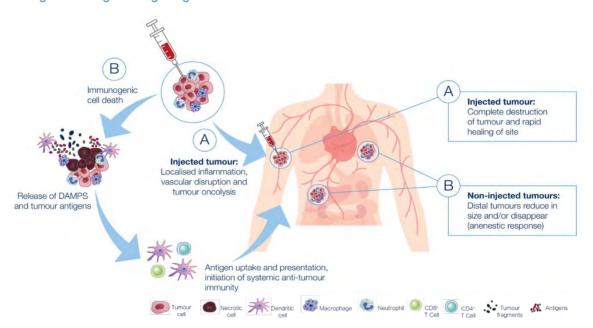


Figure 4.4: Tigilanol tiglate general mode of action

#### Potential for systemic efficacy in combination with Immune Checkpoint Inhibitor drugs

In laboratory mouse models tigilanol tiglate is demonstrating the potential to enhance the efficacy of the immune checkpoint inhibitor (ICI) drugs, such as the anti PD-1 drugs, as it not only has an oncolytic effect but is showing signs of a systemic immunotherapeutic mechanisms of action.<sup>13</sup> Tumour destruction induced by tigilanol tiglate is exhibiting the major features of a mechanism of cellular demise known as immunogenic cell death (ICD).<sup>13,17</sup> Tigilanol tiglate has been shown to induce gene expression changes in mouse stroma (supportive tissue) consistent with immune cell recruitment and the development of a Th1/M1 type immune response (IL-1ß, TNF, IFNy, IL-6 pathways).<sup>13</sup> In support of this, preliminary mouse xenograph studies using non-responsive tumour models demonstrated that tigilanol tiglate in combination with anti-PD-1 improved the restriction of tumour growth and increased survival to a greater extent than anti-PD-1 alone.<sup>13,17</sup>

#### 4.3.3 Human development

QBiotics has completed a Clinical Phase I/IIA open label safety trial (QB46C-H01/2 - for details refer to 'Clinical trial progress' section below). The Company currently has four human oncology clinical trials in progress or under development.

<sup>15</sup> De Ridder, T.R., Campbell, J.E., Burke-Schwarz, C., Clegg, D., Elliot, E.L., Geller, S., Kozak, W., Pittenger, S.T., Pruitt, J.B., Riehl, J. and White, J., 2020. Randomized controlled clinical study evaluating the efficacy and safety of intratumoral treatment of canine mast cell tumors with tigilanol tiglate (EBC-46). *Journal of Veterinary Internal Medicine*.

<sup>&</sup>lt;sup>16</sup> Campbell, J., Miller, J., Blum, A., Toole, S., Ayerbe, J., Verning, M., Poulos, C., Boyle, G., Parsons, P., Moses, R. and Steadman, R., Moseley, R., Schmidt, P., Gordon, V., Reddell, P. 2014. Exceptional *In Vivo* Wound Healing Following Destruction of Cutaneous and Subcutaneous Tumors in Domesticated Animals Treated with the Novel Epoxy-tigliane Drug EBC-46. *Wound Repair and Regeneration*, 22(5), p.A76.

<sup>&</sup>lt;sup>17</sup> Cullen, J., Boyle, G., D'Souza, M., Pierce, C., Adams, R., Cantor, A., Johns, J., Maslovskaya, L., Yap, P.Y., Gordon, V. and Reddell, P., 2016. Investigating a naturally occurring small molecule, EBC-46, as an immunotherapeutic agent to help treat cancer. *European Journal of Cancer*. 2016;69 (Suppl 1:S153).

Local treatment with tigilanol tiglate to date has concentrated on cutaneous and subcutaneous tumours.

#### **Current human clinical development**

We currently have four open label studies either underway or under development:

- 1. QB46C-H03 Clinical Phase IB/IIA dose escalation safety trial treating HNSCC is currently underway. Recruitment commenced in December 2019 at two hospitals in Australia and two in India.
- 2. QB46C-H06 Clinical Phase IB/IIA dose escalation safety trial with tigilanol tiglate in combination with the anti PD-1 drug pembrolizumab (Keytruda®) treating melanoma Stage IIIB-IV M1c. The trial is currently being implemented at the Melanoma Institute in Sydney with other Australian sites hopefully to also participate.
- QB46C-H04 Clinical Phase IIA/B efficacy trial treating Stage IIIB-IIID/M1b melanoma in transit is under development. This trial will also be undertaken at the Melanoma Institute in Sydney and other Australian sites.
- 4. QB46C-H07 Clinical pilot Phase IIA efficacy trial treating soft tissue sarcoma. The study protocol is currently in development.

#### **Clinical trial progress**

A Clinical Phase I/IIA (QB46C-H01/2) dose escalation open label study with tigilanol tiglate used here as an intratumoural injection in 22 patients with cutaneous, subcutaneous, head and neck or nodal tumours has been completed at four hospitals in Australia.<sup>14</sup> This first-in-human study was primarily undertaken to establish the safety and tolerability of the drug, with preliminary efficacy necessarily as a secondary consideration.

The results from the study were encouraging for a first-in-human trial. A maximum tolerated dose (MTD – where the study is stopped due to signs of patient toxicity) was not reached.<sup>14</sup> Study stop was determined by an efficacious dose being achieved that would support the next stage in development.<sup>14</sup>

The treatment regimen for tigilanol tiglate for this study was not calculated according to tumour volume (the efficacious dose injection for treating MCT in dogs is 50% of the tumour volume irrelevant of dog weight), but via patient weight as it was a safety trial, thus many tumours necessarily were underdosed. <sup>14</sup> In addition, patients suitable to recruit to this type of study are usually late stage and present with very large tumours, thus achieving a 50% tumour volume treatment was not possible in most cases. Consequently, under these conditions, efficacy would have been difficult to achieve. However, signs of clinical efficacy were noted in nine different tumour types including squamous cell carcinoma, basal cell carcinoma, metastatic melanoma, breast adenocarcinoma, myxoid fibrosarcoma, metastatic colorectal adenocarcinoma, adenoid cystic carcinoma and angiosarcoma. <sup>14</sup> Complete Response (full tumour destruction) was achieved when the drug dose was near the 50% tumour volume (refer to Figure 4.5 and to Figure 4.6 for a treatment example). <sup>14</sup> Two patients on the trial also showed signs of potential abscopal (anenestic) response where tumours not injected with tigilanol tiglate also responded. <sup>14</sup>

These results demonstrate the potential of tigilanol tiglate in the treatment of a variety of solid tumours and support the continued development of tigilanol tiglate for the treatment of solid tumours by intratumoural administration.

500 400 300 200 100 Change in injected tumour volume (%, Day 21) % of tumour fully dosed 100 51-90 25-50 <25 80 60 40 -20 -40 highly ulcerated tumour, leakage of tigilanol tiglate -60 two or three tumours treated -80 per patient -100 CR/PR tumour responses Tumour type correlates with dose Efficacy signals seen in Squamous Cell Carcinoma (SCC), Melanoma (BRAF), Basal Cell Carcinoma (BCC), Angiosarcoma, Atypical Fibroxanthoma (AF), Fibrosarcoma, Breast and Colorectal Adenocarcinoma (AC), and Adenoid Cystic Carcinoma (ACC)

Figure 4.5: Trial QB46C-H01/2 showing change in tumour volume over time<sup>14</sup>

Figure 4.6: Metastatic melanoma in patient from the Human Clinical Phase I/IIA trial showing full tumour destruction of injected and non-injected tumours with good healing of the treatment site<sup>14</sup>

## Human Phase I Safety Trial QB46C-H01





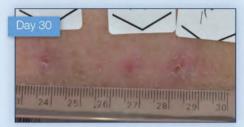
Single injection into 3 tumours. No treatment in 4th tumour.



Tumour vascular destruction evident



Tumour destruction progressing



Complete Response with good site healing of all 4 tumours

Case Summary:	
Previous treatment:	Keytruda 9 weeks washout prior to tigilanol tiglate dosing
Complete response:	Achieved by day 30 in injected and non-injected tumours
Additional treatment:	Not required
Adverse events:	None reported
Wound intervention:	Not required

### Anenestic (abscopal) response:

- 4th forearm untreated tumour CR possible bystander effect
- CT scan confirmed Complete Response of 24 mm left axilla lymph node and 29mm pleural nodule with a reduction in size of the inguinal lymph node

Panizza B. et al. EBioMedicine. 50(2019). 433 - 441

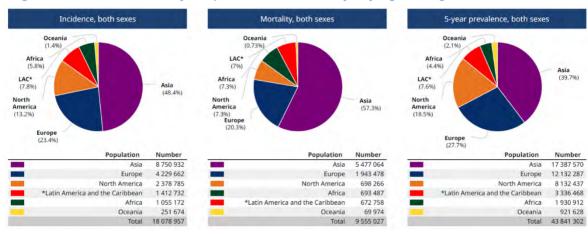
#### 4.3.4 Human commercialisation

### The human market for tigilanol tiglate

The World Health Organisation (WHO) International Agency for Research on Cancer (IARC) estimates that 1 in 6 women and 1 in 5 men are likely to develop cancer during their lifetime. In 2018, there were 18.1 million newly diagnosed cases of cancer and 9.6 million cancer deaths.

By 2040, the number of new cancer cases per year is expected to rise to 29.5 million and the number of cancerrelated deaths to 16.4 million <sup>19</sup>, reflecting poor outcomes with existing therapies and a major need for new treatment approaches.

Figure 4.7: Incidence, mortality and prevalence of cancer by major global region 20



Up to 90% of all cancers are solid tumours. <sup>21</sup> The global solid tumour cancer treatment market was valued at US\$121.3 billion in 2018 and is expected to reach US\$424.6 billion by 2027, expanding at a compound annual growth rate (CAGR) of 15.0% from 2019 to 2027, in line with the widespread prevalence of cancer and need for new treatment approaches. <sup>23</sup>

Small molecules are currently the largest market in the therapy segment for solid tumour cancer treatment with global sales of oncology small molecule drugs valued at approximately US\$66 billion in 2019, and an approximate 6% CAGR through to 2029. North America presently holds the largest market share in the regional segment for solid tumour cancer treatment, with sales of oncology small molecule drugs revenues of approximately US\$30 billion in 2019. Europe accounts for 30.2% market share in the solid tumour market, while Asia Pacific with a share of 19.5% is set to register significant growth soon owing to the rising public health awareness regarding cancer and its treatment and developing healthcare infrastructure. <sup>23</sup>

In the indication segment of the solid tumour cancer treatment market, melanoma and head and neck cancer have large patient populations with high unmet medical need where five-year survival rates are below 30

<sup>&</sup>lt;sup>18</sup> Globocan, 2019. World Fact Sheet.

<sup>19</sup> https://www.cancer.gov/about-cancer/understanding/statistics. Accessed 1 February, 2021

<sup>&</sup>lt;sup>20</sup> Globocan, 2019. World Fact Sheet.

<sup>21</sup> National Cancer Institute USA <a href="https://training.seer.cancer.gov/disease/categories/classification.html">https://training.seer.cancer.gov/disease/categories/classification.html</a>

<sup>&</sup>lt;sup>22</sup> https://www.factmr.com/report/3747/oncology-small-molecules-drugs-market

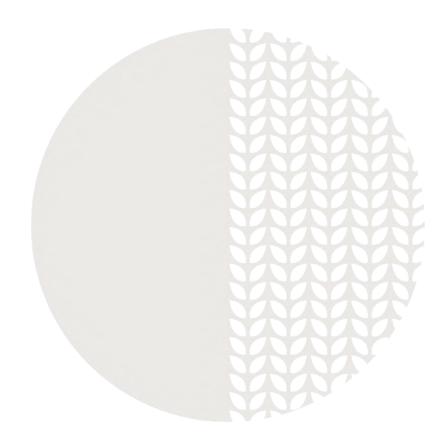
<sup>23</sup> Research and Markets, 2019. Global Solid Tumor Cancer Treatment Market Expected to Generate a Value of US\$ 424.6 Billion During the Forecast Period, 2019-2027.

percent. <sup>24</sup> Soft tissue sarcoma is also an indication with very high unmet need. <sup>25</sup> Its smaller patient populations in a niche indication may provide the opportunity for orphan approvals. <sup>25</sup>

### Key factors shaping growth of the oncology small molecule drugs market

A key factor driving growth of the oncology small molecule drug market is their use as a monotherapy, as well as their potential use as a combination partner for existing drugs, in particular check point inhibitors (CPI's).<sup>27</sup> CPI's, such as Keytruda® (pembrolizumab) are the solid tumour market leader with 2019 global sales for Keytruda® of US\$11.1 billion<sup>26</sup>. However, less than 50% of patients respond to treatment, and significant side effects, although rare, do occur.<sup>27</sup> Small molecules such as tigilanol tiglate may offer several benefits as a combination partner, such as the potential for non-overlapping toxicity. Preliminary *in vivo* data in mouse studies show that tigilanol tiglate in combination with a CPI have shown to increase survival and regress melanoma tumours than the CPI alone.<sup>13</sup>

Interest in intratumoural treatments for solid tumour cancer is on the increase and intratumoural drugs are attracting comparatively sound licencing deals.<sup>28</sup>



<sup>&</sup>lt;sup>24</sup> McKinsey and Company report, 2020. Delivering innovation: 2020 oncology market outlook

<sup>&</sup>lt;sup>25</sup> Kasper, 2019. Challenge in finding new therapeutic avenues in soft tissue sarcoma. Clin Sarcoma Res 4. <a href="https://www.cancer.net/cancer-types/sarcoma-soft-tissue/statistics">https://www.cancer.net/cancer-types/sarcoma-soft-tissue/statistics</a> (doctor approved patient information from ASCO).

<sup>&</sup>lt;sup>26</sup> Evaluate Pharma, January 2020. https://www.evaluate.com/cancer-immunotherapy-drug-classes-watch-2020-and-beyond

<sup>&</sup>lt;sup>27</sup> Schmidt, 2019. Seminars in Immunopathology. 41:21-30.

<sup>&</sup>lt;sup>28</sup> Evaluate Pharma Report 2018.

### 4.3.5 Head and neck squamous cell carcinoma

Head and neck cancer is the 7<sup>th</sup> most common cancer globally with approximately 1.38m new cases in 2018.<sup>29</sup>

Over 90% of head and neck cancer is due to squamous cell carcinoma (HNSCC). <sup>30</sup> Surgery and radiation are currently the primary treatments for HNSCC as this cancer does not readily metastasise (spread of cancer to other parts of the body). <sup>30</sup> However, there is a need for less invasive and disabling approaches for this cancer, especially so for the elderly and those suffering from human papillomavirus (HPV) oral cancer. <sup>31</sup> There is currently poor prognosis for unresectable (unable to be removed by surgery) tumours treated with existing chemotherapy options and/or radiation as 25% of oral cancer patients are over 75 years of age, 35% of tongue cancer patients have local disease at diagnosis and approximately 40% of oral cancer patients receive non-surgical or no therapeutic treatment. <sup>32</sup>

To our knowledge, there are currently no other intratumoural products approved for the specific treatment of HNSCC. Those reported to be in development for the indication are NBTXR3 nanoparticles to improve radiation therapy in Phase II development by the USA company NanoBiotix, and BB401 an antisense drug in Phase II by the Australian company Benitec. 30,28

The global market for head and neck cancer is expected to reach \$4.5 billion by 2027, growing at CAGR 17.3% over the forecast period, driven by rising epidemic of oropharyngeal cancer associated with HPV. <sup>33</sup> HNSCC tumours are highly immunogenic and have elevated expression of immune checkpoint modulators. <sup>30</sup> As such, there has been much interest in the

Head and neck cancer is the

7 TH most common cancer worldwide

Approximately
1.38 million
new cases are
diagnosed each year



Unmet need

Surgically unresectable, loco-regional recurrence



Market Size

US\$ 4.5 billion

by 2027

More than **108,000 cases** p.a. est. suitable for tigilanol tiglate

modulators.<sup>30</sup> As such, there has been much interest in the development of immunotherapies to allow for a more targeted treatment program.<sup>30</sup> More recently the PD-1

Although treatment with these drugs has shown considerable improvement over previous systemic treatments, there is still room for improvement, which is currently being assessed by combination therapy with intratumoural drugs (as previously mentioned).<sup>35</sup>

inhibitors Keytruda (pembrolizumab) and Opdivo (nivolumab) have been making inroads in this market.<sup>34</sup>

Tigilanol tiglate is demonstrating potential as a treatment for HNSCC both as a monotherapy and in combination with the ICI drugs. Systemic treatments only represents approximately 10% of patients according to insurance data<sup>32</sup> and there is a need for alternatives to surgery and radiation.<sup>31</sup>

 $\underline{https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11\#2Bb4Z0uJames/itinerary/5404/2017-09-11#2Bb4Z0uJames/5404/2017-09-11#2Bb4Z0uJames/5404/2017-09-11#2Bb4Z0uJames/5404/2017-09-11#2Bb4Z0uJames/5404/2017-09-11#2Bb4Z0uJames/$ 

<sup>&</sup>lt;sup>29</sup> Globocan 2018. https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf

<sup>30 2020</sup> Insights into Head and Neck Cancer Disease Industry - Coverage Forecast and Market Analysis to 2024 -ResearchAndMarkets.com https://www.businesswire.com/news/home/20200703005085/en/2020-Insights-into-Head-and-Neck-Cancer-Disease-Industry---Coverage-Forecast-and-Market-Analysis-to-2024

<sup>&</sup>lt;sup>31</sup> American Society of Clinical Oncology (ASCO) 2013 Education Book.

<sup>&</sup>lt;sup>32</sup> Jacobson, J., Epstein, J., Eichmiller, F., Gibson, T., Carls, G., Vogtmann, E., Wang, S. and Murphy, B. The cost burden of oral, oral pharyngeal, and salivary gland cancers in three groups: commercial insurance, medicare, and medicaid,. Head Neck Oncology 2012; 4:15.

<sup>33</sup> Global Head and Neck Cancer Market \$4.5 Billion by 2027. February 4, 2020 by <u>iHealthcareAnalyst, Inc.</u> https://www.ihealthcareanalyst.com/global-head-neck-squamous-cell-carcinoma-drugs-market/

<sup>&</sup>lt;sup>34</sup> Head and neck cancer excluding thyroid. ESMO 2017 Congress.

<sup>&</sup>lt;sup>35</sup> Sepulveda *et al*, 2019. Checkpoint inhibitors in head and neck cancer. *Magazine of European Medical Oncology*, 12: 249-252.

#### 4.3.6 Melanoma

The incidence of melanoma increases at 5% per annum with approximately 287,000 new cases in 2018. 36

Survival rates for metastatic melanoma are still unacceptably low. CPIs lead the market but less than 50% of patients benefit.  $^{37}$ 

The total market for melanoma is estimated to reach US\$15 billion by 2027.<sup>38</sup>

Keytruda and Opdivo lead the CPI market for melanoma treatment.<sup>39</sup>

In Australia alone, the mean annual cost per patient for melanoma stage 0/l/II is A\$1681 (US\$1175) rising to A\$37,729 (US\$26,365) for stage III resectable, and A\$115,109 (US\$80,440) for stage III unresectable/IV. Average three-year costs for stage III unresectable/IV melanoma were AU\$187,720.  $^{\rm 40}$ 

The Australian national annual estimated cost for treatment of all new cases of *in situ* and invasive melanomas was AU\$201 million (95% CI: AU\$187 to AU\$216 million).<sup>40</sup> When treatments for presumptive melanoma later found to be benign lesions are included, the estimated annual cost burden reached AU\$272 million.<sup>40</sup>

The unmet medical need for melanoma is surgically unresectable, inaccessible disease, with loco-regional recurrence and in transit disease. <sup>41</sup> QBiotics believes there is a significant market opportunity through:

- Improving CPI combination therapy without overlapping toxicity;
- Treating multiple lesions, in transit lesions, locally recurrent and unresectable disease;
- Addressing the current lack of injectable options for in transit disease;
- Only one intratumoural product has been approved for unresectable disease, Imlygic<sup>®</sup> (Amgen), however the drug is expensive and difficult to use; and
- There are an estimated 65,672 cases per annum that are non-resectable with no other local treatment option.<sup>38</sup>

Tigilanol tiglate is demonstrating potential as a treatment for melanoma both as a monotherapy and in combination with the ICI drugs. 14,13 The unmet need of surgically unresectable, inaccessible disease, with locoregional recurrence and in transit disease 41 is a focus indication for QBiotics.

Melanoma incidence is rising

5% per year

Approximately **287,000** 

new cases are diagnosed each year



### Unmet need

Surgically unresectable, loco-regional recurrence and in transit disease



Market Size

US\$ 15 billion

by 2027

More than **67,652 cases** p.a. est. suitable for tigilanol tiglate

<sup>36</sup> Globocan 2018. https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf

<sup>&</sup>lt;sup>37</sup> Klemen *et al*, 2019. Patterns of failure after immunotherapy with checkpoint inhibitors predict durable progression-free survival after local therapy for metastatic melanoma

<sup>&</sup>lt;sup>38</sup> Melanoma Market – Fortune Business Insights https://www.fortunebusinessinsights.com/skin-cancer-treatment-market-102806

<sup>&</sup>lt;sup>39</sup> https://dexur.com/a/keytruda-opdivo-market-share-comparison-lung-cancer-and-melanoma/1062/

<sup>&</sup>lt;sup>40</sup> T Elliott, D Whiteman, C Olsen, L Gordon. Estimated Healthcare Costs of Melanoma in Australia Over 3 Years *Post-Diagnosis Appl Health Econ Health Policy*. 2017 Dec;15(6):805-816. doi: 10.1007/s40258-017-0341-y.

<sup>&</sup>lt;sup>41</sup> Jones *et al*, 2015. Unmet clinical needs in the management of advanced melanoma: findings from a survey of oncologists. *European Journal of Cancer care*, 24: 867-872

#### 4.3.7 Soft Tissue Sarcoma

Soft tissue sarcoma (STS) is a complex and heterogenous disease with approximately 50 different types including fibrosarcoma, angiosarcoma, clear cell sarcoma, alveolar softpart sarcoma, kaposi sarcoma, malignant mesenchymoma, rhabdomyosarcoma, amongst many others. 42,44,46,

STS incidence is increasing at 0.5% per year.<sup>44</sup> Approximately 12,000 patients in the US and 28,000 patients in Europe are diagnosed with STS every year.<sup>44,44,45</sup> These numbers aren't comparatively high, however treatment for STS is limited and the unmet need is safe and effective treatments, especially for advanced disease.<sup>42,44</sup>

Sixty percent of sarcomas are localised, 19% are locally advanced (and unresectable), and 15% are metastatic.<sup>43,42</sup> Five year survival rate for localised, regional and distant STS is 81%, 57% and 16%, respectively.<sup>43</sup>The primary treatment for STS is surgery.<sup>44</sup> However, even after complete surgical resection, approximately 50% of patients with intermediate or high grade sarcoma develop metastatic disease.<sup>42</sup>

Other therapies include radiotherapy and chemotherapy.<sup>44</sup> Currently, there are very few products approved for the treatment of STS.<sup>42,44</sup>. Unmet needs within the market present a key opportunity to develop breakthrough first-in-class therapies.<sup>42,43,46</sup> Registered drugs for the disease include trabectedin (Yondelis - Janssen), sunitinib (Sutent - Pfizer), sirolimus (Rapamune - Pfizer), and doxorubicin (Adriamycin - Pfizer), bevacizumab (Avastin - Genentech).<sup>46,44</sup> The success rates for these treatments are largely marginal and side effects can be severe.<sup>44,46</sup>

There are

50 different types
of soft tissue sarcoma

Approximately **40,155** new cases are

new cases are diagnosed each year



**Unmet need** 

Safe and effective treatments, especially for advanced disease



Market Size
US\$ 1.2 billion
(by 2023)



Increase in the incidence of soft tissue sarcoma and patent expiry of branded drugs, are factors fueling the growth of the STS market.  $^{44,45,46}$  The global sarcoma market is expected to be valued at US\$1.2 billion by 2023  $^{45}$  with an expected market growth of CAGR of 11.50% during the 2020-2027.  $^{46}$ 

North America holds the largest share in the global STS market followed by Europe and Asia Pacific, respectively. 44,45,46

Eli Lilly and Company (US), GlaxoSmithKline plc. (UK), Pfizer, Inc. (US), F. Hoffmann-La Roche AG (Switzerland), Bristol-Myers Squibb (US), Johnson & Johnson Services, Inc. (US), Celgene Corporation (US), and Teva Pharmaceutical Industries Ltd (Israel), are some of the major players interested in the STS market. 46

The main problem with many STS indications is that they are locally invasive with clean surgical margins difficult to obtain.<sup>44</sup> Radiotherapy and chemotherapy offer an alternative to surgery, however success rates can be

<sup>42</sup> Kasper, 2019. Challenge in finding new therapeutic avenues in soft tissue sarcoma. Clin Sarcoma Res 4.. <a href="https://www.cancer.net/cancer-types/sarcoma-soft-tissue/statistics">https://www.cancer.net/cancer-types/sarcoma-soft-tissue/statistics</a> (doctor approved patient information from ASCO).

<sup>&</sup>lt;sup>43</sup> Cancer Net Editorial Board. Sarcomas, Soft Tissue: Statistics. February 2021. https://www.cancer.net/cancer-types/sarcomas-soft-

tissue/statistics#: -: text=About % 2060% 25% 20of % 20 sarcomas % 20 are, in % 20a% 20 locally % 20 advanced % 20 stage. The property of th

<sup>&</sup>lt;sup>44</sup> Soft Tissue Sarcoma Market Research Report – By Treatment (Targeted Therapy, Chemotherapy, Anti-Angiogenesis Drugs, Radiation Therapy), By Disease Type (Local, Regional, Metastatic Sarcoma), By Distribution Channel, By End User–Global Forecast till 2023. ID: MRFR/Pharma/3862-HCR | February 2021 | Region: Global |

 $<sup>^{45}\</sup> Grand\ View\ Research\ https://www.grandviewresearch.com/press-release/global-sarcoma-drugs-market$ 

<sup>&</sup>lt;sup>46</sup> Soft Tissue Sarcoma Market, Size, Share, Opportunities and Forecast 2020-2027. SKU: DPH57. Updated Oct 2020. https://www.datamintelligence.com/research-report/soft-tissue-sarcoma-market

marginal and side effects are often severe.<sup>44</sup> Consequently, due to the mode of activity of tigilanol tiglate, QBiotics believes the drug has potential to offer an alternative to the currently available treatments.

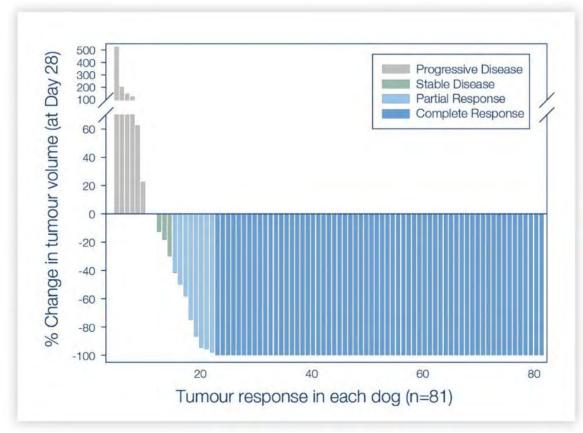
### 4.3.8 Veterinary development

#### **Veterinary clinical development**

QBiotics has registered and is marketing tigilanol tiglate as a treatment for MCT in dogs under the brand name STELFONTA®. The US FDA-CVM, the EMA, Swissmedic and the UK VMD have approved the drug as a veterinary pharmaceutical for the treatment of all grades of non-metastatic MCT in dogs, and marketing of the drug has commenced in Europe, the UK and the USA (refer to Section 4.3.9 for details). STELFONTA® is also under late stage review by the Australian veterinary regulator the APVMA.

In a fully controlled and blinded pivotal study in 123 dogs conducted in the US under the FDA-CVM, a single treatment with tigilanol tiglate completely destroyed (Complete Response) 75% of MCT in canine patients, the result of which were highly significant compared to the control (p<0.0001) (refer to Figure 4.8 below).<sup>15</sup> A second treatment increased the Complete Response success rate to 88%.<sup>15</sup>. Tigilanol tiglate was mostly well tolerated and most animals had a good quality of life during and after treatment.<sup>15</sup> Adverse Events typically were low grade, transient, and associated with the mode of action of the drug (e.g., transient local swelling and associated pain, tumour necrosis etc).<sup>15</sup> Refer to Figure 4.9 for an example of treatment progress.

Figure 4.8: Change in tumour volume over time<sup>15</sup>



01-012

Figure 4.9: MCT in a Jack Russell Terrier treated with tigilanol tiglate from the US FDA-CVM trial<sup>15</sup>

## Mast Cell Tumour Day 0 pre-treatment Tumour begins to necrose Tumour vasculature breaking down Tumour necrosing Complete tumour destruction Tumour free minimum 12 (Complete Response) months following treatment Patient Details: Sex: Female (neutered) Breed: Jack Russell Terrier Age: 11 years 8 months Weight: 6.6kg Clinical notes: Tracheal weakness and further MCTs at other sites Case Summary: Tumour - low grade subcutaneous MCT on medial elbow. Originally in control group of clinical trial. Tumour volume: 0.5cm<sup>3</sup> Dose received: 0.3mg tigilanol tiglate (0.05mg/kg) Complete response: Achieved by day 28 Additional treatment: Not required Adverse events: Mild and transient Wound intervention: No intervention

#### Other canine tumour types and other species

QBiotics is also exploring the use of STELFONTA® in other canine tumour indications as well as other species. Soft tissue sarcoma (STS) in dogs is the most advanced, with oral melanoma and squamous cell carcinoma also being investigated.

A clinical trial treating sarcoids in horses with STELFONTA $^{\odot}$  is underway with equine veterinary specialists in Australia, the UK, Sweden, Spain, Germany and the Netherlands. Equine sarcoids represents a significant unmet medical need as treatment options are limited.  $^{47}$ 

Development of STELFONTA® for solid tumour cancer in cats is also of interest to QBiotics.

### 4.3.9 Veterinary commercialisation

### **Tigilanol tiglate for the General Practitioner**

Cancer treatments are often the domain of the Specialist Oncologists.<sup>51,52</sup> STELFONTA® is a pharmaceutical that is approved as a prescription product that general practitioners and oncologists can prescribe therefore is available to a broad market of dogs with MCT, rather than only those that visit a specialist. For example, in the USA alone there are 48,898 actively practicing General Practitioners<sup>48</sup> while there are only 425 Board Certified Oncology Specialists and only 1,992 Board Certified Internal Medicine Specialists offering oncology treatments.

#### Commercialisation of tigilanol tiglate as a veterinary product

QBiotics has partnered with the global animal health company Virbac for marketing and distribution of STELFONTA® as a veterinary anticancer pharmaceutical treating all grades of non-metastatic canine MCT. Virbac is a French listed company established in 1968 and is a dedicated animal health pharmaceutical company with a presence in more than 100 countries (corporate.virbac.com/home). The deal consists of modest upfront and milestone payments with a revenue split.





#### Companion animal cancer market

Companion animals (dogs, cats and horses) have come to play an important role in the lives of many people. The number of US households that own a dog is 63.4 million, a horse 1.6 million and a cat 42.7 million.<sup>49</sup>

In the US, spending on pets has increased from US\$23 billion in 1998 to US\$95.7 billion in 2019. $^{49,50}$  Around US\$29.3 billion of this spending was on veterinary care (including medicines). $^{50}$ 

The willingness of companion animal owners to spend more on their animals' health and the ability of veterinarians to meet that need have continued to be the key drivers of the veterinary market. <sup>50</sup>

<sup>47</sup> Frandsen *et al.* 2020. Calcium electroporation of equine sarcoids. *Animals*, 10(3): 517. https://doi.org/10.3390/ani10030517

<sup>&</sup>lt;sup>48</sup> American Veterinary Medical Association 2018. U.S. Veterinarians. https://www.avma.org/resources-tools/reports-statistics/market-research-statistics-us-veterinarians-2018

 $<sup>^{49}\,\</sup>text{American Pet Products Association website http://americanpetproducts.org/press\_industrytrends.asp}$ 

<sup>&</sup>lt;sup>50</sup> Brakke Consulting Report "Cancer in Dogs and Cats"; October 2014.

It has been estimated that, worldwide, as many as 1 in 4 dogs and 1 in 6 cats will develop cancer at some time in their life and almost 50% of dogs over the age of 10 years will die of the disease.  $^{51,52}$  Cancer in horses is less prevalent compared to that in dogs and cats, however it is still a problem and there is currently no registered treatment for cancer in horses.  $^{53,54}$ 

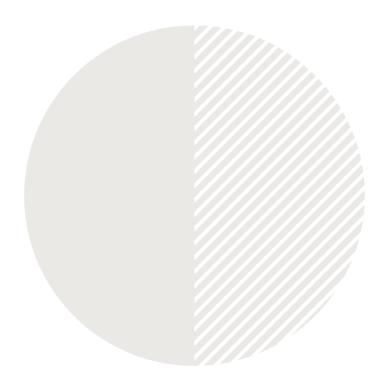
As veterinary care becomes more developed and pets are living longer, veterinarians are diagnosing cancers more frequently in companion animals and the numbers are significant.<sup>51,52</sup>

#### Canine Mast Cell Tumour and Soft Tissue Sarcoma market

MCT is the most common form of cancer in dogs representing approximately 16- 21% of all canine cutaneous cancers followed by STS making up approximately 15%.<sup>52</sup> Standard of care treatment for both MCT and STS is surgical removal, with usually wide margins, of the tumour.<sup>52,55</sup> When this is not possible, one or a combination of chemotherapy, radiotherapy or cytoreductive (debulking) surgery is undertaken.<sup>52</sup>

These therapeutic approaches are often (i) costly, (ii) have varying success rates, and (iii) result in moderate to severe adverse side effects. <sup>50</sup> Consequently, there remains a high demand for a widely available, efficacious therapy with improved quality of life outcomes for the patient.

The veterinary anticancer market is relatively new but is attracting the attention of the large pharmaceutical companies (refer to Table 4.1). 56,57,58,59,60,61,62 This attention demonstrates the significant global commercial opportunity that exists with treating cancer in companion animals. 50



<sup>&</sup>lt;sup>51</sup> Kelsey. J.L, Moore, A.S. and Glickman, L.T. Epidemiological studies of risk factors for cancer in pet dogs. Epidemiology Review 20 (2): 204-217. 1998.

<sup>&</sup>lt;sup>52</sup> Withrow, S.J. and Vail, D.M. 2007. Small Animal Clinical Oncology, Elsevier Inc, Canada 402-421.

<sup>&</sup>lt;sup>53</sup> Cotchin, E. 1977, A general survey of tumours in horses, Equine Veterinary Journal 9 (1):16-21.

<sup>&</sup>lt;sup>54</sup> Scott, W. and Miller, W. Neoplastic and non-neoplastic tumours, Equine Dermatology, Elsevier Inc., Missouri, 719-31. 2003.

Table 4.1: Current registered treatments for cancer in dogs and cats 55,56,57,58,59,60,61,62

Company	Product	Active	Cancer	Treatment and Cost	Success rate
Zoetis (formerly Pfizer)	Palladia USA – June 2009 Australia – December 2011	Toceranib phosphate	Mast Cell Tumours in dogs	Tablets ~US\$300 per month; continu ous treatment	Partial Response/ Stable Disease in 40% of cases
AB Sciences	Masivet EU – June 2009	Masitinib mesilate	Mast Cell Tumours in dogs c-Kit mutation only	Tablets ~US\$200 per month; continuous treatment	Partial Response/ Stable Disease in 40% of cases
Merial (Sanofi Aventis)	Oncept USA – March 2007 EU – March 2013 - Withdrawn	Plasmid DNA (deoxyribonuc- leic acid) pINGhT	Melanoma in dogs	Therapeutic vaccine ~US\$2,100 per treatment	Complete Response/ Stable Disease in 50% of cases
Merial (Sanofi Aventis)	Oncept IL-2 USA – March 2007 EU – March 2013	feline interleukin-2 recombinant canarypox virus	Fibrosarcoma (in combination with surgery and radiotherapy) in cats	Therapeutic vaccine	Complete Response/ Stable Disease in 50% of cases
Vet DC (Distributed by Elanco)	Tanovea-CA1 USA Conditionally approved	rabacfosadine for injection	Lymphoma in dogs	30 min IV Injection 5 doses required ~US700 per dose	Complete Response 45%
Anivive Life- sciences	Lavardia-CA1 USA conditionally ap proved	verdinexor	Lymphoma in dogs	Oral treatment	-

<sup>&</sup>lt;sup>55</sup> Blackwood, L., Murphy, S., Buracco, P., De Vos, J., De Fornel-Thibaud, P., Hirschberger, J., Kessler, M., Pastor, J., Ponce, F., Savary-Bataille, K., and Argyle, D. European consensus document on mast cell tumours in dogs and cats. Veterinary and Comparative Oncology. DOI:10, 3, e1 – e29. 2012.

<sup>&</sup>lt;sup>56</sup> Rusk J.F., Rosenberg, A., Henry M., Mitchener C., Klein K., Hintermeister M., Bergman J., Couto P., Mauldin G., and Michels G. Multi-center, placebo-controlled, double-blind, randomized study of oral toceranib phosphate (SU11654), a receptor tyrosine kinase inhibitor, for the treatment of dogs with recurrent (either local or distant) mast cell tumour following surgical excision. *Clinical Cancer Research* 2009.

<sup>&</sup>lt;sup>57</sup> Hahn, K., Ogilvie, G., Rusk, T., Devauchelle, P., Leblanc, A., Legendre, A., Powers, B., Leventhal, P., Kinet, J., Palmerini, F., Dubreuil, P., Moussy, A. and Hermine O. Masitinib is safe and effective for the treatment of canine mast cell tumors. *Journal of Veterinary Internal Medicine*; 22: 1301–1309. 2008.

<sup>&</sup>lt;sup>58</sup> Denies, S. Sanders, N.N. Recent progress in canine tumor vaccination: potential applications for human tumor vaccines. *Expert Rev Vaccines* Nov;11(11):1375-86. DOI: 10.1586/erv.12.104. 2012.

<sup>&</sup>lt;sup>59</sup> European Medicines Agency. Committee for medical products for veterinary use. Oncept IL-2. EMA/CVMP/100985/2013. 8 March 2013.

<sup>&</sup>lt;sup>60</sup> Fierce Animal Health http://www.fierceanimalhealth.com/story/five-questions-aratana-ceo-steven-st-peter/2014-10-20.

<sup>&</sup>lt;sup>61</sup> Sadowski et al. 2018. Phase II study of the oral selective inhibitor of nuclear export (SINE) KPT-335 (verdinexor) in dogs with lymphoma. *BMC veterinary research*, *14*(1), pp.1-7.

<sup>&</sup>lt;sup>62</sup> Dog Lymphoma & Advanced Cancer Treatments | Home | TANOVEA-CA1. https://vet-dc.com/tanovea/

### 4.4 Wound healing

### 4.4.1 Chronic and acute wounds and burns treated by EBC-1013

Based on clinical observations of wound healing outcomes from the tigilanol tiglate program and pre-clinical knowledge, QBiotics initiated a discovery research program to identify agents for further development as wound treatments. Of a portfolio of more than 150 novel patent protected compounds, QBiotics selected EBC-1013 for further development. EBC-1013 may have the potential to treat the spectrum of wound types including chronic and acute wounds and burns. <sup>63,64,65</sup> EBC-1013 is applied topically in a simple gel formulation.

EBC-1013 is a semi-synthetic epoxytigliane with the same base chemistry as tigilanol tiglate and is isolated from the same source, the seed of Fontainea. The compound is produced by isolation of the base structure and producing EBC-1013 via a semi-synthetic pathway. Manufacture of the drug substance under cGMP has commenced and gel formulations for the human and veterinary programs have been determined. Although still at early stage of development, EBC-1013 is proving to have potential to treat a wide range of chronic-infected and acute traumatic wounds and burns. Veterinary clinical studies in horses, dogs and calves in a range of 'real world' chronic and acute wounds and burns have demonstrated that EBC-1013 has the potential to address the main wound healing needs including induction of wound closure and re-epithelialisation, reduction of infection, and results in minimal scarring. Although still actions to the same semi-synthetic pathway.

Consequently, EBC-1013 has potential for a range of wound healing applications in the human and veterinary markets.

QBiotics' initial focus for EBC-1013 is on chronic wounds. The first indication for the human market is venous leg ulcers (VLU) as this is a potential unmet medical need as no solution specific for VLU is currently available for this debilitating disease. <sup>70,78,79</sup> The cGMP production of the drug substance is underway as is the FDA IND enabling toxicology program. The equine market is the focus for the veterinary product as there also exists the need for simple, efficacious wound healing treatments for companion animals, especially horses. <sup>67</sup>

#### 4.4.2 Mode of action

#### How EBC-1013 works

EBC-1013 is a signalling molecule with a unique mode of action. The drug has demonstrated signs of amplifying an acute inflammatory response with a resulting antimicrobial effect, disrupting bacterial biofilms, debriding chronic wounds and resetting them to an acute mode, stimulating reepithelialisation, accelerating wound closure and minimising scarring. <sup>63,65,66</sup>

Laboratory based research is showing signs that EBC-1013 (also refer to Figure 4.11A and B): 65,66,68

- Disrupts biofilm assembly and structure produced by bacteria as a 'protective' device;
- Attract and activate neutrophils (white blood cells) involved in bacterial destruction;
- Differentiates monocytes into M1 & M2 macrophage (white blood cells) phenotypes involved in both bacterial destruction and tissue repair:
- Selectively stimulating both the proliferation and the migration of keratinocytes ('wound healing' cells) thus facilitating wound closure; and

<sup>&</sup>lt;sup>63</sup> Cullen *et al.* 2019. The semi-synthetic epoxytigliane EBC-1013 promotes the closure of chronic, biofilm-infected wounds in diabetic mouse model. Poster. Australian Society for Microbiology conference

<sup>&</sup>lt;sup>64</sup> De Ridder *et al.* 2019. Topical application of the semi-synthetic epoxy-tigliane EBC-1013 induces resolution of burn wound infection and wound closure in an immunocompetent calf model. Poster. Australian Society for Microbiology conference

 $<sup>^{65}</sup>$  Powell et al. 2019. Biofilm disruption by epoxytiglianes. Poster. Australian Society for Microbiology conference

<sup>&</sup>lt;sup>66</sup>Moses *et* al. Dally, 2020. Novel epoxy-tiglianes stimulate skin keratinocyte wound healing responses and reepithelialization via protein kinase C activation. *Biochemical Pharmacology*. 178: 114048 67 Freeman et al 2021. BEVA Primary care clinical guidelines: Wound management in the horse.

Modifying the proliferation and differentiation of fibroblasts (also 'wound healing' cells) thus supporting
wound in-fill while minimising the production of scarring associated with the wound.<sup>68</sup>

Figure 4.11A: Mode of action of EBC-1013 treating chronic wounds

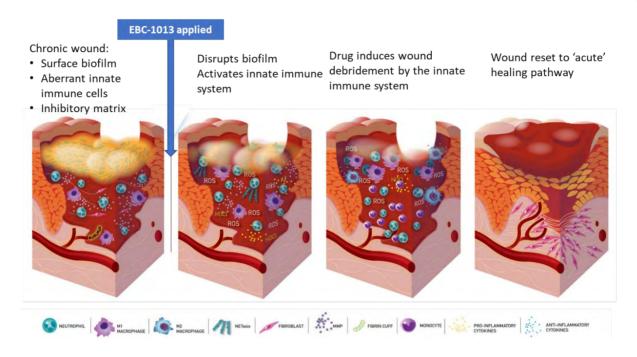
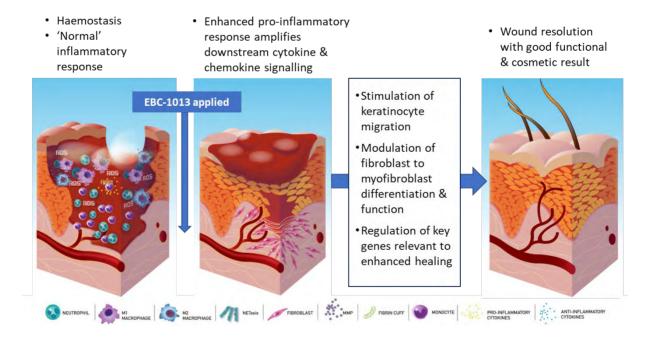


Figure 4.11B: Mode of action of EBC-1013 treating acute and 'reset' chronic wounds



<sup>&</sup>lt;sup>68</sup> Dally J, Moses R, Midgley A, Howard-Jones R, Errington R, Reddell P, Steadman R, Moseley R. 2015. Modulatory effects of novel epoxy-tigliane pharmaceuticals on dermal fibroblast-myofibroblast wound healing responses mediate their enhanced anti-scarring properties. *Wound Repair & Regeneration* 23: A6.

### 4.4.3 Human and veterinary development

There is the potential for EBC-1013 to treat the spectrum of wound types for humans and companion animals.  $^{64,65,66,68}$ 

EBC-1013 is currently in late preclinical development as a human pharmaceutical and early clinical development as a veterinary pharmaceutical.

A pathway for semi-synthetic production of the EBC-1013 has been achieved and the drug substance cGMP manufacture of the molecule is underway. Drug product gel formulation for the human program has been determined.

The toxicology program for EBC-1013 has commenced. Data from veterinary 'real world' animal models is being applied to develop the human clinical strategy for the drug. The initial first-in-human study is currently planned to be a Phase I/IIA safety trial treating VLU. Following successful outcomes of this safety study, development is planned to move into a Clinical Phase IIA.

In the veterinary environment, EBC-1013 has treated chronic and acute wounds and burns in 'real world' case studies.<sup>64</sup> Wounds generally heal to complete resolution with good cosmetic outcomes (refer to figure 4.12 for an example).

Veterinary clinical development has focused on acute wounds in horses. For burns, QBiotics takes advantage of the standard treatment in dairy calves of their horn buds being burnt out to use this as a model for treating burns.<sup>64</sup> QBiotics is currently undertaking clinical trials in horses.



Figure 4.12: EBC-1013 treating an acute wound on a horse

## EBC-1013 Veterinary Clinical Research: Equine Case

## Equine acute post surgery wound



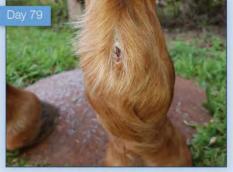
Gel applied 7 days post initial injury. Prominent exuberant granulation formed



Wound contracting and surface area reduced by 88%



Resolution of proud flesh and healing well.



Good cosmetic outcome

Patient Details	
Name:	Lil Red
Breed:	Thoroughbred gelding
Age:	9 years
Location:	Caudal aspect; front right fetlock

### Case Summary:

Fence injury causing trauma to caudal aspect of front right fetlock, with the initial wound approximately 10cm diameter and 5mm deep.

Seven days post injury (Day 0) the wound was starting to heal but with a considerable amount of exuberant granulation tissue (proud flesh). On Day 0, the wound surface area was 27.5cm<sup>2</sup>; EBC-1013 applied 1.5ml gel (3.0mg/ml).

Rapid resolution followed without further intervention required.

#### 4.4.4 Human commercialisation

Despite advances both in understanding wound biology and in treatment regimens and supportive technologies, many wounds are still challenging clinical problems which have significant social and economic costs. <sup>69,70,71,72,73</sup> Consequently, the unmet medical need in the wound healing area may be significant.

The first human market indication for EBC-1013 is planned to be VLU. This is potentially an unmet medical need as no VLU specific solution is currently available for this debilitating and life threatening disease. <sup>70,78,79</sup>

#### 4.4.5 Human market

Current standards of care for complex wounds are often multifaceted with several interventions used concurrently dependent on the type of wound, severity and patient factors. These interventions can range from basic wound bed preparation/management and infection control using debridement, surgery, dressings and/or topical wound therapies (cleansing agents, antimicrobials, hydrocolloids) through to more sophisticated technologies such as negative pressure wound therapy, hyperbaric oxygen therapy, topical growth factors, acellular matrix therapies and bioengineered skin equivalents. 69,70,72

However, despite the plethora of new techniques and products, there remains unmet medical need in three particular areas:

- Emergency care of acute traumatic wounds and burns<sup>70,74</sup>;
- Chronic wounds including venous leg ulcers, diabetic foot ulcers and pressure sores which represent a silent epidemic affecting an increasing proportion of the world's ageing population<sup>74,75,76,77,78,79</sup>; and
- Excessive scarring and fibrosis, as a result of emergency surgery or significant localised trauma, which can have long-lasting functional, cosmetic and psychological consequences for the patient.<sup>80</sup>

### 4.4.6 Advanced wound care market and venous leg ulcers

The advanced wound care market targets both chronic and serious, difficult to treat acute wounds such as burns, large traumatic wounds and non-healing surgical incisions. As shown in Table 4.5 below, chronic wounds impact 14-30 million people, while serious acute wounds occur in 3-16 million.<sup>81,82,83</sup> EBC-1013 has potential for use across both segments, for wounds not responsive to standard of care treatment.

<sup>&</sup>lt;sup>69</sup> Lazarus, G.S., Cooper, D.M., Knighton, D.R., Percoraro, R.E., Rodeheaver, G., Robson, M.C. Definitions and guidelines for assessment of wounds and evaluation of healing. *Wound Repair Regen.* 2:165–70. 1994.

<sup>&</sup>lt;sup>70</sup> Sen, C.K., Gordillo G.M, Roy, S., Kirsner, R., Lambert, L., Hunt, T.K., Gottrup, F., Gurtner, G.C., and Longaker, M.T. Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. Wound Repair Regen. 17(6): 763–771. 2009

<sup>&</sup>lt;sup>71</sup> Driver VR, Fabbi M, Lavery LA, Gibbons G. 2010. The costs of diabetic foot: the economic case for the limb salvage team. J Vasc Surg 2010; 52: 17S–22S.

<sup>&</sup>lt;sup>72</sup> Fife CE, Carter MJ, Walker D, Thomson B. 2012. Wound care outcomes and associated cost among patients treated in US out-patient wound centers: data from the US wound registry. Wounds 24: 10–7

<sup>&</sup>lt;sup>73</sup> Landro, L. A Burgeoning Market for Wound Care. WSJ Health Report. April 16. 2012.

<sup>&</sup>lt;sup>74</sup> Gordon, M.D., Gottschlich, M.M., Helvig, E.I., Marvin, J.A., Richard, R.L. Review of evidenced-based practice for the prevention of pressure sores in burn patients. *J Burn Care Rehabil.* 25:388–410. 2004.

<sup>&</sup>lt;sup>75</sup> Center for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States. 2011

<sup>&</sup>lt;sup>76</sup> Singh, N., Armstrong, D.G., Lipsky, B.A. Preventing foot ulcers in patients with diabetes. *Jama*. 293:217–28. 2005

<sup>77</sup> Kuhn, B.A., Coulter, S.J. Balancing the pressure ulcer cost and quality equation. *Nurs Econ.* 10:353–9. 1992

<sup>&</sup>lt;sup>78</sup> Fife, C., Walker, D., Thomson, B., Carter, M. Limitations of daily living activities in patients with venous stasis ulcers undergoing compression bandaging: problems with the concept of self-bandaging. *Wounds.* 19:255–57. 2007

<sup>&</sup>lt;sup>79</sup> Abbade, L.P., Lastoria, S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. *Int J Dermatol.* 44:449–<sup>56.</sup> 2005.

<sup>&</sup>lt;sup>80</sup> Jackson, W.M., Nesti, L.J., Tuan, R.S. Mesenchymal stem cell therapy for attenuation of scar formation during wound healing. *Stem Cell Res Ther.* May 31;3(3):20. doi: 10.1186/scrt111. 2012.

Table 4.5: Wound prevalence by type

Wound type	Global annual prevalence ("000")
Chronic	14,000 -29,800
Venous leg ulcers	3,000- 17,300 <sup>82</sup>
Diabetic foot ulcers	4,000 -21,000 <sup>82</sup>
Pressure ulcers	7,000 -11,90082
Acute	3,000 – 16,150
Severe burns	200- 350 <sup>,81</sup>
Infected non-healing surgical wounds	10,000 82
Severe traumatic injury	1,800-5,800 <sup>,83</sup>

VLU is the first indication for EBC-1013 in the human market which affects up to 1% of the adult population in developed countries, rising to 3% in people over 65 years of age. The global estimated annual prevalence is 3 million. In 2015 the prevalence of VLUs in the USA was estimated at 600,000 new cases annually. In the USA the overall payer burden due to VLUs is over US \$14.9 billion, making VLUs one of the most costliest diseases to manage.

VLUs are chronic, painful ulcers caused by problems in veins and/or arteries that lead to the accumulation of blood. Because legs are furthest away from the heart, the wounds take longer to heal, particularly in older patients, due to poor blood circulation.<sup>79</sup>

VLUs have a poor long-term prognosis, with one-year healing rates of around 50% and recurrence rates up to 75 percent. <sup>85</sup> VLUs are susceptible to infection, and lack of timely control can lead to serious complications including delayed healing, cellulitis and sepsis. <sup>85</sup> They are expensive and labour-intensive to manage. <sup>86</sup> VLUs remain a major clinical challenge with a high unmet medical need <sup>87</sup> because the current standardised care of compression, wound dressing and debridement leads to variable results, with slow healing, complications and recurrence. <sup>85,86,87</sup>

The current standard of therapy for venous wound care includes topical wound dressings such as foams, hydrofiber, hydrogels, hydrocolloids, collagen, etc, negative pressure wound therapy, debridement treatment and anti-infectives, wound coverage using skin substitutes, and biological products such as growth factors or platelet rich plasma containing growth factors to promote healing.<sup>84</sup> However, with the generally poor prognosis these treatments offer.<sup>85</sup>, there exists opportunities for new therapies, such as EBC-1013, to address this medical need.

To our knowledge, EBC-1013 is unique in its ability to stimulate wound infill and closure as well as to disrupt and suppress microbial infection.

<sup>&</sup>lt;sup>81</sup> Burn Incidence Fact Sheet, National Burn Registry 2016, WHO Fact Sheet Burns, Global medical burns -3.5 m, 10% hospitalised

<sup>82</sup> MedMarket Diligence, Wound Healing to 2024

<sup>&</sup>lt;sup>83</sup> WHO Violence and Injury Prevention, Key Facts, 2010

<sup>&</sup>lt;sup>84</sup> Wound Management Forecast to 2024; Xie *et al.* 2018. The venous leg ulcer continues to be a clinical challenge. Burns and Trauma, 6:18 https://burnstrauma.biomedcentral.com/articles/10.1186/s41038-018-0119-y; Agale 2013. Chronic leg ulcers eoidemiology, aetiopathogenesis, and management. Ulcers. Volume 2013 |Article ID 413604 | https://doi.org/10.1155/2013/413604

<sup>&</sup>lt;sup>85</sup> Tuttle 2015. Association Between Microbial Bioburden and Healing Outcomes in Venous Leg Ulcers a review. *Advanced wound care*, 4(1): 1-11.

<sup>&</sup>lt;sup>86</sup> Bradford Rice et al 2014. Burden of venous leg ulcers in the United States, Journal of Medical Economics, 17:5

<sup>&</sup>lt;sup>87</sup> Xie et al., 2018. The venous ulcer continues to be a clinical challenge: an update. *Burns & Trauma*. 6:18 https://burnstrauma.biomedcentral.com/articles/10.1186/s41038-018-0119-y;

### 4.4.7 Veterinary commercialisation

The first indication we are targeting in the veterinary market is equine wounds.

In the veterinary space, both acute and chronic wounds also represent a significant management challenge for veterinary surgeons. The situation is often compounded by the ability to successfully manage the wound compared to human equivalents and there remains a constant and high demand for superior products. This is especially so for wound management in horses. 89,90,91,92

Horses, due to their herbivorous nature, are usually highly strung and wounds are common. Over production of granulation tissue (proud flesh) on the legs of horses, where most wounds occur, is a significant problem for equine wound management.<sup>93</sup> There is currently no reliable product to address wounds in horses in general, and especially not the problem of proud flesh production.<sup>92,94</sup> The size of the equine wound market is difficult to estimate. However, there are currently 9.2 million horses in the USA that are used for recreational, racing and work (such as police horses) purposes each with an average of 5 wound events per annum.<sup>94</sup>

### 4.5 Fontainea raw material supply

Tigilanol tiglate and EBC-1013 are novel short-chain epoxytiglianes from the tigliane class of compounds discovered from *Fontainea picrosperma* (Fontainea), a rainforest shrub endemic to Far North Queensland. <sup>95</sup> Tigilanol tiglate, and the base compounds for semi-synthetic production of EBC-1013, are major metabolites in the seed of Fontainea.

The ability to produce Fontainea raw material in quantities to meet market demand is essential to the success of the QBiotics products. As such, QBiotics has prioritised this area of research addressing both the ability to reliably produce seed in required quantities as well as address the potential risks associated with the need for uninterrupted raw material supply.

### 4.5.1 Domestication of Fontainea

QBiotics has completed a domestication program for Fontainea which has resulted in:

- Genetic fingerprints of all known populations being established and genetic improvement in progress;
- Development of clonal production methods to underpin the genetic improvement program;
- An understanding of, and ability to control, pollinators, pests and diseases; and
- Development of cultivation methods for successful commercial scale plantation establishment (refer to Figures 4.13A, 4.13B and 4.14).

<sup>&</sup>lt;sup>88</sup> Volk S.W., Bohling MW. Comparative wound healing-Are the small animal veterinarian's clinical patients an improved translational model for human wound healing research? Wound Repair Regen. 2013 Apr 29. 2013.

<sup>&</sup>lt;sup>89</sup> Carter, C.A., Jolly, D.G., Worden, C.E., Hendren, D.G., Kane, C.J. Platelet-rich plasma gel promotes differentiation and regeneration during equine wound healing. *Exp Mol Pathol*. 74(3):244–255). 2003.

<sup>&</sup>lt;sup>90</sup> Theoret CL & Wilmink JM 2013. Aberrant wound healing in the horse: Naturally occurring conditions reminiscent of those observed in man. Wound Repair & Regeneration 21: 365-371.

<sup>&</sup>lt;sup>91</sup> Westgate SJ, Percival SL, Knottenbelt DC, Clegg PD, Cochrane CA. 2010. Chronic equine wounds: what is the role of infection and biofilms? Wounds 22:138-145.

<sup>&</sup>lt;sup>92</sup> Wilmink JM & van Weeren PR. 2005. Second-intention repair in the horse and pony and management of exuberant granulation tissue. Veterinary Clinics Equine Practice 21:15-32.

<sup>&</sup>lt;sup>93</sup> Dubey, P., Bansal, V., Mowar, A., Bansal, R., Gupta, M. and Rajput, A., 2020. Proud Flesh: a Complicated Wound Healing—Case Report and Review of Literature. *Journal of Maxillofacial and Oral Surgery*, pp.1-6.

<sup>&</sup>lt;sup>94</sup> Caston, S. 2012. Wound Care in Horses. *Veterinary Clinics Equine Practice*. 28 (1):83–100.

<sup>&</sup>lt;sup>95</sup> Lamont, *et al* 2016. Population genetic analysis of a medicinally significant Australian rainforest tree, Fontainea picrosperma CT White (Euphorbiaceae): biogeographic patterns and implications for species domestication and plantation establishment. *BMC plant biology*, *16*(1), pp.1-12.

Figure 4.13A: Seedlings of Fontainea



Figure 4.13B: Fruit produced by 12 month old seedlings of Fontainea



Figure 4.14: Fontainea grown in plantation





05

Board, Management & Governance

# Board, Management & Governance

### 5.1 Board of Directors

The Board of Directors of QBiotics has a broad range of experience in the life sciences and pharmaceutical industry combined with Australian public company, capital markets, legal, financial and commercial expertise.

### 5.1.1 Rick Holliday-Smith - Independent Non-executive Chairman

Mr Rick Holliday-Smith brings a wealth of invaluable corporate experience to the Chairman's role. Among his current senior leadership roles, Rick is Chairman of Cochlear Limited and recently retired as Chairman of ASX Limited (ASX).

Rick's extensive board career spans many years and includes long term board positions at Servcorp Limited, SFE Corporation Limited, MIA Group Limited, Exco Resources Limited and Macquarie University Faculty of Business and Economics.

Previously, Rick held several global leadership positions in the finance industry including CEO of Chicago Research and Trading, President for global trading and sales at Nations Bank-CRT and Managing Director of London based HongKong Bank Limited.

Rick holds a Bachelor of Arts (Honours), is a Chartered Accountant and is a Fellow of the Australian Institute of Company Directors.

### 5.1.2 Dr Victoria Gordon – Managing Director & Chief Executive Officer

Dr Victoria Gordon brings to QBiotics a sound scientific background combined with broad business management experience and a strong commercial emphasis. She left her position as a research scientist in chemical ecology with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to establish EcoBiotics Pty Ltd (EcoBiotics) in 2000 and QBiotics Pty Ltd (QBiotics) in 2004 and then govern the merge of EcoBiotics and QBiotics to form the QBiotics Group in 2017. Victoria has been CEO of EcoBiotics, QBiotics and the QBiotics Group since their inception.

Victoria has broad experience in the management of commercial research for Boral Timber Division, then one of Australia's largest plantation forestry companies and has owned and managed a number of small businesses. Victoria's board and committee experience includes Non-Executive Director of Biopharmaceuticals Australia, member for two consecutive terms of the Queensland Government Biotechnology Advisory Council and Non-Executive Director and Non-Executive Chairman of the Australian Rainforest Foundation. In 2004 Victoria was presented an award by the Queensland Premier for her service to the biotechnology industry in Queensland.

Victoria holds a PhD in Microbiology, Bachelor of Applied Science (Honours), Diplomas in Human and Animal Health, has undertaken extensive business management and pharmaceutical development training and is a Graduate of the Australian Institute of Company Directors.

#### 5.1.3 Dr Paul Reddell – Executive Director & Chief Scientific Officer

Dr Paul Reddell brings to the Company expert scientific knowledge combined with extensive practical experience in leadership, resourcing, management and commercialisation of complex multi-institutional research and development projects. Paul is co-founder of EcoBiotics and QBiotics and has been CSO and Executive Director of both companies since their inception.

Prior to co-founding EcoBiotics in 2000, Paul gained an international reputation for his scientific expertise in tropical forest ecology and management. During that time, he held senior leadership positions as a Senior Principal Research Scientist and Program Leader at CSIRO's Tropical Forest Research Centre and later as Principal Plant Ecologist for an environmental consulting business in the Rio Tinto group of companies.

Paul holds a PhD in Forest Ecology and a Bachelor of Science (1A Honours) from the University of Western Australia and has undertaken extensive business management and pharmaceutical development training. He had been a Fellow of the Australian Institute of Company Directors since 2007.

### 5.1.4 Nicholas Moore – Independent Non-executive Director

Mr Nicholas Moore is a former Chief Executive Officer of Macquarie Group Limited and brings experience in finance, governance and leadership to QBiotics. He retired in late 2018 after 33 years at Macquarie, and 10 years as CEO from 2008 to 2018.

Nicholas is Chairman of Screen Australia, The Centre for Independent Studies, The Smith Family, Willow Technology Corporation, the National Catholic Education Commission, and a Member (and former Chair) of the University of NSW Business School Advisory Council and the Council of the National Gallery of Australia. He was previously Chairman of PCYC NSW from 2002 to 2015 and the Sydney Opera House Trust from 2015 to 2020.

Nicholas has a Bachelor of Commerce and a Bachelor of Laws from UNSW, was admitted as a solicitor and is a Fellow of the Institute of Chartered Accountants. In 2017, Nicholas was awarded an Honorary Doctorate in Business from UNSW.

### 5.1.5 Dr Susan Foden - Independent Non-executive Director

Dr Susan Foden brings over 20 years of experience as director on the boards of small and medium size private and public healthcare companies in the UK, Norway, Germany and Belgium.

Recent board positions include BTG plc (acquired by Boston Scientific in 2019), and Vectura Group plc where she served for over 10 years as Senior Independent Director and Chair of the Remuneration Committee until 2019. Susan also chaired, and was a director of, BerGenBio ASA up to its initial public offer on the Oslo Bohrs in 2015.

Currently Susan is Chairman of Neurocentrix Ltd, a director of Evgen Pharma plc and Oxford Ancestors Ltd and is an Investment Committee member of CD3, the drug discovery initiative between the European Investment Fund and the University of Leuven in Belgium.

Susan's background is in biochemistry and with an MA and DPhil in Natural Sciences from the University of Oxford. In 1983 she joined the UK's first biotech company, Celltech Ltd and headed up Academic Liaison, establishing some of the early precedents of academic/ biotech partnering and intellectual property development and in-licensing. In 1987 she established CRCT, the technology transfer and development company of what was then Cancer Research Campaign, (now CRT/Cancer Research UK (CRUK)). Over the next 12 years, CRCT was responsible for the development and partnering many programs, significantly Temodal, Abiraterone (with BTG) and some of the early PARP inhibitors from which CRUK has benefitted from many years of royalty flow. Spin out companies Cyclacel, Kudos and Spriogen Ltd also came from CRCT.

Outside the UK, CRCT set up Cancer Research Ventures and among others, established links with cancer research centres in Germany, Denmark and New Zealand.

In 2000, Susan joined the London healthcare VC firm, Merlin Biosciences as an Investor Director and was a director on several Merlin investee company boards including the oncology-focused companies, BioVex (acquired by Amgen 2011), and Piramed (acquired by Roche 2008).

#### 5.1.6 Andrew Denver – Independent Non-executive Director

Mr Andrew (Andy) Denver has extensive expertise that is relevant to QBiotics, including assisting in the commercialisation of several technology companies. Andy has wide ranging knowledge of the life sciences industry of which QBiotics is a part including risk assessment, financial reporting and general management, which are important in the success of QBiotics' business. Andy was the interim Chief Executive Officer of Universal Biosensors, Inc. (UBI) from September 2010 to May 2011, a director of UBI from December 2002 to August 2017 and Chairman of UBI from September 2005 to August 2017. Between 2002 and 2005, Andy was President of Pall Asia, a subsidiary of Pall Corporation after the acquisition by Pall Corporation of US Filter's Filtration and Separations business, where he was also President. Pall Corporation is a technology based filtration, separation and purification multinational company.

# Board, Management & Governance

Andy is a non-executive director of Vaxxas, Inc., SpeeDx Pty Ltd and Cochlear Ltd, all of which are life sciences companies.

Andy graduated from the University of Manchester with a Bachelor of Science Degree (Honors) in Chemistry and achieved a distinction in his MBA at the Harvard Business School and is a Fellow of the Australian Institute of Company Directors.

### 5.1.7 Professor Bruce Robinson AC – Independent Non-executive Director

Professor Bruce Robinson AC is an Endocrinologist and formerly Head of the Cancer Genetics Laboratory in the Kolling Institute at Royal North Shore Hospital. He was Acting Dean and then Dean of Medicine 2006 – 2016. Bruce graduated from the University of Sydney in 1980 and then undertook studies for a Master of Science degree. His further molecular research work was performed at the Brigham and Women's Hospital and the Children's Hospital, Harvard Medical School from 1986-1989 and he was awarded a Doctorate of Medicine from the University of Sydney in 1990. He has developed and led the Cancer Genetics Laboratory since 1990 and has supervised over 35 doctoral and masters students working on the genetic basis for tumour formation and gene therapy. He has published over 300 peer-reviewed scientific articles. In 2003, Bruce was awarded the Daiichi Prize by the Asia and Oceania Thyroid Association for his work on the pathogenesis of thyroid cancer.

Until early 2016, Bruce was Dean (International) in the Faculty of Medicine at the University of Sydney and was Head of the Division of Medicine at the Royal North Shore Hospital from 1998-2006. He also served on the Council of the Endocrine Society of Australia from 2001-2005. He is on the Editorial Board of the International journals 'Nature, Clinical Practice and Endocrinology' and 'Thyroid'. Bruce has a strong interest in furthering relations between Australia and Asia and he is the Founding Chairman of Hoc Mai, the Australia-Vietnam Medical Foundation, which sponsors and supports medical nursing, allied health and scientific exchanges between Australia and Vietnam. He was awarded the People's Health Medal by the Vietnamese Government in 2008. He is a Fellow of the Australian Institute of Company Directors.

More recently Bruce was appointed Chair of the Medicare Benefits Schedule (MBS) Review Taskforce which will consider how services can be aligned with contemporary clinical evidence and improve health outcomes for patients. He has also been appointed as the Chair of the Council of NHMRC.

Bruce currently holds non-executive director roles with ASX-listed healthcare companies Cochlear Ltd and Mayne Pharma Ltd. Bruce also holds directorships with Lorica Health and Digital Health CRC.

Bruce was awarded the Companion of the Order of Australia in 2020 for his eminent service to medical research, and to national healthcare, through policy development and reform, and to tertiary education.

# 5.1.8 Associate Professor Steven Ogbourne – Independent Non-executive Director

Associate Professor Steven Ogbourne holds a PhD in Molecular Biology, a Bachelor of Science (Honours) in Plant Science and is a Member of the Australian Institute of Company Directors.

Steven brings to QBiotics expert scientific knowledge in the fields of biodiscovery and plant genetics, and significant experience in drug development having held leadership roles in both academic and pharmaceutical sectors.

Steven is an internationally recognised research scientist, having published nearly 50 peer-reviewed scientific articles, and has considerable expertise in small molecule drug development as a result of his senior role in the discovery, development and commercialisation of Picato® as Senior Director, Research & Development with Peplin and LEO Pharma.

Steven currently holds the position of Associate Professor, Plant Biotechnology at the University of the Sunshine Coast, where he undertakes research focussing on biodiscovery in therapeutic areas including cancer, wound-healing and anti-microbials and on the domestication of *Fontainea picrosperma*.

Steven is also a Deputy Director of the GeneCology Research Centre at the University of the Sunshine Coast. Steven also has a passion for conservation and his research team is actively involved in a number of conservation projects relating to several threatened species of plants and animals.

### 5.1.9 Neville Mitchell - Independent Non-executive Director

Mr Neville Mitchell has extensive international healthcare and finance experience. Neville is a qualified Charted Accountant with 27 years' experience (until March 2017) as Chief Financial Officer and Company Secretary of ASX-listed Cochlear Limited, a world leading medical device developer, manufacturer and seller.

Neville currently holds non-executive director roles with ASX-listed healthcare companies, Fisher & Paykel Healthcare (since November 2018), Sonic Healthcare (since September 2017) and Osprey Medical Inc. (since July 2012). He is also a member of the Australian Board of Taxation and a director of South East Sydney Local Health District.

He has previously performed roles with a number of industry and government committees, including Chairman of the Group of 100 (Australia's peak body for senior finance executives) and Chairman of the Standing Committee (Accounting and Audit) for the Australian Securities and Investments Commission (ASIC) and he was a member of the NSW Government's Medical Device Fund.

### 5.1.10 Hamish Corlett - Non-executive Director

Mr Hamish Corlett is a Co-Founder and Partner at TDM Growth Partners, a private investments firm specialising in high growth companies globally. Hamish brings more than 20 years' experience in investing and investment banking from multiple top-tier investment firms to his role on the QBiotics Board.

Hamish is currently a Non-Executive Director of Somnomed Limited, a medical company providing treatment solutions for sleep-related breathing disorders. He is also Chair of Somnomed's Remuneration Committee. Hamish has also been a Non-Executive Director of Tyro Payments Ltd since April 2019.

Hamish holds a Bachelor of Commerce with Honours Class 1 (Accounting and Finance) from the University of Sydney and a Graduate Diploma of Counselling from the Australian College of Applied Psychologists.

#### 5.1.11 Director disclosures

No Director of the Company has been the subject of any disciplinary action, criminal conviction, personal bankruptcy or disqualification in Australia or elsewhere in the last ten years which is relevant or material to the performance of their duties as a Director of the Company or which is relevant to an investor's decision as to whether to subscribe for Shares under the Offer.

### 5.2 Directors' remuneration, terms and interests

### 5.2.1 Directors' remuneration and terms

Table 5.1: Directors' remuneration and contract terms

Name	Remuneration	Benefits	Term	Appointment date
Rick Holliday- Smith	\$100,000 per annum, payable in Options	Superannuation contributions at the applicable statutory percentage	For the period for which the Director is appointed under the Constitution	24 February 2017
Dr Victoria Gordon	\$239,700 gross salary per annum plus Short Term Incentive (STI) of up to 20% of gross salary (≥50% to be taken as shares)	As above	As above	24 February 2017

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Name	Remuneration	Benefits	Term	Appointment date
Dr Paul Reddell	\$239,700 gross salary per annum plus Short Term Incentive (STI) of up to 20% of gross salary (≥50% to be taken as shares)	As above	As above	24 February 2017
Nicholas Moore	\$75,000 per annum, payable in Options	As above	As above	1 February 2021
Dr Susan Foden	\$75,000 per annum, payable in cash and shares	As above	As above	14 October 2019
Andrew Denver	\$75,000 per annum, payable in Options	As above	As above	1 November 2017
Professor Bruce Robinson AC	\$75,000 per annum, payable in Options	As above	As above	1 November 2017
Associate Professor Steven Ogbourne	\$75,000 per annum, payable in cash and shares	As above	As above	1 November 2017
Neville Mitchell	\$75,000 per annum, payable in Options	As above	As above	1 November 2017
Hamish Corlett	\$75,000 per annum, payable in Options	As above	As above	9 April 2021

Some Directors may elect to receive remuneration in Options, shares (at applicable market rates), cash or a combination thereof. The terms of all Options on issue have been set out in Section 10.5.

Dr Gordon's and Dr Reddell's executive contracts are summarised in Section 10.7. In respect of the other Directors, under the Constitution, the Directors may decide how the total amount payable to all Directors is divided amongst the Directors as remuneration for their services as a Director.

In addition to their annual remuneration, the Directors may also be reimbursed for expenses properly incurred by the Directors in connection with the affairs of the Company including travel and other expenses. Non-executive Directors may be paid such additional or special remuneration as the Directors decide is appropriate where a Director performs extra work or services which are not in the capacity as Director. Directors are not currently entitled to any additional remuneration for time spent in connection with acting as a member of any committee of the Board.

There are no retirement benefit schemes for Directors, other than statutory superannuation contributions.

# 5.2.2 Directors' shareholdings

Directors are not required under the Constitution to hold any Shares. Directors and officers currently hold (including through controlled entities) Shares and Options as described below. The Directors may elect to apply for Shares under the Offer.

Table 5.2: Director's relevant interests as at the date of the Prospectus

Name	Shares	Options granted and vested	Options granted and not vested**
Rick Holliday-Smith	725,000	3,510,917	901,363
Dr Victoria Gordon	32,831,975	Nil	Nil
Dr Paul Reddell	29,933,696	Nil	Nil
Nicholas Moore	12,309,523	250,000	482,334
Dr Susan Foden	80,162	361,186	Nil
Andrew Denver	250,000	1,867,491	676,022
Professor Bruce Robinson AC	350,000	1,867,491	676,022
Associate Professor Steven Ogbourne	125,744	361,186	Nil
Neville Mitchell	125,000	1,750,820	599,503
Hamish Corlett	55,555,556*	Nil	482,334

<sup>\*</sup> Shares are held by TDM Growth Partners Pty L

# 5.2.3 Deeds of access, indemnity and insurance for Directors

The Company has entered into deeds of access, indemnity and insurance with each Director.

The deeds confirm each Director's right of access to certain books and records of the Company for a period of seven years after the Director ceases to hold office.

Pursuant to the Constitution, the Company is required to indemnify all Directors and employees, past and present, against all liabilities allowed under law. The Company has entered into a deed with each Director to indemnify the Director against all liabilities to another person that may arise from their position as Director or other officer of the Company to the extent permitted by law. The deed stipulates that the Company will meet the full amount of any such liabilities, including reasonable legal costs and expenses.

Pursuant to the Constitution, the Company may arrange and maintain directors' and officers' insurance for its Directors and its officers to the extent permitted by law. The Company has entered into a deed with each Director to obtain such insurance during the Director's period of office and for a period of seven years after the Director ceases to hold office. The seven year period can be extended where certain proceedings or investigations commence before the seven year period expires.

# 5.2.4 Directors' and officers' insurance

The Company has obtained an insurance policy for the benefit of its Directors and Officers.

It indemnifies them for liability incurred as a result of their office with the Company.

<sup>\*\*</sup> Refer to Section 10.5 for terms of existing options.

# Board, Management & Governance

# **5.3 Executive Management Team**

# 5.3.1 QBiotics' team

QBiotics' team structure consists of directly employed key individuals who manage a strong team of contracted personnel for both the business, and research and development activities. This approach has the benefit of reducing the typically high infrastructure and maintenance spend of a life sciences company while providing access to world class providers. Product development activities are also supported by scientific advisory committees consisting of key opinion leaders in human and veterinary indications that we pursue. For details of the risks associated with this approach refer to Section 6 and for information of contracted providers who are material to Company operations refer to Section 10.7.

Our pharmaceutical development team are focused on patient safety and product quality. The Company incorporates these principles in every aspect of product development including discovery, preclinical, clinical development, manufacturing and quality assurance.

The Company has a highly experienced Executive Management Team, as set out below:

Name	Qualifications	Position
Dr Victoria Gordon	BAppSc (Hons) PhD GAICD	Chief Executive Officer
Dr Paul Reddell	BSc (Hons) PhD FAICD	Chief Scientific Officer
Michael Wenzel	BCom CA CIA GIA(Cert) GAICD	Chief Financial Officer & Company Secretary
Dr Peter Schmidt	BSc (Hons) PhD	Chief Operating Officer & Head of Veterinary Clinical Development
Mary Phipps	BBus MCom (Mktg) GAICD	Chief Marketing Officer

# 5.3.2 Dr Victoria Gordon – Managing Director & Chief Executive Officer

Please see details of Dr Gordon's experience in Section 5.1 above.

#### 5.3.3 Dr Paul Reddell – Chief Scientific Officer

Please see details of Dr Reddell's experience in Section 5.1 above

# 5.3.4 Michael Wenzel - Chief Financial Officer & Company Secretary

Mr Michael Wenzel has worked for QBiotics since 2011. Prior to this, Mr Wenzel worked for over 13 years in the audit and advisory divisions of KPMG. During this time, Michael has gained a wealth of experience across a range of industries, including biotechnology, as a senior engagement manager, key client contact, and quality control reviewer on a variety of external and internal audits of publicly listed companies, unlisted companies, foreign owned subsidiaries, government entities and not-for profit entities.

Michael holds a Bachelor of Commerce, is a Registered Company Auditor, a Certified Internal Auditor and is an Associate Member of Chartered Accountants Australia and New Zealand and the Institute of Internal Auditors – Australia. Michael is also a Certificated Member of the Governance Institute of Australia and is a Graduate Member of the Australia Institute of Company Directors.

# 5.3.5 Dr Peter Schmidt – Chief Operating Officer & Head of Veterinary Clinical Development

Dr Peter Schmidt has considerable expertise in the development of drug candidates for submission to both the Therapeutic Goods Administration in Australia and the FDA in the USA up to Clinical Phase III including

preparation of CMC and Preclinical data packages required for IND submissions, and the clinical practices required during Clinical Phase I and II trials.

Peter's human development expertise compliments and strengthens QBiotics' veterinary drug development team. Peter came to QBiotics from the drug discovery and development company Xenome Limited where he was Director of CMC and Preclinical drug development for 6 years. Prior to Xenome, he was Senior Scientist at Agen Biomedical for 7 years and Professional Officer at Radiopharmaceuticals Australian Nuclear Science and Technology Organisation for 8 years.

Peter holds a Bachelor of Science (Honours) and a PhD in Experimental Medicine.

# 5.3.6 Mary Phipps – Chief Marketing Officer

Ms Mary Phipps has extensive experience in marketing of human pharmaceutical and animal health products spanning more than 25 years.

Mary has held senior management and business roles with Novartis Animal Health for 15 years including Head of Sales ANZ, Marketing Director Therapeutics Brands USA, and Business Unit Head Companion Animals ANZ. Prior to Novartis Mary was employed by Novogen, Alcon and Sanofi Aventis.

Mary holds a Bachelor of Business and Masters of Commerce (both with marketing majors) and a recent graduate of the Australian Institute of Company Directors.

# 5.3.7 Leadership Team disclosures

No officer listed above has been the subject of any disciplinary action, criminal conviction, personal bankruptcy or disqualification in Australia or elsewhere in the last ten years which is relevant or material to the performance of their duties as officers of the Company or which is relevant to an investor's decision as to whether to subscribe for Shares under the Offer.

No officer listed above has been an officer of a company that has entered into any form of external administration as a result of insolvency during the time that they were an officer or within a 12 month period after they ceased to be an officer.

# 5.4 Executive Management compensation and terms

QBiotics' current executive compensation program consists of the following components:

Base salary – Base salary for QBiotics executives is set by reference to the executive's background and position, the executive's achievement of business objectives and goals, relevant market data, internal salary bands, the executive's contribution to the business and performance over the previous financial year and recommendations received from QBiotics' Chief Executive Officer. In setting the 2021 base salary for QBiotics' current executives, research and benchmarking based on industry standards was used as a reference point, as well as internal equity data and annual CPI movement;

**Incentives** – QBiotics executives are eligible to participate in a short-term incentive (STI) and additional incentive performance scheme, on the following terms:

**Short Term Incentive (STI):** The Employee is eligible to receive a payment in respect of STI, of up to 20% of gross base salary, based on achievement of the key performance indicators set as part of the Employee's annual Performance Review process.

A minimum of fifty percent (50%) of any amount awarded in respect of STI will be granted in the form of QBiotics Group Limited ordinary shares, calculated using the fair value of share on the day the grant occurs. As the Company's shares are not traded on a public exchange, the fair value of shares is calculated with reference to the 60-day weighted average price of shares traded by existing shareholders leading up to the grant date. The remaining amount will be paid as a cash bonus, less any applicable taxes. The Employee may choose to have all or part of the cash bonus amount paid to the Employee in the form of QBiotics Group Limited ordinary shares, calculated using the share price on the day the grant occurs. Any tax amounts owing upon the issue or vesting of QBiotics Group Limited ordinary shares are the sole responsibility of the Employee.

# Board, Management & Governance

Long Term Incentive (LTI): The Employee is invited to participate in the QBiotics LTI Plan. LTI Plan details will be provided in a separate document, which is currently being drafted.

# 5.5 Employee share and option plan

The Company has adopted an employee share and option plan (Plan). Pursuant to the terms of the Plan, the Board has discretion to offer Shares and options to subscribe for Shares to eligible employees as a form of long term equity incentive. The Plan intends to assist the Company to attract and retain skilled and experienced employees and provide them with an incentive to have a greater involvement with the long term goals of the Company.

A summary of the Plan is set out below:

- The Plan is open to eligible employees including full time, part time and casual employees as well as contractors, Directors and any other persons as determined by the Board.
- The Board may invite eligible employees to participate in the Plan. Participation is voluntary. The Board may determine the number of Shares and options to be issued under the Plan and other terms of issue.
- Shares and options issued under the Plan may be subject to certain vesting conditions or holding locks.
- Each option enables the holder to be issued one Share upon exercise, subject to the Plan. Option
  holders are not permitted to participate in new issues of securities by the Company but adjustments
  may be made to the number of Shares over which the options are granted or the exercise price to take
  into account changes in the capital structure of the Company that occur by way of pro rata and bonus
  issues as the Board sees fit.
- The Plan limits the number of Shares that the Company may issue under the Plan to 20% of the total number of Shares currently on issue in that class.

As at the date of this Prospectus, the Company has issued \$39,000 worth of Shares to eligible employees under the Plan.

# 5.6 Corporate governance

The Company's Constitution provides that the maximum number of Directors is ten and that this maximum may only be changed by a resolution passed at a general meeting. The Company currently has ten Directors serving on the Board.

The Board is responsible for the overall corporate governance of the Company. Issues of substance affecting the Company are considered by the full Board, with advice from external advisers as required. Each Director must bring an independent view and judgement to the Board and must declare all actual or potential conflicts of interest. Any issue concerning a Director must be provided to the Board at a Board meeting as soon as practicable, and Directors may not participate in discussions or resolutions pertaining to any matter in which the Director has a material personal interest.

The Board's role in risk oversight includes receiving reports from the Chief Executive Officer and Chief Financial Officer on a regular basis regarding material risks faced by the Company and applicable mitigation strategies and activities. The reports cover the critical areas of operations, sales and marketing, development, regulatory and quality affairs, intellectual property, clinical development and legal and financial affairs. The Board considers these reports, discusses matters with management and identifies and evaluates any potential strategic or operational risks, and appropriate activity to address those risks.

All Non-Executive Directors have confirmed to the Company that they anticipate being available to perform their duties as Non-Executive Directors without constraint from other commitments.

The Board considers an independent Director to be a non-executive Director who is not a member of the Company's management and who is free of any business or other relationship that could materially interfere with or reasonably be perceived to interfere with the independent exercise of their judgement. The Board will consider the materiality of any given relationship on a case-by-case basis. The Board reviews the independence

of each Director in light of interests disclosed to the Board from time to time. For this purpose, a Director will (among others) not be considered to be independent if the Director:

- is a substantial shareholder of the Company or an officer of, or otherwise associated directly with, a substantial shareholder of the Company;
- is employed, or has previously been employed in an executive capacity by the Company, and there has not been a period of at least three years between ceasing that employment and serving on the Board;
- is, or has within the last three years been a partner, director or senior employee of a provider of material professional services to the Company;
- is, or has been within the last three years, in a material business relationship (e.g. as a supplier or customer) with the Company, or an officer of, or otherwise associated directly or indirectly with, someone with such a relationship:
- has a material contractual relationship with the Company other than as a director of the Company;
- has close family ties with any person who falls within any of the categories described above; or
- has been a director of the Company for such period that his or her independence may have been compromised.

In each case, the Board will consider whether there are any factors or considerations which may mean that the Director's interest, business or relationship could, or could reasonably perceived to, materially interfere with the Director's ability to act in the best interests of the Company.

The Board considers that Rick Holliday-Smith, Professor Bruce Robinson AC, Andrew Denver, Neville Mitchell, Dr Susan Foden and Nicholas Moore are free from any business or other relationship that could materially interfere with, or reasonably be perceived to interfere with the independent exercise of their judgement. Notwithstanding the existence of the related party arrangement with Associate Professor Steven Ogbourne referred to in section 10.8, the Board considers him to be independent because the arrangement is for an immaterial sum and the dealings are considered to be at arm's length.

# 5.7 Continuous disclosure

The Company has an obligation to keep Shareholders fully informed of information which may have a material effect on the share price or value of the Company and to correct any material mistake or misinformation. The Company discharges these obligations by regularly releasing information to the Shareholders in the form of periodic Shareholder newsletters and updates which are sent to Shareholders and made available on its website. The Company also releases a written Annual Report which is provided to Shareholders as well as provided verbally in a CEO presentation given at Annual General Meetings. This CEO report is also recorded and uploaded to the Company's website.

The information to Shareholders is not selectively disclosed (i.e. to analysts or the media) before it is announced to Shareholders. Once the Company becomes aware of any information concerning it that a reasonable person would expect to have a material effect on the price or value of the Company, the entity informs the Shareholders.

The Company's disclosure obligation does not apply to particular information while any of the following are satisfied:

- A reasonable person would not expect the information to be disclosed;
- The information is confidential; and
- One or more of the following apply:
  - It would be a breach of law to disclose the information;
  - The information comprises matters of supposition or is insufficiently definite to warrant disclosure;
  - The information concerns an incomplete proposal or negotiation;
  - The information is generated for internal management purposes; or
  - The information is confidential or a trade secret.



O6
Risk Factors

# Risk Factors

The sector in which the Company operates is subject to numerous risk factors both of a general nature and risks which are specific to the Company's business activities. The potential effect of these risk factors, either individually or in combination, may have an adverse effect on the future financial (including potential profits and losses) and operating performance of the Company, its assets and liabilities, financial position and prospects and the value of the Shares.

This Section 6 describes what the Company considers to be the key risks associated with investing in the Company. You should carefully consider these risk factors in light of your personal circumstances and seek professional advice from your stockbroker, accountant, lawyer or other professional adviser before deciding whether to invest. Investment in the Company is speculative.

This Section 6 should not be considered to be an exhaustive list of every possible risk associated with an investment in the Company. The types of risks the Company is exposed to can change over time and vary with changes in economic, technological and regulatory conditions both generally and within the pharmaceutical industry specifically.

Before making any decision to invest in the Company, potential investors should read this Prospectus in full. In particular, potential investors should be aware that there is no certainty that the Company will achieve its stated objectives or that any forward-looking statement will occur. Any investment in the Company should only be considered in light of these risks, as the occurrence of any of the risks set out in this Section 6 either individually or in combination could have a material adverse impact on the Company's operating performance and profits.

# 6.1 Risks associated with QBiotics' human pharmaceutical products

#### 6.1.1 Failure of current clinical trials

The Company cannot guarantee that the current human clinical trials of tigilanol tiglate will be successful or produce the desired evidentiary endpoints at all, or with statistical probative value, or that there will be no significant adverse events in the human patients.

#### 6.1.2 Failure of future clinical trials

The Company cannot guarantee that future follow-up human clinical trial of tigilanol tiglate, or human clinical trials of EBC-1013 will be successful or produce the desired evidentiary endpoints at all, or with statistical probative value, or that there will be no significant adverse events in the human patients.

# 6.1.3 Competitive reactions

There are many large and specialist established anticancer and wound healing pharmaceutical companies who may attempt to compete with, delay or prevent the launch of tigilanol tiglate and EBC-1013, and we cannot control or anticipate their actions. Similarly, there are established standard treatment protocols accepted by medical specialists, their professional colleges, and their insurers, as the standard of care in the treatment of certain cancers and wounds, which the Company's products may need to disrupt.

#### 6.1.4 Commercialisation

Tigilanol tiglate for human application and EBC-1013 for the treatment of wounds are still in clinical development and are unregistered for commercial use. If products fail during human clinical development or the data from the clinical trials does not indicate efficacy according to the clinical trial protocol, the prospects and potential profitability of QBiotics will be reduced. Even with successful trial data, investors must be aware that tigilanol tiglate, or EBC-1013 may ultimately not be commercialised. In addition to the risk of tigilanol tiglate clinical efficacy results being insufficient to convince a human pharmaceutical partner to fund completion of development, there also exists the risk of the occurrence of serious adverse events which can, in the worst case, halt development or severely limit commercial opportunity.

This is also the case with other QBiotics' unregistered human and veterinary products.

There is no assurance that QBiotics will be able to commercialise or obtain regulatory approval for products for the human or veterinary markets, generate any revenue, achieve profitability or attract appropriate strategic partners.

# 6.1.5 Partnering to complete human clinical development and to commercialise

The Company cannot guarantee the successful negotiation or completion of sufficient, or appropriately remunerative, or any, human licensing or co-development contracts that would lead to the approval and commercialisation of our products in anticancer or wound healing.

#### 6.1.6 Health care insurers and reimbursement

In both domestic and foreign markets, sales volumes are likely to be influenced by the availability of reimbursements of part or all of the patients' treatment expenses by third party payer organisations including government agencies, private healthcare insurers and other health care payers. There is no assurance that reimbursements for any products or services developed and commercialised by QBiotics or our pharmaceutical partners will be available to patients at all or without substantial delay, in any country. Even if such reimbursement is provided, the approved reimbursement amounts may not be sufficient to incent patients and medical practitioners to adopt and use the Company's products in numbers sufficient to drive profitability for the Company.

# 6.2 Risks associated with QBiotics' animal health pharmaceutical products

## 6.2.1 Reliance on Virbac

All of the Company's revenues is reliant on its sales and distribution partner, Virbac. Refer to Section 10.7.2 for a summary of the agreement. Virbac is a French corporation listed on the Paris stock exchange, whose business focuses on the sale, distribution and marketing of medicines and vaccines for companion and food-producing animals. QBiotics depends on the ability of Virbac to build the requisite sales, marketing and distribution capabilities to successfully promote, market and sell STELFONTA® and gain market share in the licensed territories to help grow QBiotics' revenues derived from STELFONTA®. Being a publicly listed company, Virbac's interests to grow revenue are aligned with those of QBiotics in this regard. However, a slowdown, decrease in demand or failure to grow demand from Virbac, including as a consequence of COVID-10, could adversely impact QBiotics' operating and financial performance.

# 6.2.2 Regulatory approval is delayed

The commercialisation of the Company's products is subject to regulatory approvals. Delays or failure in obtaining regulatory approvals could result in failure to launch or delays in launching products and thus have an adverse effect on the value of the Company and consequently impact the financial performance of the Company.

# 6.2.3 Slower than anticipated market adoption and ongoing acceptance

The Company's commercialisation strategy relies on medical specialists, human and veterinary medical facilities, human and companion animal patients and pet owners accepting the Company's products for routine use. Medical specialists are historically slow to adopt new technologies, regardless of perceived merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires significant marketing expenditure or definitive product performance and/or pricing superiority. Market acceptance of a new technology such as QBiotics' can be difficult to obtain and may involve time consuming clinical studies to provide further evidence of the medical benefits of the Company's products in order to overcome any inertia.

# **Risk Factors**

# 6.3 Risks specific to an investment in the Company

# 6.3.1 Coronavirus (COVID-19)

Since 31 December 2019, the spread of COVID-19 has severely impacted many local economies around the globe. In many countries, businesses are being forced to cease or limit operations for long or indefinite periods of time. Measures taken to contain the spread of the virus, including travel bans, quarantines, social distancing, and closures of non-essential services have triggered significant disruptions to businesses worldwide, resulting in an economic slowdown. Global stock markets have also experienced great volatility during this time. Governments and central banks have responded with monetary and fiscal interventions to stabilise economic conditions.

For QBiotics, COVID-19 has impacted the marketing and sales of STELFONTA® in most European countries as many veterinary practices were subject to operating restrictions. In addition, the recruitment of patients for the Group's human clinical trial QB46C-H03 treating head and neck squamous cell carcinoma was halted from February to mid July 2020 in Australia and India. Human clinical trials continue to be affected by COVID-19 restrictions world wide. Consequently, the implementation of QBiotics' planned clinical trials may also be negatively impacted by ongoing effects of COVID-19. QBiotics has received COVID-19 related incentives from the Australian Federal Government. The incentives have been used to help fund ongoing employee costs which allow continued work on human clinical trials and marketing initiatives.

The duration and impact of the COVID-19 pandemic, as well as the effectiveness of government and central bank responses, remains unclear at this time. It is not possible to reliably estimate the duration and severity of these consequences, as well as their impact on the financial position and results of the Group for future periods. The Group's ability to recruit patients for its planned human clinical trials may also be negatively impacted.

# 6.3.2 The regulatory environment changes adversely

The Company's operations are also subject to laws, regulatory restrictions and certain government directives, recommendations and guidelines relating to, amongst other things, occupational safety, laboratory practice, the use and handling of hazardous materials, prevention of illness and injury and environmental protection. There can be no assurance that future legislation will not impose further government regulation, which may adversely affect the business or financial condition of the Company.

## 6.3.3 Product liability

The testing, marketing and sale of the Company's products whether directly or through licensees, involves a risk of product liability claims being brought against the Company. The Company seeks to limit its liability for such claims in its agreements with licensees and customers and is also entitled to be indemnified by its licensees in various circumstances. However, limitations of liability are not necessarily effective at law and indemnification may not always be available. The Company maintains product liability insurance in respect of its products, however, if the Company is unable to continue to obtain sufficient product liability insurance at an acceptable cost, it could prevent or inhibit the commercialisation of our products.

## 6.3.4 Intellectual property

One of the Company's assets is its current and planned intellectual property (IP) rights that support its current technology and other future products. The commercial value of the IP is dependent on legal protections provided by a combination of patent, registered trademarks, copyright, confidentiality, trade secret laws, and other IP rights. These legal mechanisms, however, do not guarantee that the IP will be protected, is valid, that the commercial activities and technology of the Company will be adequately protected or that the Company's competitive position will be maintained.

The grant of IP rights does not inevitably follow after making an application for such rights. Examination of patents, for example, may be expensive and time consuming and with no guarantee that patent rights will be secured. The scope of patent claims may vary as amendments are filed during examination if required to overcome objections raised by an examiner. The grant of patent rights does not guarantee the non-infringement of another party's

patent rights. Examination in one country is not binding in another country. Patent applications lodged in each country are generally subject to an independent search and examination by local patent officers.

The publication of an invention will take place approximately 18 months after filing the earliest patent application for the invention. By that publication, other parties will potentially be made aware of the invention, including the details of the processes necessary to implement the invention, and if patent rights are not successfully secured, other parties may be free to practice this invention, informed of the details for doing so by virtue of the patent application.

No assurance can be given that others will not challenge the Company's IP rights in the technology. The Company will make assessments on the patent protection strategies in different countries to determine whether patent protection is required and if it is available. Patent protection may not be sought in all countries either because such protection might not be commercially practical or may be unavailable or limited in certain countries. There may be countries where registered patent rights are desirable to protect IP but commercially unattractive because of the risk of IP theft arising in that country from disclosure of our technology through the patent publication process. Countries may also change their laws relating the scope and enforceability of IP (including patent) protection which may impact on the effectiveness, validity and scope of the Company's IP portfolio.

Litigation may be necessary, where commercially feasible, from time to time to enforce the Company's rights in the technology. Such litigation can be costly and could have adverse effects on the Company's activities, business, operating results, reputation and financial position. Likewise, a failure to succeed in protecting any such rights may equally have a material adverse effect on the Company's activities, business, operating results, reputation and financial position. The Company is actively considering the cost and benefit of insurance to cover such litigation costs, not only to enforce but also to defend against third party claims in relation to our IP.

Although the Company's patent attorney Griffith Hack has conducted patent searches on some publicly available databases, there are limitations on searching. Searches are dependent on the accuracy and effectiveness of the searching method used and the accuracy and scope of the records held.

Even if the accuracy of the records is guaranteed, any search strategy involves a compromise between scope and costs. For this reason, the Company's searches were restricted to reveal the most relevant disclosures. Another limitation is that in most major jurisdictions, patent applications are not published until 18 months from the earliest priority date. This means that for any given search, it is generally not possible to detect patent applications filed within the previous 18 months. No search can ever be entirely inclusive or exhaustive because some forms of disclosure such as prior public use, oral disclosure, prior commercial exploitation or prior publication is non patent literature cannot be searched systematically.

It is possible that third parties might assert IP infringement, IP invalidity, unfair competition or like claims against the Company under patent, confidentiality, trade secret or other laws. Whilst the Company is not aware of any claims of this nature, in relation to its IP rights, such claims if made may harm directly or indirectly the Company's business. If the Company is forced to defend claims of intellectual property infringement or invalidity whether they are with or without merit or are determined in the Company's favour, the cost of such litigation will potentially be significant and will divert management's attention from normal commercial operations. Again, the Company is actively considering the cost and benefit of insurance to cover such costs in relation specifically to IP disputes. Such disputes may require the Company to develop non-infringing technology or enter into royalty or licensing agreements. Such agreements, if necessary, may be unavailable on terms acceptable to the Company, if at all.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions.

# 6.3.5 Defensible ownership of IP

Applying the scientific rigour of EcoLogic™ gives QBiotics a well-documented, clearly defined and readily defensible pathway to discovery of new pharmaceuticals. QBiotics focus collection area is the Australian tropical rainforest. The Company has established access and benefit sharing agreements with the Queensland State Government and private landholders that are compliant with the United Nations Convention on Biodiversity and the Nagoya Protocol. These agreements supports QBiotics unencumbered ownership of all intellectual property associated with our discovery process. However, conventions may change as may the way the Queensland

# **Risk Factors**

state and Australian Federal governments recognise existing and future conventions which could inhibit or even halt QBiotics' biodiscovery activities.

# 6.3.6 Future product development

There are many risks inherent in the development and use of new products for the human and veterinary markets and they may fail during clinical trials or may fail to gain regulatory approval if required. The Company cannot guarantee that the development work being undertaken will result in the development of any products, or even if they do, that the products will be marketed or commercially successful.

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.

#### 6.3.7 Raw material

The Company has undertaken extensive domestication research and development for the grow out of Fontainea over the past 9 years. These activities have culminated in established plantations of Fontainea for supply of raw material. The Company has implemented strategies to reduce the impact of the environment on raw material supply including establishing plantations at different locations and physical growing structures to reduced wind damage (espaliers). However, adverse weather conditions and other unpredictable factors may adversely affect the availability of the Fontainea shrub and therefore QBiotics' operations.

## 6.3.8 Clinical validation

A core component of the Company's strategy is the commercialisation and registration of its products. For the registration process, a successful clinical trial will be necessary for the Company to obtain regulatory approval for its products. Such trials can be expensive, time consuming, may be delayed or may fail. This may delay the market adoption rate.

# 6.3.9 Reputational damage

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:

- inadequate services or unsatisfactory clinical outcomes for patients;
- error, malpractice or negligence of the Company's employees; or
- error, malpractice or negligence of the licensed medical specialists performing the treatments.

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

# 6.3.10 Technological development and competitors

The Company's future success will depend on the Company's ability to market or licence its intellectual property rights and products successfully, and to develop products that are competitive in the markets where it operates. The Company's current and potential future competitors include companies that have significantly greater resources than the Company. Due to the time it may take for QBiotics to commercialise its products, there is a risk that other competing or superior products may enter the market. Further, there is no assurance that our competitors will not succeed in developing alternative products that are more effective, easier to use, or more economical than those which has been developed or will be developed by the Company.

## 6.3.11 Manufacturing and product quality

QBiotics currently contracts out all GMP manufacturing activities for tigilanol tiglate and EBC-1013, and as such the Company is reliant on contract providers adhering to regulatory requirements for production of human and veterinary pharmaceuticals.

# 6.3.12 Dependencies on service providers

The Company is dependent on service providers to perform many activities such as toxicology studies, project management of clinical trials and manufacturing of products. While these service providers are replaceable, the sourcing of effective replacements in a timely manner may have an adverse effect on the future financial performance of the business.

# 6.3.13 Reliance on Key Personnel

The key personnel in QBiotics include Dr Victoria Gordon (CEO) and Dr Paul Reddell (CSO). Dr Gordon and Dr Reddell have managed the Company from inception and are integral to the workings of the Company. Consequently, the loss of Dr Gordon's and Dr Reddell's services could materially and adversely affect the Company. Both Dr Gordon and Dr Reddell have a substantial shareholding in QBiotics (refer to Section 8.8) which potentially mitigates the risk of loss to the Company of these personnel. However, there can be no assurance that the Company will be able to retain these key personnel or adequately replace them.

The Company is dependent on its scientific team to continue to develop products, the loss of whose services could also materially and adversely affect the Company. The Company is similarly dependent on its commercial team to commercialise its products, the loss of whose services could also materially and adversely affect the Company. The Company is committed to providing an attractive employment environment and prospects to assist in retaining its principal personnel. However, there can be no assurance that the Company will be able to retain these key personnel.

# 6.3.14 Sufficiency of funding

The Company commenced earning revenue from the launch of tigilanol tiglate into veterinary markets during the financial year ended 30 June 2020. It will be a number of years before product adoption delivers revenue sufficient to fully cover the Company's operating costs. This means that, until then, the Company's ongoing operations will depend on its ability to raise funds, which will be subject to factors beyond the control of the Company and its Directors including cyclical factors affecting the economy and financial and share markets generally.

If the Company raises funds by issuing shares (as is its present intention), the issue of shares will dilute the ownership of Shareholders.

# 6.3.15 Speculative nature of investment

Any potential investor should be aware that subscribing for Shares involves various risks. The Shares to be issued carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares. The success of the Company is largely dependent the results of its technology development, revenue from sales of STELFONTA®, the outcome of its proposed human clinical trials and obtaining regulatory approvals. An investment in the Company should therefore be considered speculative.

# 6.3.16 Capability

As the Company and its operations expand, it will be required to continue to improve, and where appropriate, upscale its operational, financial and manufacturing systems, procedures and controls and expand, retain, manage and train its employees.

There is a risk of material adverse impact on the Company's financial performance if it is not able to manage its expansion and growth efficiently and effectively.

# 6.3.17 R&D Tax Incentive Scheme

QBiotics intends to keep applying for the tax concessions on research and development expenditure under the Federal Government's R&D Tax Incentive Scheme. The R&D Tax Incentive Scheme may change or be removed should governments be replaced or their policies alter.

# **Risk Factors**

While refunds from the R&D Tax Incentive Scheme would enhance the Company's funding position, they are not necessary for the implementation of the plan outlined in this Prospectus.

# 6.3.18 No independent valuation

No independent valuation has been carried out on the Company or its products for the purpose of this Prospectus. The Directors do not believe that an independent valuation would be meaningful given the likely qualifications and limitations of such valuations and difficulties in determining the likely commercial success of the Company and its products.

# 6.4 General risks related to the Shares

# 6.4.1 Liquidity

QBiotics Shares are not listed on any stock exchange and there is no liquid public market for the trading of Shares. Therefore, an investment in QBiotics should be considered a long term, high risk, illiquid investment. The Company's current intention is to eventually pursue a listing of its Shares on an appropriate stock market provided favourable market conditions exist at the time and it is in the best interest of the Company and shareholders to do so. Listing of the Company's shares on a securities exchange will result in public market where shares in the Company may be sold or transferred. However, there can be no guarantee that the proposed capital raising or a listing on the ASX or any other securities exchange will occur or will be successful.

#### 6.4.2 General economic conditions

Factors such as inflation, interest rates, levels of tax, taxation law and accounting practices, government legislation or intervention, natural disasters, social upheaval, climate change and war may have an impact on prices, operating costs and market conditions generally. Accordingly, the Company's future revenue and operations can be affected by these factors which are beyond the control of the Company.

Revenue and expenditure of the Company may be affected by changes in international, federal, state, or local government laws, regulations or policies, or in taxation legislation. Government legislation and policies are subject to review and change from time to time. Such changes are beyond the control of the Company and may affect industry profitability. Factors beyond the control of the Directors that could affect the revenues and value of the Company include, but are not limited to, inflation, currency fluctuation, interest rates, supply and demand of relevant inputs and outputs and industrial disruption.

# 6.4.3 Accounting standards

Changes in accounting standards or the interpretation of those accounting standards that occur after the date of this Prospectus may adversely impact the Company's reported financial statements.

## 6.4.4 Absence of dividends

The ability of the Company to pay any dividend in the future is dependent on many factors including the outcome of the Company's commercialisation activities and clinical trials. Many of the factors that will affect the Company's ability to pay dividends and the timing of those dividends will be outside the control of the Company and its Directors. The Directors cannot give any assurance regarding the payment of dividends in the future.

# 6.4.5 Currency fluctuations

The Company is party to a marketing, supply and distribution contract with Virbac under which Virbac will sell tigilanol tiglate in various overseas markets which each have different currencies than Australia, and under which the Company consequently takes some currency exchange rate risk. The Company is also party to a number of contracts with various international suppliers of services to the Company and under which it must make payments in different currencies. The currency impacts arising under these contracts may affect future profitability of QBiotics.

# 6.4.6 Geo-political factors

The Company may be affected by the impact that geo-political factors have on the world or Australian economy or on financial markets and investments generally or specifically. This may include international climate change, wars, terrorist activities and governmental responses to such factors.

# 6.4.7 Government policies and legislation

The Company may be affected by changes to government policies and legislation, including those relating to domestic and international taxation regimes, grants for research and development, policies regarding technology companies, international incentive programs, regulatory regimes which govern the registration and commercialisation of the products and intellectual property.







# 7.1 Introduction

The financial information for QBiotics contained in this Section 7 includes:

- summary audited historical consolidated Statement of Profit or Loss and Other Comprehensive income
  for the year ended 30 June 2018 (FY2018), 30 June 2019 (FY2019), year ended 30 June 2020
  (FY2020) and summary reviewed consolidated Statement of Profit or Loss and Other Comprehensive
  income for the 6 months ended 31 December 2020 (1HFY2021) with 6 months ended 31 December
  2019 comparative information (1HFY2020);
- summary audited historical consolidated Statement of Cash Flows for FY2018, FY2019, FY2020, and summary reviewed historical consolidated statement of cash flows for 1HFY2021 with 1HFY2020 comparative information;
- reviewed historical and pro forma consolidated statements of financial position as at 31 December 2020, and the associated details of the pro forma adjustments;

(together, the "Historical Financial Information").

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

- management's discussion and analysis set out in this Section 7;
- the risk factors described in Section 6;
- the description of the use of proceeds of the Offer described in Section 8.3;
- The Independent Limited Assurance Report, set out in Section 7.11; and
- The indicative capital structure described in Section 8.8.

Investors should note that past performance is not an indication of future performance.

# 7.2 Basis of preparation and presentation of the Historical Financial Information

The Directors of QBiotics are responsible for the preparation and presentation of the Historical Financial Information.

The Historical Financial Information is presented in an abbreviated form insofar as it does not include all of the disclosures required by Australian Accounting Standards adopted by the Australian Accounting Standards Board which are consistent with the International Financial Reporting Standards (IFRS) used by the International Accounting Standards Board and QBiotics' accounting policies. QBiotics' significant accounting policies are described in Section 7.10. The accounting policies of QBiotics have been consistently applied throughout the periods, with the exception of that set out in Section 7.4.

All amounts disclosed in Section 7 and the Appendices are presented in Australian dollars and, unless otherwise noted, are rounded to the nearest thousand. Some numerical figures included in this Prospectus have been subject to rounding adjustments. Any differences between totals and sums of components in figures or tables contained in this Prospectus are due to rounding.

The Historical Financial Information (other than the proforma adjustments to the historical statement of financial position as at 31 December 2020 and the results of those adjustments) has been derived from the audited general purpose financial reports of QBiotics for FY2018, FY2019, FY2020 and reviewed consolidated financial report for 1HFY2021. The financial statements for FY2018, FY2019, FY2020 and 1HFY2021 were audited and reviewed by Grant Thornton Audit Pty Limited. The audit/review opinions issued to the Directors in respect of FY2018, FY2019, FY2020 and 1HFY2021 were unqualified.

The Historical Financial Information is presented in an abbreviated form and does not contain all of the disclosures, statements of comparative information required by Australian Accounting Standards applicable to financial reports prepared in accordance with the Corporations Act 2001.

The Historical Financial Information presented in this Prospectus has been prepared assuming the Company will continue as a going concern, which contemplates the realisation of assets and satisfaction of liabilities in the normal course of business for the foreseeable future. The Company's ability to achieve profitability is dependent

primarily on its ability to successfully further develop and commercialise drugs for the human and veterinary markets. As such, the Company is dependent on the Offer (together with its cash reserves) to support operations until recurring revenue sources or liquidity events can be obtained. The Company intends to raise sufficient capital to finance its operations as set out in this Prospectus. See Section 8.3 for further details.

The Historical Financial Information has been reviewed in accordance with the Australian Standard on Assurance Engagements ASAE 3450 Assurance Engagements involving Fundraising and/or Prospective Financial Information by Grant Thornton Corporate Finance Pty Ltd as set out in the Independent Limited Assurance Report in Section 7.11. Investors should note the scope and limitations of the Independent Limited Assurance Report.

The Historical Financial Information has been prepared for the purpose of the Offer.

# 7.3 Changes in Accounting Standards and Accounting Policies

AASB 9 Financial Instruments and AASB 15 Revenue from Contracts with Customers became mandatorily effective on 1 January 2018. AASB 16 Leases became mandatorily effective 1 January 2019. The nature and effect of changes arising from these standards are summarised below.

#### AASB 9 Financial Instruments

AASB 9 Financial Instruments replaces AASB 139 Financial Instruments: Recognition and Measurement requirements. It changes the previous guidance on the classification and measurement of financial assets and introduces an 'expected credit loss' model for impairment of financial assets. The Group's financial assets include trade and other receivables. The classification of trade and other receivables changed from loans and receivables to amortised cost. No adjustment was required as a result of this change. The standard does not have a material impact on the transactions and balances recognised in the Historical Financial Information.

## AASB 15 Revenue from Contracts with Customers

AASB 15 Revenue from Contracts with Customers replaces AASB 118 and covers contracts for goods and services. AASB 15 is based on the principle that revenue is recognised when control of a good or service transfers to a customer so the notion of control replaces the existing notion of risks and rewards.

The implementation of this new guidance did not have a significant impact on the timing or amount of revenue recognised during the historical period. No adjustments were required to account for the impact of AASB 15 initial adoption as revenues from commercial operations first occurred during FY2020.

## AASB 16 Leases

AASB 16 Leases replaces AASB 117 Leases. The new standard has been applied using the modified retrospective approach. The Group measured the cumulative effect of adopting AASB 16 Leases and found the amount to be immaterial and as such no entry was booked as an adjustment to the opening balance of retained earnings at the time of adoption. Prior periods have not been restated. A detailed reconciliation of total operating lease commitments as at 30 June 2019 to the lease liabilities recognised at 1 July 2019 has been provided in Section 7.10.

# 7.4 Historical consolidated statement of profit or loss and other comprehensive income

The table below presents the audited and reviewed historical consolidated statement of Profit and Loss and other Comprehensive Income for FY2018, FY2019, FY2020, 1HFY2021 and 1HFY2020.

Table 7.1 Historical consolidated Statement of Profit or Loss and other Comprehensive Income

\$'000	Note	FY2018 Audited	FY2019 Audited	FY2020 Audited	1HFY2021 Reviewed	1HFY2020 Reviewed
Revenue	1	5,777	-	1,593	126	-
Government grants and other income		3	4,776	5,058	2,911	2,576
		5,780	4,776	6,651	3,037	2,576
Expenses						
Inventory expenses	2	-	-	(1,109)	(767)	(1,404)
Business compliance and advisory expenses Depreciation and	3	1,085	1,291	1,988	1,044	1,050
amortisation expenses	4	1,801	1,952	2,201	1,150	1,098
Facilities expenses	5	479	543	331	333	145
Personnel expenses	6	5,629	5,614	6,777	3,658	3,449
R&D contractor expenses Travel and	7	8,169	6,901	7,171	4,147	3,439
accommodation expenses	8	824	948	603	31	398
Other expenses	9	356	702	614	194	298
Total expenses		18,343	17,951	18,576	9,790	8,473
Results from operating activ	rities	(12,563)	(13,175)	(11,926)	(6,753)	(5,897)
Finance income		471	445	333	168	193
Finance costs		(90)	(66)	(216)	(42)	(59)
Net finance income	10	381	379	117	126	135
Loss before tax		(12,182)	(12,796)	(11,809)	(6,627)	(5,763)
Tax expense		-	-	-	-	-
Loss for the period		(12,182)	(12,796)	(11,809)	(6,627)	(5,763)
Other comprehensive income		-	-	-	-	-
Total comprehensive incomfor the period	е	(12,182)	(12,796)	(11,809)	(6,627)	(5,763)

# 7.4.1 Description of key financial terms

Set out below is a description of the key financial terms used in the presentation of the Historical Financial Information:

- 1. Revenue: Revenue relates to sales of STELFONTA® from European markets through the supply and distribution agreement with Virbac. Refer to Section 4.1 and Section 10.7.2 for further details;
- 2. Inventory expenses: Inventory expenses relates to any inventory purchases and the movement of finished goods and work in progress;
- 3. Business compliance and advisory: Business compliance and advisory expenses comprise of legal fees, corporate advisory costs and other professional services engaged;
- 4. Depreciation and amortisation: Depreciation and amortisation refers to the depreciation of leasehold improvements, plant, and office equipment. Amortisation is incurred on the intellectual property, patents, and trademarks;
- 5. Facilities expenses: Facilities refers to rent and utility costs;

- 6. Personnel expenses: Personnel expenses comprise of wages & salaries, superannuation and any employee incentives;
- 7. R&D contractor expenses: Research and development contractor expenses represent costs incurred with contractor research organisations who support QBiotics' research & development programs. It includes costs for universities, labs, and clinical trial research organisations;
- 8. Travel and accommodation expenses: Travel and accommodation expenses refer to any domestic or international travelling including flights, meals and accommodation of staff;
- 9. Other expenses: Other expenses include insurance and other miscellaneous items such as donations, stationery and freight; and
- 10. Net finance income: Net finance income refers and interest income from cash in bank and term deposits held and is offset by bank charges and foreign exchange gains and losses.

# 7.5 General factors affecting the historical operating results of QBiotics

Below is a discussion of the main factors which affected QBiotics' operations and relative financial performance in FY2018, FY2019, FY2020 and 1HFY2021, which QBiotics expects may continue to affect it in the future. The discussion of these general factors is intended to provide a summary only and does not detail all factors that affected QBiotics' historical operating and financial performance, nor everything which may affect QBiotics' operations and financial performance in the future.

# 7.5.1 Management discussion and analysis on the historical statements of profit or loss and other comprehensive income

QBiotics commenced receiving commercial revenue following the marketing approval from the European Marketing Agency in November 2019, with the first and second shipment of product occurring in February 2020 and June 2020, respectively. The revenue was generated through QBiotics' supply and distribution agreement with Virbac. This agreement has been summarised in Section 10.7.2.

Historically, QBiotics has received the Australian Government's R&D Tax Incentive each year which is accounted for as government grants. During FY2020 QBiotics also received various government incentives related to COVID-19 measures. The COVID-19 related grant income is not expected to continue in the medium to long term of the business.

Inventory expenses is a credit (i.e. recorded as income) in FY2020. Prior to marketing approval of STELFONTA® all product related expenditure was expensed as R&D. However, once the product was deemed commercially viable QBiotics was able to capitalise previously expensed items to inventory based on the quantity of product on hand. This results in an adjustment to recognise inventory for the first time in FY2020 which brought about a credit to the Statement of Profit and Loss and Other Comprehensive Income for inventory expenses. Inventory expenses incurred in relation to the actual sale of product totalled \$0.6 million. A similar adjustment occurred in 1HFY2021 following FDA-CVM approval.

Business compliance and advisory expenditure has increased as the business has shifted its focus towards greater marketing activities in anticipation of regulatory approval for STELFONTA®. In addition to this, greater legal expenses were incurred to prepare the company for institutional investors and the Offer.

Facilities expenses have decreased in FY2020 onwards due to the adoption of AASB 16 as at 1 July 2019 in which rental expenses have been reclassified to finance costs and depreciation charges. The overall impact of AASB16 on the historical Statement of Profit or Loss and Other Comprehensive Income is immaterial.

Personnel expenses increased in FY2020 and 1HFY2021 in line with headcount as QBiotics have invested internally to support anticipated growth in the future. FY2020 and 1HFY2021 personnel expenses were also impacted by three-year contracts signed with the majority of directors in July 2019. Four of the non-executive directors are being compensated by option grants. Under the requirements of AASB 2, *Share Based Payments*,

expense recognition is heavily weighted to earlier periods. It is expected this expense will decrease substantially over the two years following FY2020.

R&D contractors expenses include clinical trial costs, costs for contract research organisations, such as universities, and costs for outsourced lab work and material purchases. R&D decreased in FY2019 as the business shifted towards commercial marketing in preparation for the commercialisation stage of STELFONTA®. R&D increased in FY2020 and 1HFY2021 with the business focusing on the Human and Wound Healing programs, although the effects of COVID-19 slowed the pace of human clinical trials.

Travel and accommodation expenses increased in FY2019 due to additional planning of overseas clinical trials, meeting with regulators, and planning the launch of STELFONTA®. The onset of the global pandemic COVID-19 has caused the reduction in travel in FY2020 and 1HFY2021.

Other expenses include insurance and other ad hoc expenditure such as donations, freight and cartage, memberships and subscriptions, postage and stationery. Expenses increased in FY2019 due to amounts paid to the European Marketing Agency for the marketing authorisation of tigilanol tiglate (marketed as STELFONTA®).

Net finance income relates to interest received on term deposits held as well as cash at bank. This is partially offset by finance costs incurred in relation to leases held.

Potential investors should also refer to the impact of COVID-19 on QBiotics' business and strategies in Section 6.3.1.

# 7.6 Historical statements of cash flows

The table below presents the summary audited and reviewed historical statements of cash flows for FY2018, FY2019, FY2020 and 1HFY2021.

**Table 7.2 Historical statement of Cash Flows** 

\$'000	FY2018 Audited	FY2019 Audited	FY2020 Audited	HY2021 Reviewed	HY2020 Reviewed
Operating cash flows					
Loss for the period	(12, 182)	(12,796)	(11,808)	(6,627)	(5,763)
Depreciation	1,801	1,952	2,200	1,150	1,098
Net finance income	(381)	(379)	(116)	(126)	(134)
Non-cash adjustments	783	529	790	747	466
Movement in working capital	267	657	(7,910)	5,556	(3,559)
Movement in other assets and					
liabilities	556	658	453	(23)	149
Net operating cash flows	(9,156)	(9,379)	(16,391)	677	(7,743)
Investing cash flows					
Investments in PP&E	(1,261)	(471)	(164)	(526)	(27)
Investment in intangible assets	(328)	(480)	(338)	(118)	(192)
Term deposits movements	11,426	(7,550)	(2,208)	1,826	3,829
Interest received	682	324	427	148	274
Acquisition of subsidiary	1,175	-	-	-	-
Net investing cash flows	11,694	(8,177)	(2,283)	1,330	3,884
Financing cash flows					
Lease payments	-	-	(191)	(163)	(85)
Proceeds from shares issued	500	18,228	17,756	654	10,439
Transaction costs on capital					
raising	-	(328)	(13)	-	(13)
Net financing cash flows	500	17,900	17,552	491	10,341
Net cash flows	3,038	344	(1,122)	2,498	6,482
Cash at the beginning of the					
period	2,044	5,082	5,426	4,304	5,426
Closing cash	5,082	5,426	4,304	6,802	11,908

# 7.6.1 Management discussion and analysis on the historical statements of cash flow

QBiotics has historically generated negative cash flow from operations, which together with the expenditure of plant & equipment and patent and trademark assets has been historically funded through capital raisings and investing activities (i.e. proceeds from term deposits). The working capital movement in FY2020 is attributable to \$4.9 million of R&D tax incentive receivable still outstanding as at 30 June 2020 relating to FY2019 due to delays in obtaining approvals for advance and overseas findings necessary to enable lodgement of the R&D tax incentive application and income tax return. This amount was received on 29 August 2020 which resulted in the positive net working capital movement and net operating cash flows seen in 1HFY2021. Non-cash adjustments relate to share-based payments.

Investing cash flows in FY2018 was largely in relation to the acquisition of QBiotics Pty Ltd and EcoBiotics Pty Ltd through the implementation of a scheme of arrangement approved by the shareholders at the time. Since FY2018 the most significant component of investing cash flows relates to investments in/proceeds from term deposits.

QBiotics has largely been financed by capital raisings through the issue of new share capital, with \$18.2 million and \$18.7 million raised in FY2019 and FY2020 respectively. A further \$0.7 million was raised in 1HFY2021. The funds raised are reinvested in term deposits except for a portion kept as cash to meet short term working capital requirements.

# 7.7 Historical and pro-forma historical balance sheets

# 7.7.1 Consolidated statement of financial position

The table below sets out the reviewed historical consolidated statement of financial position as at 31 December 2020, the pro forma adjustments that have been made to the reviewed consolidated statement of financial position (further discussed in Section 7.8.2) and the pro forma consolidated statement of financial position as at 31 December 2020. The pro forma consolidated statement of financial position is provided for illustrative purposes only and is not represented as being necessarily indicative of QBiotics' view of its future financial position.

Table 7.3 Historical consolidated statement of financial position

As at 31 December 2020 \$'000	Note	Reviewed	Minimum Subscription	Maximum Subscription	Over- subscription
Current assets					
Cash and cash equivalents	7.8.3	6,802	84,694	89,694	92,194
Term deposits		17,302	17,302	17,302	17,302
Trade and other					
receivables		3,314	3,314	3,314	3,314
Inventory		3,169	3,169	3,169	3,169
Prepayments		650	650	650	650
Total current assets		31,237	109,129	114,129	116,629
Non-current assets					
PP&E		2,301	2,301	2,301	2,301
Intangibles		2,989	2,989	2,989	2,989
Right of use assets		1,178	1,178	1,178	1,178
Contract assets		431	431	431	431
Total non-current assets		6,899	6,899	6,899	6,899
Total assets		38,136	116,028	121,028	123,528

As at 31 December 2020 \$'000	Note	Reviewed	Minimum Subscription	Maximum Subscription	Over- subscription
Current liabilities					
Trade and other payables		2,998	2,757	2,757	2,757
Contract liability		510	510	510	510
Lease liabilities		357	357	357	357
Employee benefits		970	970	970	970
Total current liabilities		4,835	4,594	4,594	4,594
Non-current liabilities					
Contract liability		417	417	417	417
Lease liabilities		1,034	1,034	1,034	1,034
Employee benefits		201	201	201	201
Provision		19	19	19	19
Total non-current liabilities		1,671	1,671	1,671	1,671
Total liabilities		6,506	6,265	6,265	6,265
Net assets		31,630	109,763	114,763	117,263
Equity					
Share capital	7.8.4	101,155	178,767	183,767	186,266
Share-based payments reserve	7.8.4	3,124	3,911	3,911	3,911
Accumulated losses	7.8.4	(72,649)	(72,915)	(72,915)	(72,914)
Total shareholder's equity		31,630	109,763	114,763	117,263

# 7.7.2 Description of pro forma adjustments

The following transactions and events had not occurred prior to 31 December 2020 but have taken place or will take place on or before the Allotment Date. The pro forma financial information in this Section 7.8 assumes that they occurred on or before 31 December 2020.

The following subsequent event transactions have occurred:

- 1. The issue of 342,012 new shares to employees in March 2021 and April 2021 as part of bonus scheme. The share issue is recorded against an expense;
- 2. Private placement of \$50.0m from TDM Growth Partners in March 2021;
- 3. Further capital of \$22.5m raised from existing shareholders in April 2021;
- 4. Costs incurred as part of the private placements, amount to \$1.0m with \$0.9m being share options issued to non-executive directors being non cash;
- 5. The exercise of 750,000 options in April 2021 for \$0.6m cash. An associated \$0.1m of share-based payment reserve was transferred to share capital;

In addition, the following pro forma transactions and events will take place pursuant to this Prospectus:

- 6. The completion of the Offer, raising between \$5.0 million through the issue of 5,555,556 ordinary shares (Minimum Subscription) to \$10.0 million through the issue of 11,111,111 ordinary shares (Maximum Subscription) with the ability to accept oversubscriptions for a further \$2.5 million (Oversubscription) at an issue price of \$0.90; and
- 7. Expenses associated with the Offer of \$0.1 million with varying amounts being capitalised and expensed based on it the Minimum Subscription, Maximum Subscription and Oversubscription amounts are raised.

A deferred tax asset has not been recognised in relation to the capitalised Offer costs due to the uncertainty surrounding the flow of economic benefits that will flow in future periods.

# 7.7.3 Calculation of the pro forma cash position

The table below sets out the audited cash and cash equivalents of QBiotics as at 31 December 2020, the proforma adjustments that have been made to the reviewed cash and cash equivalents (further described in Section 7.8.2) and the Company's proforma cash and cash equivalents as at 31 December 2020. The numbers in the 'Proforma adjustment' column correspond to the numbering of the proforma transactions set out in 7.8.2 above.

QBiotics expects that it will have sufficient cash to funds its operational requirements and business objectives following the Offer.

**Table 7.4 Cash and cash equivalents** 

As at 31 December 2020 \$'000	Pro forma adjustment #	Pro-forma assuming gross proceeds of \$5 million	Pro-forma assuming gross proceeds of \$10 million	Pro-forma assuming gross proceeds of \$12.5 million
Reviewed cash and cash equivalents as at 31 December 2020		6,802	6,802	6,802
New shares issued to TDM	2	50,000	50,000	50,000
New shares issued to existing shareholders	3	22,551	22,551	22,551
Cost of private placements	4	(157)	(157)	(157)
Share options issued and exercised Proceeds from Shares issued under the	5	601	601	601
Offer	6	5,000	10,000	12,500
Offer costs	7	(103)	(103)	(103)
Pro forma cash and cash equivalents		84,694	89,694	92,194

Cash and cash equivalents at 31 December 2020 referred to above does not include term deposits of \$17.3 million disclosed separately in the pro-forma historical balance sheets.

# 7.7.4 Calculation of the pro forma capital structure

The pro forma capital structure shown below is based on the following adjustments:

**Table 7.5 Pro forma capital structure** 

As at 31 December 2020	Pro forma adjustment #.	No. of shares #	Share capital \$'000	Accumu- lated losses \$'000	Share- based payments reserve \$'000	Net assets \$'000
Reviewed as at 31 December 2020		388,654,463	101,155	(72,649)	3,124	31,630
Subsequent events New shares issued and options	1	342,012	308	(67)	-	241
New shares issued to TDM	2	55,555,556	50,000	-	-	50,000
New shares issued to existing shareholders	3	25,056,197	22,551	-	-	22,551
Costs of private placement	4	-	(954)	(97)	894	(157)
Share options issued and exercised	5	750,000	708	-	(107)	601
Pre Offer capital structure		470,358,228	173,768	(72,813)	3,911	104,866

	Pro forma adjustment #	No. of shares	Share capital	Accumu- lated losses	Share- based payments reserve	Net assets
As at 31 December 2020	Pro f adju	#	\$'000	\$'000	\$'000	\$'000
Pro forma transactions in rela	ation to	the Minimum S	ubscription	(\$5 million)		
Proceeds from Shares issued under the Offer Offer Costs	6 7	5,555,556	5,000 (1)	- (102)	-	5,000 (103)
Pro form capital structure (\$5 million)		475,913,784	178,767	(72,915)	3,911	109,763
Pro forma transactions in rela	ation to	the Maximum S	Subscription	(\$10 million	1)	
Proceeds from Shares issued under the Offer	6	11,111,111	10,000	-	-	10,000
Offer costs Pro form capital structure (\$10 million)	7	481,469,339	(1) <b>183,767</b>	(102) (72,915)	3,911	(103) <b>114,763</b>
Pro forma transactions in rela	ation to	the Oversubsci	ription (\$12.	5 million)		
Proceeds from Shares issued under the Offer	6	13,888,889	12,500	-	-	12,500
Offer costs  Pro form capital structure (\$12.5 million)	7	484,247,117	(2) <b>186,266</b>	(101) (72,914)	3,911	(103) <b>117,263</b>

# 7.8 Dividend Policy

The Directors may pay to Shareholders any interim and final dividends as they see fit. The Directors may fix the amount, the time for payment and the method of payment. The Directors may establish and make rules for a dividend reinvestment plan or a dividend election plan in relation to any dividend payable by the Company. Note, the Directors do not foresee any payments of dividends in the near future.

# 7.9 Significant accounting policies

The accounting policies applied by QBiotics in the preparation of the Historical Financial Information are the same as those applied by the Company in its financial statements.

## 7.9.1 Basis of consolidation

The Historical Financial Information consolidates those of the Parent Company and its subsidiaries. The parent controls a subsidiary if it is exposed, or has rights, to variable returns from its involvement with the subsidiary and can affect those returns through its power over the subsidiary. All entities in the Group have a reporting date of 30 June. All transactions and balances between Group companies are eliminated on consolidation as at 30 June, including unrealised gains and losses on transactions between Group companies. Where unrealised losses on intra-Group asset sales are reversed on consolidation, the underlying asset is also tested for impairment from a Group perspective.

# 7.9.2 Functional and presentation currency

The Historical Financial Information are presented in Australian dollars which is the functional currency of QBiotics Group, QBiotics and EcoBiotics. Transactions related to QBiotics Netherlands, whose functional currency is Euros, and QBiotics UK, whose functional currency is British Pounds, have been translated to Australian dollars (the presentation currency) in accordance with AASB 121 *The Effects of Changes in Foreign Exchange Rates*.

# 7.9.3 Revenue

Revenue from contracts with customers is measured and recognised in accordance with the five-step model prescribed by AASB 15 *Revenue from Contracts with Customers*. First, contracts with customers within the scope of AASB 15 are identified. Distinct promises with the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration the Group expects to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, non-cash consideration, or amounts payable to customers also determine the transaction price. Revenue is recognised when, or as, performance obligations are satisfied, which is when control of the promised good or services is transferred to the customer.

Revenue is measured on the relative stand-alone selling price of the performance obligation delivered. If the contract contains variable consideration, the variable consideration is estimated at contract inception and constrained until it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

## (i) Product sales

Product sales revenue not yet invoiced under the contract are recorded as contract assets within the consolidated balance sheet. Amounts expected to be invoiced within the 12 months following the end of the financial period are classified within current assets. Amounts not expected to be invoiced within 12 months following the end of the financial period are classified within non-current assets. Where recognition as revenue has occurred more than 12 months prior to invoicing, consideration is made as to whether a financing arrangement has been entered into. At reporting date, no such contracts have been identified.

For contracts that permit the customer to return an item, revenue is recognised to the extent that it is highly probable that a significant reversal in the amount of revenue recognised for the contract will not occur, in which instance, the amount of revenue recognised is adjusted for expected returns, which are estimated based on the historical data for the specific type of product. In these circumstances, a refund liability and an asset representing the right to recover returned goods are recognised.

The right to recover returned goods asset is measured at the former carrying amount of the inventory less any expected costs to recover goods. The refund liability is included in other payables and the right to recover returned goods is included in inventory. The Group reviews its estimate of expected returns at each reporting date and updates the amounts of the asset and liability accordingly.

# (ii) Milestone payments

The receipt of milestone payments is often contingent on meeting certain regulatory or commercial targets and is therefore considered variable consideration. The Group estimates the transaction price of the contingent milestone using the estimated amount method. Milestone payments that are contingent upon events not within the control of the Group, such as regulatory approvals, are considered subject to constraint and not recognised until they are highly probable of being achieved. Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations.

When consideration for milestones is able to be reliably estimated and not constrained, revenue is recognised on a systematic basis representing the proportion of achievement of the milestone.

Milestone payments received prior to satisfying the revenue recognition criteria are recorded as contract liabilities within the consolidated statement of financial position. Amounts expected to be recognised as revenue within the 12 months following the end of the financial period are classified within current liabilities. Amounts not expected to be recognised as revenue within 12 months following the end of the financial period are classified within non-current liabilities. Where recognition as revenue is expected to extend beyond 12 months following the date of the contract becoming effective, consideration is made as to whether a financing arrangement has been entered into. At reporting date, no such contracts have been identified.

#### (iii) Sales-based revenues

When consideration is based on the customer's sale of the products, the Group applies the specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based payments. The exception requires such revenue to be recognised at the later of when (or as) the subsequent sale occurs and the performance obligation to which some or all of the sales-based payments has been allocated has been satisfied.

# 7.9.4 Government grants

The Company undertakes research and development activities which are eligible for tax incentives under Australian tax law. Eligible research and development costs incurred include expenses from all expenditure categories disclosed by nature in the statement of operations.

The Australian Government's R&D Tax Incentive has been based on the following calculation:

Table 7.6 R&D Tax Incentive calculation	FY2018 \$'000	FY2019 \$'000	FY2020 \$'000	HY2021 \$'000	HY2020 \$'000
Eligible research and development costs recognised in profit or loss during the period	13,360	11,431	10,793	5,993	5,922
Amount recognised as government grants in profit or loss during the period	5,777	4,775	5,056	2,588	2,576

The Company recognises R&D tax incentives as follows:

- Refundable tax offsets are recognised as a government grant when there is reasonable assurance that
  the grant will be received and all conditions have been complied with. The grant is recognised in profit
  or loss on a systematic basis over the periods in which the Company recognised as expenses the
  related eligible research and development activities which the grant is intended to compensate.
- Non-refundable tax offsets will be recognised as part of tax expense during the period in which the Company recognised the related eligible research and development activities.

Other government grants and incentives are recognised when there is reasonable assurance that the grant will be received and all conditions have been complied with.

# **7.9.5 Taxes**

Tax expense comprises current and deferred tax. Current tax and deferred tax is recognised in profit or loss except to the extent that it relates to a business combination or items recognised directly in equity, or in other comprehensive income.

## (i) Current tax

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years. Current tax payable also includes any tax liability arising from the declaration of dividends.

## (ii) Deferred tax

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognised for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss;
- temporary differences related to investments in subsidiaries, associates and jointly controlled entities
  to the extent that the Company is able to control the timing of the reversal of any temporary differences
  and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

The measurement of deferred tax reflects the tax consequences that would follow the manner in which the Group expects, at the end of the reporting period, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax is measured at the tax rates that are expected to be applied to the temporary differences when they reverse, using tax rates enacted or substantively enacted by the reporting date.

Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different tax entities, but they intend to settle current tax liabilities and assets on a net basis or their tax assets and liabilities will be realised simultaneously.

A deferred tax asset is recognised for unused tax losses, tax credits and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilised. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realised.

#### (iii) Tax exposure

In determining the amount of current and deferred tax, the Group takes into account the impact of uncertain tax positions and whether additional taxes and interest may be due. This assessment relies on estimates and assumptions and may involve a series of judgements about future events. New information may become available that causes the Group to change its judgement regarding the adequacy of existing tax liabilities. Such changes to tax liabilities will impact tax expense in the period that such a determination is made.

## (iv) Tax consolidation

From 1 August 2017, the Company and its wholly-owned Australian resident subsidiaries are part of a tax-consolidated group under Australian tax law. QBiotics Group is the head entity in the tax-consolidated group (the "Head Company").

Current tax liabilities and assets, and deferred tax assets arising from unused tax losses and relevant tax credits of the members of the tax-consolidated group are recognised by the Head Company.

Entities within the tax-consolidated group have entered into a Tax Funding Agreement and a Tax Sharing Agreement with the Head Company. Under the terms of the Tax Funding Agreement, QBiotics Group and each of the entities in the tax-consolidated group has agreed that current and deferred tax balances must be determined in accordance with the requirements of Urgent Issues Group Interpretation 1052 *Tax Consolidation Accounting* ("UIG 1052") and that the current and deferred tax balances be recognised and measured as if each party was a stand-alone taxpayer, with the necessary modifications to ensure there is no equity adjustment under UIG 1052. The Head Company will recognise current tax liabilities or assets, and deferred tax assets arising from unused tax losses and unused relevant tax credits, assumed from the entities in the tax-consolidated group and the members of the tax consolidated group will recognise deferred taxes relating to temporary differences.

## 7.9.6 Inventory

Inventories are stated at the lower of cost and net realisable value. Cost includes all expenses directly attributable to the manufacturing process as well as suitable portions of related production overheads, based on normal operating capacity. Costs of work in progress and finished goods that are specifically identifiable by production batch are assigned using the specific identification of costs to the batch and weighted average within the batch. Costs of ordinarily interchangeable items (mainly raw materials and consumables) are assigned using the first in, first out cost formula. Net realisable value is the estimated selling price in the ordinary course of business less any applicable selling expenses.

# 7.9.7 Property, plant and equipment

## (i) Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditures that are directly attributable to the acquisition of the asset. Purchased software that is integral to the functionality of the related equipment is capitalised as part of that equipment. When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment. Any gain or loss on disposal of an item of property, plant and equipment (calculated as the difference between the net proceeds from disposal and the carrying amount of the item) is recognised in profit or loss.

# (ii) Subsequent costs

Subsequent expenditure is capitalised only when it is probable that the future economic benefits associated with the expenditure will flow to the Group. Ongoing repairs and maintenance is expensed as incurred.

## (iii) Depreciation

Items of property, plant and equipment are depreciated from the date that they are installed and are ready for use, or in respect of internally constructed assets, from the date that the asset is complete and ready for use. Depreciation is calculated to write off the cost of property, plant and equipment less their estimated residual values using the straight-line basis over their estimated useful lives. Depreciation is generally recognised in profit or loss unless the amount is included in the carrying amount of another asset. Land is not depreciated.

The estimated useful lives in the current and comparative year of significant items of property, plant and equipment are as follows:

Buildings 3 - 40 years
 Plant and equipment 2 - 15 years
 Furniture and fittings 5 - 20 years
 Motor vehicles 7 years
 Computer system 2 - 4 years

Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate.

# 7.9.8 Right of use assets

The right-of-use asset is depreciated using the straight-line method from the commencement date of the lease to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property plant and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain re-measurements of the lease liability.

# 7.9.9 Intangible assets

## (i) Recognition and measurement

Intangible assets include the costs of know-how, patents and trademarks that are acquired by the Group, which have finite useful lives. They are measured at cost less accumulated amortisation and accumulated impairment losses

Intangible assets also include water licences which have an indefinite useful life as they do not expire and can be sold. Water licences are measured at cost less accumulated impairment losses.

# (ii) Subsequent expenditure

Subsequent expenditure is capitalised only when it increases the future economic benefits embodied in the specific asset to which it relates. All other expenditure, including expenditure on internally generated goodwill and brands, is recognised in profit or loss when incurred.

#### (iii) Amortisation

Intangible assets are amortised on a straight-line basis in profit or loss over their estimated useful lives, from the date that they are available for use, that is, when they are in the location and condition necessary for them to be capable of operating in the manner intended by management. Water licences are not amortised.

The estimated useful lives for the current and comparative year are as follows:

Know-how 4 – 15 years
 Patents 20 years
 Trademarks 10 years

Amortisation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate.

## (iv) Impairment

The carrying amounts of the Group's non-financial assets are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. Water licences are tested annually for impairment by reference to current market prices. An impairment loss is recognised if the carrying amount of an asset or its related cash-generating unit (CGU) exceeds its estimated recoverable amount.

The recoverable amount of an asset or CGU is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or CGU. For impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or CGUs.

The Group's corporate assets do not generate separate cash inflows and are utilised by more than one CGU. Corporate assets are allocated to CGUs on a reasonable and consistent basis and tested for impairment as part of the testing of the CGU to which the corporate asset is allocated.

Impairment losses are recognised in profit or loss. Impairment losses recognised in respect of CGUs are allocated first to reduce the carrying amount of any goodwill allocated to the CGU (or group of CGUs), and then to reduce the carrying amounts of the other assets in the CGU (or group of CGUs) on a pro rata basis.

An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

# 7.9.10 Leases

A lease is defined as 'a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration'. To apply this definition the Group assesses whether the contract meets three key evaluations which are whether:

- the contract contains an identified asset, which is either explicitly identified in the contract or implicitly specified by being identified at the time the asset is made available to the Group;
- the Group has the right to obtain substantially all of the economic benefits from use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract; and whether
- the Group has the right to direct the use of the identified asset throughout the period of use. The Group
  assesses whether it has the right to direct 'how and for what purpose' the asset is used throughout the
  period of use.

At the lease commencement date, the Group recognises a right-of-use asset and a lease liability on the balance sheet. The right-of-use asset is measured at cost, which is made up of the initial measurement of the lease liability and any initial direct costs incurred by the Group, and any lease payments made in advance of the lease commencement date (net of any incentives received).

The Group depreciates the right-of-use assets on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Group assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Group measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available or the Group's incremental borrowing rate.

Lease payments included in the measurement of the lease liability are made up of fixed payments, variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in-substance fixed payments.

When the lease liability is remeasured, the corresponding adjustment is reflected in the right-of-use asset, or profit and loss if the right-of-use asset is already reduced to zero.

The Group has elected to account for short-term leases and leases of low-value assets using the practical expedients. Instead of recognising a right-of-use-asset and lease liability, the payments in relation to these are recognised as an expense in profit or loss on a straight-line basis over the lease term.

## Significant accounting policies applicable before 1 July 2019

## (i) Leased assets

Assets held by the Group under leases which transfer to the Group substantially all the risks and rewards of ownership are classified as finance leases. The Group has no finance leases.

## (ii) Lease payments

Payments made under operating leases are recognised in the statement of profit or loss and other comprehensive income on a straight-line basis over the term of the lease. Lease incentives received are recognised as an integral part of the total lease expense, over the term of the lease.

AASB 16 Leases replaces AASB 117 Leases. The new standard has been applied using the modified retrospective approach. The Group measured the cumulative effect of adopting AASB 16 Leases and found the amount to be immaterial and as such no entry was booked as an adjustment to the opening balance of retained earnings for the current period. Prior periods have not been restated.

For contracts in place at the date of initial application, the Group has elected to apply the definition of a lease from AASB 117 and has not applied AASB 16 to arrangements that were previously not identified as leases under AASB 117.

The Group has elected not to include initial direct costs in the measurement of the right-of-use asset for operating leases in existence at the date of initial application of AASB 16 *Leases*, being 1 July 2019. At this date, the Group has also elected to measure the right-of-use assets at an amount equal to the lease liability adjusted for any prepaid or accrued lease payments that existed at the date of transition.

Instead of performing an impairment review of the right-of-use assets at the date of initial application, the Group has relied on its historical assessment as to whether leases were onerous immediately before the date of initial application of AASB 16.

On transition, for leases previously accounted for as operating leases with a remaining lease term of less than 12 months and for leases of low-value assets the Group has applied the optional exemptions to not recognise the right-of-use assets but to account for the leases expense on a straight-line basis over the remaining lease term.

On transition to AASB 16 the weighted average incremental borrowing rate applied to lease liabilities recognised under AASB 16 was 7.2%.

The following is a reconciliation of total operating lease commitments at 30 June 2019 to the lease liabilities recognised at 1 July 2019.

**Table 7.7 Operating lease reconciliation** 

	\$'000
Total operating leases commitments disclosed at 30 June 2019	1,082
Recognition exemptions:	
Leases of low value assets	(8)
Other minor adjustments relating to commitment disclosures	(25)
Leases prepaid at 30 June 2019	(56)
Leases surrendered at 1 July 2019	(111)
Operating lease liabilities before discounting	882
Discounted using incremental borrowing rate	(129)
Total lease liabilities recognised under AASB 16 at 1 July 2019	753

# 7.9.11 Employee benefits

## (i) Short-term benefits

Short-term employee benefits are expensed as the related service is provided. A liability is recognised for the amount expected to be paid if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

## (ii) Share-based payment transactions

The grant date fair value of share-based payment awards granted to employees is recognised as an employee expense, with a corresponding increase in equity, over the vesting period of the awards. The amount recognised as an expense is adjusted to reflect the number of awards for which the related service and non-market vesting conditions are expected to be met, such that the amount ultimately recognised as an expense is based on the number of awards that meet the related service and non-market performance conditions at the vesting date. For share-based payment awards with non-vesting conditions, the grant date fair value of the share-based payment is measured to reflect such conditions and there is no true-up for differences between expected and actual outcomes.

# (iii) Defined contribution plan

A defined contribution plan is a post-employment benefit plan under which an entity pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution superannuation plans are recognised as a personnel expense in profit or loss in the periods during which services are rendered by employees. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in future payments is available.

## (iv) Other long-term employee benefits

The Group's net obligation in respect of long-term employee benefits is the amount of future benefit that employees have earned in return for their service in the current and prior periods. That benefit is discounted to determine its present value. Remeasurements are recognised in profit or loss in the period in which they arise.

# 7.9.12 Equity

# (i) Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of ordinary shares and share based payments are recognised as a deduction from equity, net of any tax effects.

#### (ii) Share-based payments reserve

Where Australian Accounting Standards require a transaction to be recognised as a component of equity, the Group classifies such amounts as a reserve.

The Group's share-based payments reserve consists of share-based payments accounted for under AASB 2 Share-based Payment. Share-based payment transactions are measured by reference to the fair value of the

goods or services received unless that fair value cannot be estimated reliably. If the Group cannot estimate reliably the fair value of the goods or services received, the Group measures the share-based payment transactions by reference to the fair value of the equity instruments granted. The fair value of the equity instruments granted is determined as follows:

- If a market price is available for the equity instrument granted, then the estimate of fair value is based on this market price; or
- If no market price is available for the equity instrument granted, then the fair value is estimated using an appropriate valuation technique.

When instruments granted as share-based payments have vested and are exercised by the holder, the amount is transferred to share capital. When options lapse unexercised, the amount is transferred to accumulated losses.

# 7.9.13 Financial instruments

#### (i) Non-derivative financial assets

The Group initially recognises loans and receivables on the date that they are originated. All other financial assets are recognised initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument.

The Group derecognises a financial asset when the contractual rights to the cash flows from the asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. Any interest in transferred financial assets that is created or retained by the Group is recognised as a separate asset or liability.

Financial assets and liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group has a legal right to offset the amounts and intends either to settle on a net basis or to realise the asset and settle the liability simultaneously.

The Group has the following non-derivative financial assets:

## Trade and other receivables

Trade and other receivables are financial assets with fixed or determinable payments that are not quoted in an active market. Such assets are recognised initially at fair value plus any directly attributable transaction costs. Subsequent to initial recognition trade and other receivables are measured at amortised cost using the effective interest method, less any impairment losses.

## Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits with original maturities of less than 90 days.

# Term deposits

Term deposits comprise cash balances held on deposit with financial institutions with original maturities of more than three months.

## (ii) Non-derivative financial liabilities

The Group initially recognises financial liabilities on the trade date at which the Group becomes a party to the contractual provisions of the instrument.

The Group derecognises a financial liability when its contractual obligations are discharged or cancelled or expire.

The Group classifies non-derivative financial liabilities into the other financial liabilities category. Such financial liabilities are recognised initially at fair value plus any directly attributable transaction costs. Subsequent to initial recognition these financial liabilities are measured at amortised cost using the effective interest rate method.

Other financial liabilities comprise trade and other payables and certain employee benefits.

#### (iii) Derivative financial instruments

The Group holds derivative financial instruments to hedge its foreign currency risk exposures. Embedded derivatives are separated from the host contract and accounted for separately if certain criteria are met.

Derivatives are initially measured at fair value; any directly attributable transaction costs are recognised in profit or loss as incurred. Subsequent to initial recognition, derivatives are measured at fair value, and changes therein are generally recognised in the statement of profit or loss and other comprehensive income.

## (iv) Impairment

A financial asset not carried at fair value through profit or loss is assessed at each reporting date to determine whether there is any objective evidence that it is impaired. A financial asset is impaired if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset, and that the loss event(s) had an impact on the estimated future cash flows of that asset that can be estimated reliably.

Objective evidence that financial assets are impaired can include default or delinquency by a debtor, restructuring of an amount due to the Group on terms that the Group would not consider otherwise, or indications that a debtor will enter bankruptcy.

The Group considers evidence of impairment for loans and receivables (financial assets measured at amortised cost) at a specific asset level.

An impairment loss in respect of a financial asset measured at amortised cost is calculated as the difference between its carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognised in profit or loss and reflected in an allowance account against loans and receivables. When an event occurring after the impairment was recognised caused the amount of impairment loss to decrease, the decrease in impairment loss is reversed through profit or loss.

# 7.10 Investigating Accountant's Report



The Board of Directors QBiotics Group Limited Taringa Central Suite 3A Level 1, 165 Moggill Road TARINGA QLD 4068

Grant Thornton Corporate Finance Pty Ltd Level 17 383 Kent Street Sydney NSW 2000 Locked Bag Q800 Queen Victoria Building NSW 1230

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17 May 2021

#### Dear Directors

#### INDEPENDENT LIMITED ASSURANCE REPORT AND FINANCIAL SERVICES GUIDE

#### Introduction

Grant Thornton Corporate Finance Pty Limited ("Grant Thornton Corporate Finance") has been engaged by QBiotics Group Limited and its controlled entities. ("QBiotics" or "the Group") to prepare this report for inclusion in the prospectus (the "Prospectus") to be issued by the Group on or about 17 May 2021 in respect of the issue of fully paid ordinary shares in the Group (the "Offer").

Grant Thornton Corporate Finance Pty Ltd ("Grant Thornton Corporate Finance") holds an Australian Financial Services Licence (AFS Licence Number 247140). This report is both an Independent Limited Assurance Report, the scope of which is set out below, and a Financial Services Guide, as attached at Appendix A

Expressions defined in the Prospectus have the same meaning in this report, unless otherwise specified

#### Scope

## Statutory Historical Financial Information

Grant Thornton Corporate Finance has been engaged by the Directors to perform a limited assurance engagement in relation to the statutory historical consolidated financial information, being:

- the statutory historical consolidated statement of profit or loss and other comprehensive
  income for the financial years ended 30 June 2018 (FY2018), 30 June 2019 (FY2019), 30
  June 2020 (FY2020) and 6 months ended 31 December 2020 (1HFY2021) with the 6
  months ended 31 December 2019 (1HFY2020) comparative information which are included
  in Section 7.4 of the Prospectus;
- the statutory historical consolidated statement of cash flows for FY2018, FY2019, FY2020 and 1HFY2021 with 1HFY2020 comparative information which are included in Section 7.6 of the Prospectus; and

# ABN-59 003 265 987 ACN-003 265 987 AFSL-247140

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 the statutory historical consolidated statement of financial position as at 31 December 2020 which is included in Section 7.8 of the Prospectus.

#### Pro Forma Historical Financial Information

 the pro forma historical consolidated statement of financial position as at 31 December 2020 and the pro forma adjustments applied as at that date which is included in Section 7.7 of the Prospectus.

#### (together the "Historical Financial Information").

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

The Statutory Historical Financial Information has been derived from the audited consolidated financial statements of the Group for FY2018, FY2019 and FY2020 and reviewed consolidated financial statements of the Group for 1HFY2021. The financial statements for FY2018, FY2019 and FY2020 were audited with 1HFY2021 being reviewed by Grant Thornton Audit Pty Ltd in accordance with Australian Auditing Standards. The audit opinions issued to the Directors for all periods were unqualified.

As described in Section 7.2 of the Prospectus, the stated basis of preparation is the recognition and measurement principles contained in International Financial Reporting Standards ("IFRS") and the Group's adopted accounting policies (as described in Appendix A) applied to the Historical Financial Information and the events or transactions to which the proforma adjustments relate, as set out in Section Section 7.7.2 of the Prospectus, as if those events or transactions had occurred as at the date of the Pro-Forma Historical Financial Information. Oue to its nature, the Pro-Forma Historical Financial Information does not represent the Group's actual or prospective financial position, financial performance, or cash flows.

#### DIRECTORS' RESPONSIBILITY

The Directors are responsible for:

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

This responsibility includes the operation of such internal controls as the Directors determine are necessary to enable the preparation of the Historical Financial Information that are free from material misstatement, whether due to fraud or error.

#### OUR RESPONSIBILITY

Our responsibility is to express a limited assurance conclusion on the Statutory 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 Australian Standard on Assurance Engagements (ASAE) 3450 Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information.

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## **Financial Information**

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

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

We have performed the following procedures as we, in our professional judgement, considered reasonable in the circumstances:

- consideration of work papers, accounting records and other documents of the Group, including those dealing with the extraction and compilation of the Statutory Historical Financial Information from the audited consolidated financial statements of the Group for the financial years ended 30 June 2018, 30 June 2019 and 30 June 2020 and reviewed consolidated financial statements for the 6 months ended 31 December 2020;
- enquiry of the Directors, management and others in relation to the Statutory Historical Financial Information;
- · analytical procedures on the Historical Financial Information;
- a review of the work papers, accounting records and other documents of the Group and its auditors;
- a review of the consistency of the application of the stated basis of preparation and adopted
  accounting policies, as described in the Prospectus, to the Historical Financial Information;
- consideration of the appropriateness of the Pro Forma Adjustments described in Section 7.7.2 of the Prospectus; and
- . a review of the application of Australian Accounting Standards.

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

We have assumed, and relied on representations from certain members of management of the Group, that all material information concerning the Historical Financial Information and historical operations of the Group has been disclosed to us and that the information provided to us for the purpose of our work is true, complete and accurate in all respects. We have no reason to believe that those representations are false.

#### Conclusions

Based on our limited assurance engagement, which is not an audit, nothing has come to our attention that causes us to believe that:

Statutory Historical Financial Information

- The Statutory Historical Financial Information as set out in the Prospectus and comprising:
  - the historical consolidated statement of consolidated profit or loss and other comprehensive income for FY2018, FY2019, FY2020 and 1HFY2021 (including 1HFY2020 comparative information);
  - the historical consolidated statement of cash flows for FY2018, FY2019, FY2020, and 1HFY2021 (including 1HFY2020 comparative information); and
  - the historical consolidated statement of financial position as at 31 December 2020;

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are not presented fairly, in all material aspects, in accordance with the stated basis of preparation described in Section 7.2 of the Prospectus.

Pro Forma Historical Financial Information

- . The Pro Forma Historical Financial Information as set out in the Prospectus and comprising:
  - the pro forma consolidated statement of financial position as at 31 December 2020; and
  - the pro forma transactions set out in Section 7.7 of the Prospectus

are not presented fairly, in all material aspects, in accordance with the stated basis of preparation described in Section 7.2 of the Prospectus.

#### Restrictions on Use

Without modifying our conclusions, we draw attention to Section 7.2 of the Prospectus, which describes the purpose of the Historical Financial Information, being for inclusion in the Prospectus. As a result, this Independent Limited Assurance Report may not be suitable for use for another purpose.

#### Consent

Grant Thornton Corporate Finance Pty Limited has consented to the inclusion of this Independent Limited Assurance Report in the Prospectus in the form and context in which it is included.

#### Liability

The liability of Grant Thornton Corporate Finance Pty Limited is limited to the inclusion of this report in the Prospectus. Grant Thornton Corporate Finance makes no representation regarding, and has no liability, for any other statements or other material in, or omissions from the Prospectus.

#### Independence or Disclosure of Interest

Grant Thornton Corporate Finance does not have any pecuniary interests that could reasonably be regarded as being capable of affecting its ability to give an unbiased conclusion in this matter. Grant Thornton Corporate Finance will receive a professional fee for the preparation of this Independent Limited Assurance Report.

Yours faithfully,

GRANT THORNTON CORPORATE FINANCE PTY LTD

J.A. Malw

Jonathan Mather

Partner

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# **Financial Information**



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## Appendix A (Financial Services Guide)

This Financial Services Guide is dated 17 May 2021.

#### 1 About us

Grant Thornton Corporate Finance Pty Ltd (ABN 59 003 265 987 and Australian Financial Services Licence no 247140) ("Grant Thornton Corporate Finance") has been engaged by QBiotics Group Limited and its controlled entities ("Qbiotics" or the "Group") to provide general financial product advice in the form of an Independent Limited Assurance Report (the "Report") in relation to the offer of fully paid ordinary shares in the Group (the "Offer"). This report is included in the prospectus dated on or about 17 May 2021 (the "Prospectus"). You have not engaged us directly but have been provided with a copy of the Report as a retail client because of your connection to the matters set out in the Report.

#### 2 This Financial Services Guide

This Financial Services Guide (FSG) is designed to assist retail clients in their use of any general financial product advice contained in the report. This FSG contains information about Grant Thornton Corporate Finance generally, the financial services we are licensed to provide, the remuneration we may receive in connection with the preparation of the report, and how complaints against us will be dealt with.

#### 3 Financial services we are licensed to provide

Our Australian financial services licence allows us to provide a broad range of services, including providing financial product advice in relation to various financial products such as securities and superannuation products and deal in a financial product by applying for, acquiring, varying or disposing of a financial product on behalf of another person in respect of securities and superannuation products.

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#### 4 General financial product advice

The report contains only general financial product advice. It was prepared without taking into account your personal objectives, financial situation or needs. You should consider your own objectives, financial situation and needs when assessing the suitability of the Report to your situation. You may wish to obtain personal financial product advice from the holder of an Australian Financial Services License to assist you in this assessment.

Grant Thornton Corporate Finance does not accept instructions from retail clients. Grant Thornton Corporate Finance provides no financial services directly to retail clients and receives no remuneration from retail clients for financial services. Grant Thornton Corporate Finance does not provide any personal financial product advice directly to retail investors nor does it provide market-related advice directly to retail investors.

#### 5 Fees, commissions and other benefits we may receive

Grant Thornton Corporate Finance charges fees to produce reports, including the report. These fees are negotiated and agreed with the entity which engages Grant Thornton Corporate Finance to provide a report. Fees are charged on an hourly basis or as a fixed amount depending on the terms of the agreement with the person who engages us. In the preparation of this report, Grant Thornton Corporate Finance will receive from the Company a fee of \$50,000 (plus GST), which is based on commercial rates plus reimbursement of out-of-pocket expenses.

Partners, Directors, employees or associates of Grant Thornton Corporate Finance, or its related bodies corporate, may receive dividends, salary or wages from Grant Thornton Australia Ltd. None of those persons or entities receive non-monetary benefits in respect of, or that is attributable to, the provision of the services described in this FSG.

#### 6 Referrals

Grant Thornton Corporate Finance - including its Partners, Directors, employees, associates and related bodies corporate - does 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.

#### 7 Associations with issuers of financial products

Grant Thornton Corporate Finance and its Partners, Directors, employees or associates and related bodies corporate may from time to time have associations or relationships with the issuers of financial products. For example, Grant Thornton Australia Ltd may be the auditor of, or provide financial services to the issuer of a financial product and Grant Thornton Corporate Finance may provide financial services to the issuer of a financial product in the ordinary course of its business.

In the context of the report, Grant Thornton Corporate Finance considers that there are no such associations or relationships which influence in any way the services described in this FSG.

#### 8 Independence

Grant Thornton Corporate Finance is required to be independent of QBiotics Group Limited in order to provide this report. The following information in relation to the independence of Grant Thornton Corporate Finance is stated below.

"Grant Thornton Corporate Finance and its related entities do not have at the date of this report, and have not had within the previous two years, any shareholding in or other relationship with QBiotics Group Limited (and associated entities) that could reasonably be regarded as capable of affecting its ability to provide an unbiased opinion in relation to the Offer.

ACCION.

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# **Financial Information**

Grant Thornton Corporate Finance has no involvement with, or interest in the outcome of the Offer, other than the preparation of this report.

Grant Thornton Corporate Finance will receive a fee based on commercial rates for the preparation of this report. This fee is not contingent on the outcome of the Offer.

Grant Thornton Corporate Finance's out of pocket expenses in relation to the preparation of the report will be reimbursed. Grant Thornton Corporate Finance will receive no other benefit for the preparation of this report.

#### 9 Complaints

Grant Thornton Corporate Finance has an internal complaint handling mechanism and is a member of the Australian Financial Complaints Authority (AFCA) (membership no. 11800). All complaints must be in writing and addressed to the Head of Corporate Finance at Grant Thornton Corporate Finance. We will endeavour to resolve all complaints within 30 days of receiving the complaint. If the complaint has not been satisfactorily dealt with, the complaint can be referred to AFCA who can be contacted at:

#### Australian Financial Complaints Authority

GPO Box 3 Melbourne, VIC 3001 Telephone: 1800 367 287

Email: info@afca.org.au

Grant Thornton Corporate Finance is only responsible for the report and FSG. Grant Thornton Corporate Finance will not respond in any way that might involve any provision of financial product advice to any retail investor.

#### 10 Compensation arrangements

Grant Thornton Corporate Finance has professional indemnity insurance cover under its professional indemnity insurance policy. This policy meets the compensation arrangement requirements of section 912B of the Corporations Act, 2001.

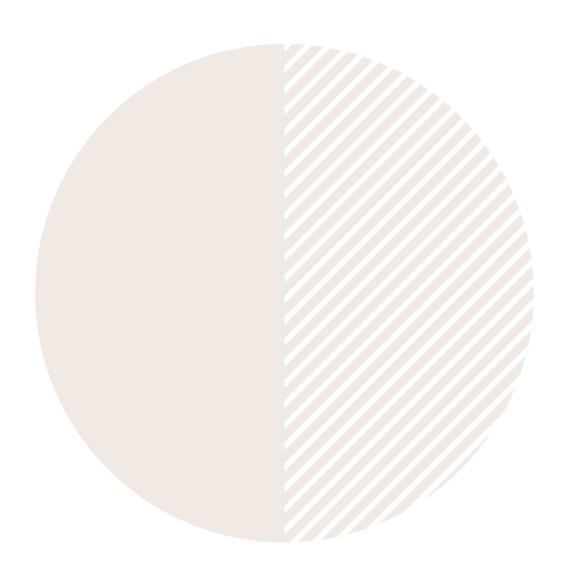
#### 11 Contact Details

Grant Thornton Corporate Finance can be contacted by sending a letter to the following address:

Head of Corporate Finance Grant Thornton Corporate Finance Pty Ltd Level 17, 383 Kent Street Sydney, NSW, 2000

HD=09

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08

Details of the Offer

# Details of the Offer

#### 8.1 What is the Offer?

#### 8.1.1 Maximum Subscription

The Company is seeking to raise \$10 million from Existing Shareholders (before deduction of fees and costs of the Offer) through the placement of 11,111,111 Shares at a price of \$0.90 per Share (Maximum Subscription).

#### 8.1.2 Minimum Subscription

The Minimum Subscription which is being sought under the Offer is \$5 million representing 5,555,556 Shares at \$0.90 per Share.

If the Minimum Subscription is not obtained within three months after the date of this Prospectus, the Company will repay all Application Monies in full without interest as soon as practicable or issue a supplementary or replacement prospectus and allow Applicants one month to withdraw their Applications and be repaid their Application Monies in full without interest.

#### 8.1.3 Oversubscription

The Company may (at its sole discretion) accept Oversubscriptions under the Offer for up to 2,777,778 Shares at an issue price of \$0.90 per Share to raise up to a further \$2.5 million. The maximum amount which may be raised under the Offers is therefore \$12.5 million.

#### 8.1.4 Rights attaching to the Shares

All Shares will be issued at the Offer Price and will rank equally with each other and Shares on issue before the Offer. The Shares are fully paid ordinary shares and will, once issued, rank equally with the Shares on issue as at the date of this Prospectus. A summary of the rights and liabilities attaching to the Shares is set out in Section 10.4.

#### 8.1.5 Conduct of Offer

The Company reserves the right not to proceed with the Offer at any time before the allotment of Shares under the Offer. Application Monies received by the Company will be refunded in full (without interest).

The Company reserves the right to decline any Applications in whole or in part without giving any reason. An Application may be accepted by the Company in respect of the full number of Shares specified in the Application or part only, without further notice to the Applicant. Acceptance of an Application will give rise to a binding contract.

The Company reserves the right to close the Offer early, to accept late Applications or to extend the Offer without notifying any recipient of this Prospectus or any Applicant.

# 8.2 Allocation policy

The Board has absolute discretion regarding the basis for allocation of Shares, and there is no assurance that any Applicant will be allocated any Shares, or the number of Shares for which they have applied.

# 8.3 Purpose of the Offer and use of proceeds of the Offer

QBiotics has raised \$72.55 million from institutional and sophisticated investors in early 2021 to fund human clinical development of the anticancer drug candidate tigilanol tiglate, expand the market for the anticancer veterinary pharmaceutical STELFONTA®, expand the raw material supply capabilities for tigilanol tiglate and EBC-1013 and strengthen the team.

Funds raised under this Offer are planned to support human and veterinary clinical development of QBiotics' wound healing drug candidate EBC-1013.

The proceeds of the Offer are intended to be used for:

- EBC-1013 human Clinical Phase I/IIA safety trial treating Venous Leg Ulcers;
- Equine dose determination study;
- Equine target animal safety study;
- Equine pivotal field efficacy trial;
- Provide further working capital; and
- Pay the expenses of the Offer.

Table 8.1: Summary of the proposed use of the funds raised under the Offer

Activity \$'000	Based on Minimum Subscription of \$5 million	Based on Maximum Subscription of \$10 million	Based on Oversubscrip tion of \$12.5 million
Wound Healing EBC-1013 human clinical VLU PI/IIA safety Wound Healing EBC-1013 veterinary clinical	4,800	4,800	4,800
Dose determination study	-	300	300
Pivotal field trial	-	2,500	2,500
Target animal safety study	-	1,800	1,800
Other			
Working capital	97	497	2,997
Expenses of the Offer*	103	103	103
Total	5,000	10,000	12,500

<sup>\*</sup> General funds raised will contribute towards paying for estimated costs associated with the Offer, depending on the level of subscription (refer to Table 10.2 for details about the Offer expenses), with remaining costs paid from existing cash.

The use of funds set out above represents the Company's current intentions based on the Company's current plans and current business conditions. The amounts and timing of actual expenditure may vary and will depend on various factors. In the opinion of the Directors, on completion of the Offer the Company will have sufficient working capital to carry out is objectives as stated in this Prospectus. The Directors also believe that QBiotics' current financial position is sufficient to fund the Company's activities for at least the coming 2 years.

#### 8.4 Is the Offer underwritten?

No, the Offer is not underwritten.

# 8.5 How do I apply under the Offer?

If you wish to apply for Shares under the Offer, the **preferred method is via the Company's online Offer website**. Please go to <a href="https://www.qbiotics.com/prospectus">www.qbiotics.com/prospectus</a> and follow the instructions for how to apply for Shares via the Online Application Form.

If you wish to apply manually, you can do so by completing the Application Form accompanying this Prospectus in accordance with the instructions set out on that form.

Applications must be for a minimum of 10,000 Shares (\$9,000).

There is no maximum amount that may be applied for under the Offer. The maximum subscription including Oversubscriptions under the Offer is \$12.5 million.

The Company reserves the right to aggregate any Applications which it believes may be multiple Applications from the same person.

The Company reserves the right to reject any Application or to allocate a lesser number of Shares than which the Applicant applied for.

# Details of the Offer

Application Monies should be paid using the following methods unless otherwise determined by the Board:

By BPAY®: by following the instructions on the Application Forms. BPAY® is the preferred payment method.

**By Cheque**: Cheques should be crossed "Not Negotiable" and made out to "QBiotics Group Limited" and posted, together with the Application Form, to the address shown on the Application Form.

Cheques must be drawn on an Australian branch of a financial institution.

By making an Application to purchase Shares under the Offer:

- you agree that your Application is an irrevocable offer which cannot be withdrawn;
- you authorise the Company and the Share Registry (and their officers, employees or agents) to correct any error or omission in your Application Form and to complete the Application Form by the insertion of any missing details;
- you accept the risk associated with any refund of your Application Payment that may be paid to you by cheque to your address shown on the Company's register of members or your Application (as the case may be); and
- you irrevocably and unconditionally agree to be bound by the terms and conditions set out in this Prospectus and the Company's Constitution.

#### 8.5.1 Timing, fees and costs for Applications

Question	Response
When does the Offer open? What is the deadline to submit an Application under the Offers?	The Offer is expected to open for Application on 25 May 2021. It is your responsibility to ensure that your Application Form and Application Monies are submitted before <b>5.00pm (AEST)</b> on the <b>Closing Date</b> for the Offer which is 21 June 2021.
	The Company and the Share Registry take no responsibility for any acts or omissions committed by your Broker in connection with your Application.
Is there any brokerage, commission or stamp duty payable by Applicants?	No. Brokerage, commission or stamp duty is not payable by Applicants on the acquisition of Shares under the Offers.

If you have queries about investing under the Offers, you should contact your stockbroker, financial adviser, accountant or other professional adviser.

If you have queries about how to apply under the Offers or would like additional copies of this Prospectus, please contact QBiotics by emailing <a href="mailto:investors@qbiotics.com">investors@qbiotics.com</a> or phoning (07) 3870 8933.

# 8.6 Application monies

All Application Monies will be held by the Share Registry on trust in a separate cash management account until Shares are issued to successful Applicants.

Application Monies will be refunded in Australian dollars to the extent that an Application is rejected or scaled back, or the Offer is withdrawn. No interest will be paid on refunded amounts. The Company will retain any interest earned on Application Monies.

#### 8.7 Professional advice

If you are in any doubt as to whether to accept the Offer, please consult your licensed financial adviser, accountant, stockbroker, lawyer or other professional adviser.

The Directors do not consider it appropriate to give Shareholders or investors advice regarding the taxation consequences of subscribing for Shares under this Prospectus.

The Company, its advisers and its officers do not accept any responsibility or liability for any such taxation consequences to Shareholders or investors. As a result, Shareholders and investors should consult their professional tax adviser in connection with any aspect of the Offer and/or applying for Shares under this Prospectus.

## 8.8 Shareholding structure

#### 8.8.1 Ownership

At 21 April 2021, the Company had 2,384 shareholders. The following table illustrates the ownership structure of the Company before and after the Offer.

Table 8.2: Ownership changes under various subscription scenarios

	Shareholding Prospectus D		Based on Minimum Subscription of \$5 million		Based on Maximum Subscription of \$10 million		Oversubscription of \$12.5 million	
		%		%		%		%
Interest associated with the Directors	132.286.656	28.1	132.286.656	27.8	132.286.656	27.5	132.286.656	27.3
Other shareholders	338,071,572	71.9	338,071,572	71.0	338,071,572	70.2	338,071,572	69.8
Shares to be issued under the Offer	-	_	5,555,556	1.2	11,111,111	2.3	13,888,889	2.9
Total	470,358,228	100.0	475,913,784	100.0	481,469,339	100.0	484,247,117	100.0

Any discrepancies between totals and sums of components in this table are due to rounding.

The table above does not include any shares that may be issued on the exercise of any of the outstanding Options on issue. If all outstanding Options on issue were exercised (including those which have not yet vested), the indicative percentage of Shares to be issued under the Offer or at Completion of the Offer: (1) assuming Minimum Subscription would be 1.1%; (2) assuming Maximum Subscription would be 2.2%; and (3) assuming Oversubscription would be 2.8%.

#### 8.8.2 Substantial shareholders

Any entity (including their associates) that holds a 5% interest in the Company is a substantial shareholder.

There are three substantial shareholders in the Company. One Managed Investment Funds Limited as custodian for TDM Growth Partners Pty Ltd holds 11.81%, Dr Victoria Gordon holds 6.98% and Dr Paul Reddell holds 6.36% of the shares on issue in the Company at the date of this Prospectus. Mr Hamish Corlett is a director of TDM Growth Partners Pty Ltd. Details of Dr Gordon, Dr Reddell and Mr Corletts holdings are set out in section 5.2.



# O O Intellectual Property

# Intellectual Property

The primary patent portfolio of QBiotics consists of patent families / applications for its anticancer products tigilanol tiglate (referred to as "Tiglien-3-one" in patents) and its wound healing products EBC-1013 (referred to as "Methods and Compositions for Wound Healing"). The Company believes that it is in a strong position with these patents as they cover both composition-of-matter and use (application against the target disease).

## 9.1 Tigilanol tiglate or Tiglien-3-one

Patents covering composition of matter and use for tigilanol tiglate (and analogues) have been granted in the USA, Australia, Canada, Europe, Hong Kong, Japan, New Zealand, India and China. US Patent No. 8,598,229 has been granted a term adjustment and the original term of the patent has been extended by 1,249 days to May 2030. Furthermore, a patent term extension has been requested in relation to this US patent based on a veterinary approval of the tigilanol tiglate product STELFONTA® from the FDA-CVM. Supplementary Protection Certificates, to extend the term of the European patents have been requested in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom based on the European registration of the tigilanol tiglate product STELFONTA®. A Supplementary Protection Certificate has also been requested in Switzerland based on the registration of the tigilanol tiglate product STELFONTA® by Swissmedic. Supplementary Protection Certificates have been granted in the Czech Republic, Denmark, Hungary, Italy, The Netherlands, Portugal, Slovenia and Sweden and are pending in other jurisdictions. The extended expiry date is 22 December 2031.

An additional patent covering tigilanol tiglate in combination with the immune checkpoint inhibitors is pending in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, Ukraine and USA and has been granted in South Korea. An additional patent providing extended veterinary coverage is pending in Australia, Brazil, Europe, Hong Kong, Japan and USA.

Further patents relating to solid tumour therapy and Biofilm disruption are currently pending under the Patent Cooperation Treaty.

# 9.2 Methods of Compositions for Wound Healing

An Australian provisional application covering composition of matter for use for EBC-1013 (and analogues) was submitted in April 2013. This application progressed through International phase under the Patent Cooperation Treaty and is currently being pursued in Australia, Brazil, Canada, China, Colombia, Eurasia, Europe, Indonesia, Hong Kong, Israel, India, Japan, Korea, Sri Lanka, Mexico, Malaysia, New Zealand, Philippines, Singapore, Thailand, Ukraine, United States of America, Vietnam and South Africa. Patents have been granted in Australia, China, Colombia, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, New Zealand, Philippines, Singapore, Ukraine and USA. Applications Malaysia, Vietnam and South Africa are allowed or accepted and are in pre-grant stage. Applications in Brazil, Canada, Sri Lanka and Thailand are awaiting examination or under examination.

## 9.3 Patent report



#### Status Report as at 21 April 2021 **QBiotics Limited**

#### Tiglien-3-one Derivatives - EBC46

This family of patents and patent application generally relates to Tiglien-3-one compounds, pharmaceutical and agricultural compositions containing them and their use in methods of treating bacterial infections, parasitic infections, cell proliferative disorders, protozoan infections, methods of stimulating localised inflammatory response, as well as methods of controlling pests.

Our Ref	Patent No	Country	Status	Expiry Date	Comments
P99797.AU	2005907278	Australia	Expired at end of life	-	Provisional application
P99797.PCT	PCT/AU2006/002001	International	Expired at end of life		International application
P99797.AU.1	2006326872	Australia	Granted	22 Dec 26	- Committee
P99797.CA	2634469	Canada	Granted	22 Dec 26	
P99797.EP	06840409,4	Europe	Granted	22 Dec 26	Validated in: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom;
	SPC of 06840409.4 (other jurisdictions still pending	Czech Republic Denmark Hungary Italy Netherlands Portugal Slovenia Sweden	Granted Granted Granted Granted Granted Granted Granted Granted	22 Dec 31 22 Dec 31 22 Dec 31 22 Dec 31 21 Dec 31 22 Dec 31 22 Dec 31 22 Dec 31 22 Dec 31	Supplementary Protection Certificates (SPC) requested in all jurisdictions except Monaco to provide extension of term for veterinary cancer treatment with Stelfonta <sup>TM</sup>
P99797.HK	09102814.1	Hong Kong	Granted	22 Dec 26	
P99797.IN	5864/DELNP/2008	India	Granted	22 Dec 26	

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Level 22 Allendale Square 77 St Georges Terrace Perth WA 6000 Australia

T+61.8 9213.8300

Level 22, 300 Queen Street Brisbane QLD 4000 Australia GPO Box 3125 Brisbane QLD 4001 Australia

T +61 7 3232 1700

GH PTM Pty Ltd (ACN 615 493 053) t/as Gr[ffith Hack is a member of the IPH Ltd group, and pc Trade Marks Attorneys 2018 (see Intps://www.

# **Intellectual Property**



Our Ref	Patent No	Country	Status	Expiry Date	Comments
P99797.JP	2008-546041	Japan	Granted	22 Dec 26	
P99797.NZ.1	597019	New Zealand	Granted	22 Dec 26	
P99797.CN	200680053214.9	China	Granted	22 Dec 26	
P99797.US	8598229 (12/158461)	USA	Granted	24 May 30	
P99797.US.1	9289410 (14/084949)	USA	Granted	22 Dec 26	
P99797.US.2	9770431 (15/041960)	USA	Granted	22 Dec 26	
P99797.US.3	15/426744	USA	Abandoned	-	
P99797.US.4	10543188 (16/149,977)	USA	Granted	22 Dec 26	
P99797.US.5	10980769 (16/702,296)	USA	Granted	22 Dec 26	
P99797.US.6	17/204747	USA	Pending	(E)	

#### **Methods of Wound Healing**

QBiotics Limited

This family of patents and patent applications generally relates to epoxy-tigliane compounds and their use in inducing or promoting wound healing, reducing scarring and improving cosmetic outcomes upon healing of wounds. Some epoxy-tigliane compounds and pharmaceutical compositions containing them are also described.

Our Ref	Application No.	Country	Status	Expiry date	Comments
P99795.AU	2013901359	Australia	Expired at end of life		Provisional Application
P99795.PCT	PCT/AU2014/050018	International	Expired at end of life	-	International Application
P99795.AU.1	2014253608	Australia	Granted	17 April 34	NAME OF TAXABLE PARTY.
P99795.BR	BR1120150263887	Brazil	Pending		Under Examination
P99795.CA	2909653	Canada	Pending		Under Examination
P99795.CN	201480030942.2	China	Granted	17 Apr 34	Contract to the Contract of th
P99795.CO	15-274.895	Colombia	Granted	17 Apr 34	
P99795.EA	201591996	Eurasia	Granted	17 Apr 34	Granted Armenia, Belarus, Turkmenistan, Tajikistan, Russia, Kazakhstan, Azerbaijan, Kyrgyzstan
P99795.EP	14784998.8	Europe	Granted	17 April 34	Validated: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia,



Our Ref	Application No.	Country	Status	Expiry date	Comments
					Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia Lithuania, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.
P99795.HK	16102151.3	Hong Kong	Granted	17 Apr 34	
P99795.ID	P-00201507384	Indonesia	Granted	17 April 34	
P99795.IL	242137	Israel	Granted	17 April 34	
P99795.IN	10524/DELNP/2015	India	Granted	17 April 34	
P99795.JP	2016-507958	Japan	Granted	17 April 34	
P99795.KR	10-2015-7032991	Korea	Granted	17 April 34	
P99795.LK	18466	Sri Lanka	Pending	I GIO	Under Examination
P99795.MX	MX/a/2015/014607	Mexico	Granted	17 April 34	
P99795.MY	PI2015703714	Malaysia	Accepted	1 %	Awaiting Grant
P99795.NZ	713954	New Zealand	Granted	17 April 34	
P99795.PH	1-2015-502405	Philippines	Granted	17 April 34	Awaiting Grant
P99795.SG	11201508588X	Singapore	Granted	17 Apr 34	
P99795.TH	1501006371	Thailand	Pending		Examination requested
P99795.UA	118670 (A2015 10792)	Ukraine	Granted	17 Apr 34	
P99795.US	10183921 (14/785127)	USA	Granted	17 April 34	- 1
P99795.US.1	10183922 (15/425739)	USA	Granted	17 April 34	
P99795.US.2	10822317 (16/197785)	USA	Granted	17 April 34	
P99795.VN	1-2015-04418	Vietnam	Allowed	-	Awaiting grant
P99795.ZA	2015/08186	South Africa	Allowed	1 4	Awaiting Grant

# Method of Treatment (Epoxy tiglianes for treatment of mast cell tumours and soft tissue sarcomas in dogs)

This family of patent applications generally relates to the use of 6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one compounds in combination with at least one other pharmaceutically active agent for treating mast cell tumours and soft tissue sarcomas.

QBiotics Limited -3- 22 April 2021

# **Intellectual Property**



Our Ref	Application No.	Country	Status	Expiry date	Comments
P103717.AU	2016902980	Australia	Expired at end of life	÷	Provisional Application
P103717.PCT	PCT/AU2017/050791	International	Expired at end of life	-2-	International Application
P103717.AU.2	2017304228	Australia	Pending	1	Under Examination
P103717.BR	11 2019 001365 2	Brazil	Pending		Examination requested, awaiting report
P103717.EP	17833112.0	Europe	Pending		Under Examination
P103717.HK	19130535.8	Hong Kong	Pending		Stage 1 published
P103717.JP	2019-526349	Japan	Pending		Examination requested, awaiting report
P103717.US	16/320762	US	Pending		Under Examination

## QBiotics Pty Ltd

#### EBC-46 PD-1 (Combinations of epoxytiglianes with checkpoint inhibitors)

This family of patent applications generally relates to the administration of an epoxy-tigliane compound in combination with an immune checkpoint inhibitor for treating a tumour and/or treating or preventing one or more bystander tumours. Pharmaceutical compositions and kits containing epoxy-tigliane compounds and immune checkpoint inhibitors are also described.

Our Ref	Application No.	Country	Status	Expiry date	Comments
P104575.AU	2017901027	Australia	Expired at end of life	*	Provisional Application
P104575.PCT	PCT/AU2018/050277	International	Expired at end of life	÷	International Application
P104575.AU.1	2018238202	Australia	Pending	141	filed
P104575.BR	BR11 2019 019748 6	Brazil	Pending		Under examination
P104575.CA	3056685	Canada	Pending		filed
P104575.CN	201880019617.4	China	Pending	-	Examination requested, awaiting report
P104575.EA	201992220	Eurasia	Pending	-	Under examination
P104575.EP	18770812.8	Europe	Pending	1 4	Under Examination
P104575.HK	62020003816.9	Hong Kong	Pending	1-	Stage 1 published
P104575.IN	201917037469	India	Pending	+	Under Examination
P104575.ID	P00201908898	Indonesia	Pending	+	filed
P104575.IL	269522	Israel	Pending	100	Under Examination
P104575.JP	2019-552088	Japan	Pending	(+)	Under examination
P104575.MY	PI2019005163	Malaysia	Pending	14/	Examination requested
P104575.MX	MX/a/2019/011221	Mexico	Pending	4	filed
P104575.NZ	756754	New Zealand	Pending	÷	Examination Requested

QBiotics Limited - 4 - 22 April 202



Our Ref	Application No.	Country	Status	Expiry date	Comments
P104575.PH	1-2019-502132	Philippines	Pending	4	Examination Requested
P104575.SG	11201907891X	Singapore	Pending		Under Examination
P104575.ZA	2019/06001	South Africa	Pending	*	filed
P104575.KR	2019-7031149	South Korea	Granted	23 March 2038	
P104575.UA	a201910449	Ukraine	Pending	12	Under Examination
P104575.US	16/496333	USA	Pending		Under Examination

#### **EBC-46 Method of Treatment**

This family of patents generally relates to the localised administration, for example, intratumourally or topically, of an epoxytiglienone compound (as a monotherapy) to cancerous tumours to generate a systemic anticancer abscopal and/or bystander effect.

Our Ref	Application No.	Country	Status	Expiry date	Comments
P110949.AU	2019901280	Australia	Expired at end of life	4	Provisional Application
P110949.PCT	PCT/AU2020/050360	International	Pending	12 Oct 2021	IPRP Received

#### **Biofilm Disruption**

This patent family generally relates to methods of dispersing biofilms comprising Gram-negative bacteria, the methods comprising exposing the biofilm to an epoxytiglienone compound or a salt thereof. Methods of treating infections involving established biofilms comprising Gram-negative bacteria to disrupt the structure of that biofilm and methods of preventing biofilms comprising Gram-negative bacteria forming or dispersing biofilms comprising Gram-negative biofilms that have formed on medical devices are also described.

Our Ref	Application No.	Country	Status	Expiry date	Comments
P111271.AU	2019902144	Australia	Expired at end of life	19 June 2020	Provisional Application
P111271.AU	PCT/AU2020/050623	International	Pending	19 Dec 2021	IRS & WO Received

QBiotics Limited -5- 22 April 2021

# **Intellectual Property**



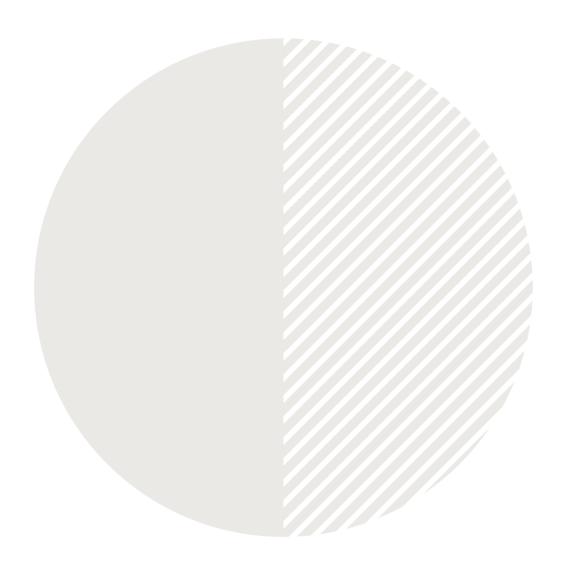
#### **EcoBiotics Ltd**

#### **Spiroketals**

This family of patents and patent application generally relates to spiroketal compounds that are useful in methods of treating or prevent protozoal infections, parasitic infections, bacterial infections, cell proliferative disorders and anti-inflammatory disorders. The spiroketal compounds are also useful as immunosuppressive agents, and also in methods of controlling pests.

Our Ref	Application No.	Country	Status	Expiry date	Comments
P99775.AU	2005907277	Australia	Expired at end of life	-	X
P99775.PCT	PCT/AU2006/002000	International	Expired at end of life	-	
P99775.AU.1	2006326871	Australia	Granted	22 Dec 26	
P99775.CA	2634468	Canada	Granted	22 Dec 26	
P99775.CN	101389632	China	Granted	22 Dec 26	
P99775.EP	EP1971608	European Patent Office	Granted	22 Dec 26	Validated in: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom
P99775.IN	5863/DELNP/2008	India	Granted	22 Dec 26	
P99775.JP	5324922	Japan	Granted	22 Dec 26	
P99775.NZ	569403	New Zealand	Granted	22 Dec 26	
P99775.US	8013012	USA	Granted	25 May 28	
P99775.US.1	8466194	USA	Granted	22 Dec 26	
P99775.US.2	8680141	USA	Granted	22 Dec 26	
P99775.US.3	8921414	USA	Granted	22 Dec 26	

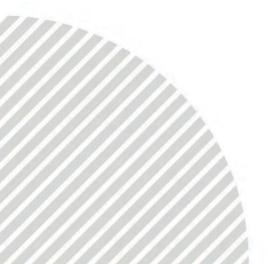
QBiotics Limited - 6 - 22 April 2021





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Additional Information



# Additional Information

#### 10.1 Incorporation

The Company was incorporated as a public company limited by shares in the State of Queensland, Australia on 24 February 2017.

## 10.2 Company tax status

The Company is taxed in Australia as a public company for the purposes of Australian income tax law. The tax payable by you in relation to any investment in the Shares issued under this Prospectus depends on your individual circumstances. You should consult a professional tax adviser about the consequences of you acquiring, holding or selling the Shares.

## 10.3 Current capital structure

The capital structure of the Company as at the date of this Prospectus and following completion of the Offer based on the Minimum Subscription, Maximum Subscription and Oversubscription is set out in Section 8.8. As at Completion of the Offer, the Company will have on issue the following Options:

Table 10.1: Options on issue post Offer

Class of Securities	Vested	Unvested	Total	Exercise Price
Options over Ordinary Shares	4,523,740	-	4,523,740	\$0.670
Options over Ordinary Shares	5,026,875	-	5,026,875	\$0.801
Options over Ordinary Shares	1,268,502	2,852,910	4,121,412	\$1.000
Options over Ordinary Shares	2,223,714	-	2,223,714	\$1.170
Options over Ordinary Shares	1,750,000	964,668	2,714,668	\$1.510
	14,792,831	3,817,578	18,610,409	

Of the options on issue, the exercise period for 5,026,875 of the options is 5 years from the vesting date and the exercise period for the remaining 13,583,534 options is 6 years from the grant date.

Of the options on issue, 3,538,874 options will expire during 2022, 1,774,877 options will expire during 2023, 3,891,680 options will expire during 2024, 4,466,596 options will expire during 2025, 2,223,714 options will expire during 2026 and 2,714,668 options will expire during 2027.

Each Option entitles its holder to one fully paid ordinary Share in the Company. All Shares issued upon exercise of the Options will rank equally in all respects with the Company's then issued Shares.

# 10.4 Rights attaching to Shares

The rights attaching to fully paid ordinary Shares in the capital of the Company are set out in the Constitution. A summary of the rights attaching to Shares under the Constitution is set out below. This summary is qualified by the full terms of the Constitution (copies of the Constitution may be inspected at the registered office of the Company during normal business hours by appointment with the Company secretary) and does not purport to be exhaustive or to constitute a definitive statement of the rights and liabilities of Shareholders. These rights and liabilities can involve complex questions of law arising from an interaction of the Constitution with statutory and common law requirements. For an investor to obtain a definitive assessment of the rights and liabilities which attach to Shares in any specific circumstances, that investor should seek legal advice.

#### 10.4.1 General

Subject to the Constitution and the terms of issue of a Share, attached to each Share is the right to receive notice of, attend and vote at all meetings of Shareholders, to receive dividends, and in a winding up to participate equally in the distribution of assets of the Company subject only to the amounts unpaid on any Share.

#### 10.4.2 Voting

At a meeting of Shareholders, subject to the Constitution and the Corporations Act, on a show of hands each Shareholder present in person or by proxy has one vote. At the taking of a poll, each Shareholder present in person, present online at a virtual meeting or by proxy has one vote for each fully paid Share, and for each partly paid Share a fraction of a vote equivalent to the proportion which the amount paid (not credited nor paid in advance of a call) bears to the total amount paid and payable (excluding amounts credited). A Shareholder is entitled to be counted in a vote only in respect of Shares on which all calls due and payable have been paid. The chair at a meeting of the Company's members does not have a casting vote.

A resolution put to vote at a meeting must be decided on a show of hands unless a poll is demanded.

#### 10.4.3 Proxy

An instrument appointing a proxy and the power of attorney or other authority must be deposited with the Company at a place permitted by the Company not less than 48 hours (or such lesser period as the Directors may permit) before the time for holding the meeting.

#### 10.4.4 General meetings and notices

A Director of the Company may call a general meeting and the Directors must call an annual general meeting in accordance with the Corporations Act. Shareholders may request or call and arrange to hold a general meeting in accordance with the Corporations Act. Subject to any relevant laws, general meetings may be held wholly or partly online.

Each Shareholder is entitled to receive notice of, attend and vote at general meetings of the Company and to receive all notices, financial statements and other documents required to be sent to Shareholders under the Company's Constitution and the Corporations Act.

The quorum for a meeting of Shareholders is two Shareholders entitled to vote at the meeting.

#### 10.4.5 Dividends and share plans

The Directors may pay to Shareholders any interim and final dividends as they see fit. The Directors may fix the amount, the time for payment and the method of payment.

The Directors may establish and make rules for a dividend reinvestment plan/or a dividend election plan in relation to any dividend payable by the Company.

The Directors may declare dividends on a class of Shares to the exclusion of and in different amounts than other classes. Dividends on partly paid shares must not exceed the proportion which the amount paid (not credited) bears to the total amount paid and payable (excluding amounts credited) on that Share.

Note, the Directors do not foresee any payments of dividends in the near future.

#### 10.4.6 Issue of Shares

Subject to the Constitution, the Corporations Act and any special rights conferred on holders of Existing Shares or a class of Shares, the Directors may issue or otherwise dispose of, or grant options in respect of, shares to such persons on such terms as they think fit. In particular, the Directors may issue shares with preferred, deferred or special rights or restrictions in relation to their transferability, dividends, voting, return of capital and payment of calls.

The Company may issue preference shares which are or at the option of the Company are to be, liable to be redeemed. Holders of preference shares will only have the right to vote at a meeting convened for the purpose of reducing capital, in certain circumstances upon winding up, where the resolution effects the rights attached to the preference shares, when a dividend on the preference shares is in arrears or on a resolution to approve the terms of a buy-back.

# **Additional Information**

#### 10.4.7 Transfer of Shares

Generally, all Shares are freely transferable subject to the procedural requirements of the Constitution, and to the provisions of the Corporations Act. Some Shares may be subject to a restriction deed or notice limiting that shareholder's right to transfer some or all of their Shares to a third party. The Company will enter into restriction deeds or provide restriction notices in compliance with relevant laws, stock exchange rules or where prudent from a governance perspective. The Directors may also decline to register an instrument of transfer received where refusal is permitted under the Constitution.

#### 10.4.8 Proportional takeover provisions

The registration of a transfer of Shares which would give effect to a proportional takeover bid is prohibited unless and until an approving resolution approving the proportional takeover bid is passed. The proportional takeover provisions will cease to have effect on the third anniversary of the adoption of the Constitution, unless renewed.

#### 10.4.9 Winding up

Subject to any special rights attaching to a class of shares, if the Company is wound up the liquidator in a winding up may, with the sanction of a special resolution of the Shareholders, divide the assets of the Company among the Shareholders and/or vest all or any of the Company's assets in a trustee on trusts determined by the liquidator for the benefit of the contributories.

#### 10.4.10 Liability of Shareholders

As all Existing Shares on issue are fully paid, and the Shares to be issued pursuant to this Prospectus will be fully paid, Shareholders will not be subject to any further call for money by the Directors and therefore Shares will not become liable to forfeiture.

#### 10.4.11 Variation of rights

The rights attaching to the Shares may only be varied, modified or cancelled with the prior written consent of at least 75% of the holders of votes in that class or by a special resolution of the holders of shares in that class at a meeting of those holders.

#### 10.4.12 Directors - Appointment, retirement and removal

The minimum number of Directors is three (3) and the maximum is ten (10). The Directors are not required to hold any Shares.

Directors may be appointed by resolution of Shareholders at a general meeting. The Directors may appoint a Director either in addition to existing Directors or to fill a casual vacancy, and such Director will hold office until the next annual general meeting.

Directors may only be removed by resolution of Shareholders at a general meeting.

A Director must retire from office at the end of the third annual general meeting following that Directors last appointment or three (3) years, whichever is longer. The requirement to retire does not apply to the Managing Director. If there is more than one Managing Director then the requirement to retire will not apply to just one Managing Director. A retiring Director is eligible for re-election.

#### **Founder Directors**

Subject to the Corporations Act, while the Company is an unlisted public company, for so long as Dr Victoria Gordon or any entity controlled by her holds shares in the Company, she is entitled to be a director or to nominate a person to be a director, and remove any director appointed by her and appoint another director in her place.

Subject to the Corporations Act, while the Company is an unlisted public company, for so long as Dr Paul Reddell or any entity controlled by him holds shares in the Company, he is entitled to be a director or to nominate a person to be a director, and remove any director appointed by him and appoint another director in his place.

#### 10.4.13 Decisions of Directors

The quorum for a meeting of Directors is two (2). Questions arising at a meeting of Directors are decided by a majority of votes cast by Directors entitled to vote on the resolution. The Chair of a board meeting does not have a casting vote.

#### 10.4.14 Alteration to the Constitution

The Constitution can only be amended by a special resolution passed by at least 75% of Shareholders present and voting at a general meeting. At least 21 days' notice (if the Company is not listed) or 28 days' notice (if the Company is listed) of the meeting at which the special resolution is proposed must be given.

## 10.5 Terms of existing Options

The terms of the Directors' existing Options on Completion of the Offer are outlined below.

#### 10.5.1 Rick Holliday-Smith

Under the terms of Rick Holliday-Smith's appointment, the non-executive Chairman is awarded 3,911,609 options (Chairman Remuneration Options) to acquire ordinary shares as payment for six years of his remuneration based on \$75,000 per annum in 2017 and 2018, which was increased to \$100,000 per annum in 2019. Each of these amounts excludes superannuation. The options vest and expire in the following manner:

- 750,000 options vested on 1 August 2017 and were exercised on 12 April 2021 at an exercise price of \$0.801.
- 583,334 options vested on 1 August 2017, will expire on 18 April 2022 and have an exercise price of \$0.801;
- 583,334 options vested on 18 April 2018, will expire on 18 April 2023 and have an exercise price of \$0.801;
- 583,334 options vested on 18 April 2019, will expire on 18 April 2024 and have an exercise price of \$0.801;
- 510,244 options vested on 4 July 2020, will expire on 4 July 2025 and have an exercise price of \$1.00;
- 449,655 options will vest on 4 July 2021, expiring on 4 July 2025 with an exercise price of \$1.00; and
- 451,708 options will vest on 4 July 2022, expiring on 4 July 2025 with an exercise price of \$1.00.

The Chairman Remuneration Options which have not yet been vested, will lapse if QBiotics terminates the Chairman's appointment for cause or if the Chairman terminates for convenience.

If however, QBiotics terminates the appointment for convenience or the Chairman terminates as a result of the Chairman reasonably considering that his directorship or actions required in association with the directorship will cause him risk or reputational damage, then the unvested Chairman Remuneration Options will vest immediately.

If there is any reconstruction of the issued share capital of QBiotics, the Director must be put in the same position as if no reconstruction had occurred.

In addition to the Chairman Remuneration Options the Chairman was also awarded:

- 1,000,671 options in recognition of his commitment to the Company and the substantial funds raised from investors introduced by the Chairman. These options vested on 17 February 2020, expire on 16 February 2026 and are exercisable at a price of \$1.170 per option; and
- 250,000 options in recognition of his support over an extended time frame to the ongoing capital raise activities of the Company. These options vested on 19 April 2021, expire on 30 March 2027 and are exercisable at a price of \$1.51 per option.

Rick Holliday-Smith holds 4,412,280 options in total.

# Additional Information

#### 10.5.2 Professor Bruce Robinson AC and Andrew Denver

Under the terms of Professor Bruce Robinson's and Andrew Denver's agreements for appointment as Director, each non-executive Director is awarded 1,904,363 options to acquire ordinary shares as payment for six years of his remuneration based on \$55,000 per annum in 2017 and 2018, which was increased to \$75,000 per annum in 2019. Each of these amounts excludes superannuation. The options vest and expire in the following manner:

- 301,472 options vested on 1 August 2017, will expire on 20 July 2022 and have an exercise price of \$0.801;
- 301,472 options vested on 20 July 2018, will expire on 20 July 2023 and have an exercise price of \$0.801;
- 301,473 options vested on 20 July 2019, will expire on 20 July 2024 and have an exercise price of \$0.801;
- 323,924 options vested on 4 July 2020, will expire on 4 July 2025 and have an exercise price of \$1.00;
- 337,241 options will vest on 4 July 2021, expiring on 4 July 2025 with an exercise price of \$1.00; and
- 338,781 options will vest on 4 July 2022, expiring on 4 July 2025 with an exercise price of \$1.00.

If there is any reconstruction of the issued share capital of QBiotics, the Directors must be put in the same position as if no reconstruction had occurred.

In addition to the abovementioned options Professor Bruce Robinson and Andrew Denver were also awarded:

- 389,150 options each in recognition of their commitment to the Company and the fundraising assistance provided to the Chairman. These options vested on 17 February 2020, expire on 16 February 2026 and are exercisable at a price of \$1.170 per option.
- 250,000 options each in recognition of their support over an extended time frame to the ongoing capital
  raise activities of the Company. These options vested on 19 April 2021, expire on 30 March 2027 and are
  exercisable at a price of \$1.51 per option.

Professor Bruce Robinson and Andrew Denver each hold 2,543,513 options in total.

#### 10.5.3 Neville Mitchell

Under the terms of Neville Mitchell's agreement for appointment as Director, the non-executive Director is awarded 1,877,952 options to acquire ordinary shares as payment for six years of his remuneration based on \$55,000 per annum in 2017 and 2018, which was increased to \$75,000 in 2019. Each of these amounts excludes superannuation. The options vest and expire in the following manner:

- 438,599 options vested on 1 November 2018, will expire on 1 November 2023 and have an exercise price of \$0.801:
- 384,256 options vested on 1 November 2019, will expire on 1 November 2024 and have an exercise price of \$0.801:
- 110,410 options vested on 4 July 2020, will expire on 4 July 2025 and have an exercise price of \$1.00;
- 345,184 options vested on 1 November 2020, will expire on 1 November 2025 and have an exercise price of \$0.801;
- 260,722 options will vest on 4 July 2021, expiring on 4 July 2025 with an exercise price of \$1.00; and
- 338,781 options will vest on 4 July 2022, expiring on 4 July 2025 with an exercise price of \$1.00.

If there is any reconstruction of the issued share capital of QBiotics, the Director must be put in the same position as if no reconstruction had occurred.

In addition to the abovementioned options Neville Mitchell was awarded:

 222,371 options in recognition of his commitment to the Company and the fundraising assistance provided to the Chairman in 2019. These options vested on 17 February 2020, expire on 16 February 2026 and are exercisable at a price of \$1.170 per option.

• 250,000 options in recognition of his support over an extended time frame to the ongoing capital raise activities of the Company. These options vested on 19 April 2021, expire on 30 March 2027 and are exercisable at a price of \$1.51 per option.

Neville Mitchell holds 2,350,323 options in total.

#### 10.5.4 Associate Professor Steven Ogbourne and Dr Susan Foden

Associate Professor Steven Ogbourne and Dr Susan Foden were each awarded 111,186 options in recognition of their commitment to the Company and the fundraising assistance provided to the Chairman. These options vested on 17 February 2020, expire on 16 February 2026 and are exercisable at a price of \$1.170 per option.

Similarly, in 2021 Associate Professor Steven Ogbourne and Dr Susan Foden were awarded 250,000 options each in recognition of their support over an extended time frame to the ongoing capital raise activities of the Company. These options vested on 19 April 2021, expire on 30 March 2027 and are exercisable at a price of \$1.51 per option.

Associate Professor Steven Ogbourne and Dr Susan Foden hold 361,186 options each.

#### 10.5.5 Nicholas Moore

Under the terms of Nicholas Moore's agreement for appointment as Director, the non-executive Director is awarded 482,334 options to acquire ordinary shares as payment for three years of his remuneration based on \$75,000 per annum plus superannuation. The options vest and expire in the following manner:

- 160,778 options vested on 1 February 2022, will expire on 30 March 2027 and have an exercise price of \$1.51;
- 160,778 options vested on 1 February 2023, will expire on 30 March 2027 and have an exercise price of \$1.51: and
- 160,778 options vested on 1 February 2024, will expire on 30 March 2027 and have an exercise price of \$1.51.

Similarly, in 2021 Nicholas Moore was awarded 250,000 options in recognition of the support over an extended time frame to the ongoing capital raise activities of the Company. These options vested on 19 April 2021, expire on 30 March 2027 and are exercisable at a price of \$1.51 per option.

Nicholas Moore holds 732,343 options in total.

#### 10.5.6 Hamish Corlett

Under the terms of Hamish Corlett's agreement for appointment as Director, the non-executive Director is awarded 482,334 options to acquire ordinary shares as payment for three years of his remuneration based on \$75,000 per annum plus superannuation. The options vest and expire in the following manner:

- 160,778 options vested on 9 April 2022, will expire on 21 April 2027 and have an exercise price of \$1.51;
- 160,778 options vested on 9 April 2023, will expire on 21 April 2027 and have an exercise price of \$1.51; and
- 160,778 options vested on 9 April 2024, will expire on 21 April 2027 and have an exercise price of \$1.51.

#### 10.6 Dividends

The policy of the Company will be to invest all cash flow into the business in order to maximise its growth. The ability of the Company to pay any dividend in the future is dependent on many factors including the outcome of the Company's commercialisation activities and clinical trials. Many of the factors that will affect the Company's ability to pay dividends and the timing of those dividends will be outside the control of the Company and its Directors. The Directors cannot give any assurance regarding the payment of dividends in the future.

# **Additional Information**

## 10.7 Summary of material contracts

The Directors consider that the material contracts summarised below and elsewhere in this Prospectus are the contracts which an investor would reasonably regard as material and which investors and their professional advisers would reasonably expect to find described in this Prospectus for the purpose of making an informed assessment of the Offer.

#### 10.7.1 Key employment contracts

Dr Victoria Gordon and Dr Paul Reddell entered into renewed employment contracts with the Company on 14 August 2018 and 11 June 2018 respectively. Dr Gordon is the Managing Director and performs the role of Chief Executive Officer and Dr Reddell is also an Executive Director and performs the role of Chief Scientific Officer. Dr Gordon's and Dr Reddell's remuneration details are set out in sections 5.2 and 5.4.

Dr Gordon and Dr Reddell are both employed on an ongoing basis. However, the employment of Dr Gordon and Dr Reddell can be terminated by either party giving three months' notice in writing to the other party. The Company can terminate the employment contracts immediately for serious breaches of the terms of the agreements and for serious misconduct. On termination, the directors must resign from all official positions (e.g. director or officer) held in any group company.

Both agreements contain intellectual property clauses and confidentiality clauses that are robust and survive termination of the agreements. Both agreements also contain restraint clauses prohibiting Dr Gordon and Dr Reddell from performing any role in which she or he may use or be required to use any confidential information of the Group, from using any confidential information of the Group, or from infringing any intellectual property rights of the Company.

#### 10.7.2 Distribution Agreements

Virbac has been appointed as the exclusive distributor of the finished product 'tigilanol tiglate' injectable in the area of animal health developed for the treatment of non-metastatic subcutaneous mast cell tumours located at or distal to the elbow or the hock and non-metastatic cutaneous mast cell tumours in dogs. In line with marketing authorisations, the initial territories in which the product is being distributed is the United Kingdom and various countries in the EU and the next territory for distribution will be the USA. QBiotics has granted rights to Virbac for Australia (subject to obtaining marketing authorisation) and may decide to extend Virbac distribution rights to other countries and territories.

Virbac is contracted through a master supply, marketing and distribution agreement and individual memoranda entered into from time to time which grant rights on certain terms in respect of certain countries, on the terms and conditions of the memoranda and the master agreement.

#### **Term**

There are currently two memorandums in force, one granting rights to the EU and North American territories and the other in relation to Australia (which is subject to obtaining marketing authorisation). The agreement commenced on 7 August 2018 and continues until the termination of the last memorandum in force. The initial term of the EU / North America Memorandum ends no later than 31 December 2025. The agreement will automatically renew for a further term of 5 years should Virbac meet the agreed annual minimum quantities of the product in the EU / North America Memorandum. The agreement will then continue to be automatically renewed for 3 year periods (unless terminated by either party). The term of the Australian memorandum is consistent with that of EU/ North America Memorandum.

#### **Product launch and minimum purchases**

The product was registered in Europe on 15 January 2020 and formally launched in April 2020. The product was registered in the USA on 17 November 2020 and formally launched in March 2021. After issuance of a marketing authorisation Virbac will provide QBiotics with firm purchase orders for the product and QBiotics will deliver the stock to Virbac for the purposes of the launch. Virbac must then launch the product within 4 months after receipt of unlabelled products and otherwise within 2 months, unless otherwise agreed or due to the

unavailability of stock. The agreement provides a mechanism for agreed annual minimum quantities of the product.

#### First option to new products

Virbac has been granted a first option to negotiate with QBiotics, for a period of 3 months unless extended by mutual agreement in writing, if a new product becomes available during the term of the agreement.

#### Revenue

In Europe Virbac will pay QBiotics a fixed price per vial of 'tigilanol tiglate', which will increase by a fixed percentage each year until 31 December 2024. In North America Virbac will also pay QBiotics a fixed price per vial which will be subject to the same price increases. Subject to marketing authorisation, vials supplied for sale in Australia will be acquired by Virbac unlabelled and at a discounted fixed price (as with those supplied to Europe). In relation to Europe and the USA, Virbac is also obliged to make deferred yearly payments beginning in year 2020 for each region in which tigilanol tiglate is made available. A similar deferred payment arrangement will apply to Australian sales. The parties will negotiate any price increases in accordance with the agreement. In addition, Virbac will pay QBiotics certain lump sum amounts on the occurrence of certain agreed events or at agreed dates.

Virbac will fund the majority of expenses devoted to marketing and launching the drug in the relevant countries, on training and educating veterinary general practitioners and veterinary oncology specialists to use the drug, and distribution and sales efforts. QBiotics will fund the process to secure and maintain regulatory approval in the relevant countries, to develop global product branding, and education and training of Virbac staff in the use and sales of the drug.

#### **Termination rights**

The agreement contains a number of termination rights including:

- Termination of the agreement by either party (including all memoranda) on written notice for unremedied breach, insolvency or unlawfulness.
- Partial termination by either party of the agreement in specific regions/countries (subject to appeal
  avenues and extensions granted by the joint steering committee) if a marketing authorisation has not
  been issued for that specific region/country within certain timelines.
- Termination by Virbac for a specific country/region in case of infringement of third party rights (as
  determined by a Court after all appeal rights have been exhausted) and Virbac is prevented from
  exercising its rights to distribute.
- QBiotics may also terminate an individual memorandum for a specific country/region, with 90 days'
  prior written notice for a certain number of reasons such as non-payment by Virbac under the
  agreement, failure by Virbac to meet agreed minimum objectives despite mutually agreed improvement
  plans, or in the event the summary of product characteristics granted for a product in the territory is
  agreed between the parties to be significantly limited so as to render the business case for the launch
  of the product not viable.

#### **Indemnity and consequential loss**

Each party indemnifies the other against any claims arising directly or indirectly from, a breach of any representation or warranty by the party under the agreement, a product recall in accordance with the agreement, negligent or wilful misconduct of the party in performing its obligations under the agreement or infringement by a party's intellectual property rights. QBiotics further indemnifies in relation to the manufacture, testing, handling or storage of the product by or on behalf of QBiotics and Virbac indemnifies in relation to product handling, obligations in relation to labelling of the product and acts or omissions of its sub-distributors and/or affiliates. All indemnities are reduced to the extent a claim arises from the act or omission of another party. Liability for consequential loss is excluded for both parties unless the liability relates to product recalls, intellectual property infringement or confidentiality.

#### Confidentiality

Confidentiality provisions apply and survive termination or expiration of the agreement.

# Additional Information

#### 10.7.3 Research and Development Contracts

#### Manufacturing Contracts with IDT Australia Limited for the manufacture of tigilanol tiglate

IDT Australia Limited (IDT) perform GMP drug substance manufacture for the Company. The service performed by IDT is currently essential for the manufacture of the drug substance for tigilanol tiglate. QBiotics provides IDT with raw material and IDT produces the drug substance under GMP. This drug substance is necessary for the development of the drug product (drug substance in carrier) and to supply commercial product. IDT is engaged by the Company for the ongoing commercial manufacture of the drug substance. The parties enter into an individual project agreement for each order made by the Company.

The most recent project commenced on 1 June 2020. If QBiotics cancels the project after work has commenced, QBiotics must pay a termination payment equal to the fees for any work that has already been completed, any work that cannot be cancelled, and a cancellation fee equal to 15% of the remainder of any uncompleted work.

QBiotics indemnifies IDT against all loss and claims arising out of services provided by IDT, other than for usual carve outs such as negligence or breach of agreement by IDT.

# AAIPharma Services Corp (now called Alcami) general terms and conditions for pharmaceutical development services and pharmaceutical quality agreement

Alcami is the GMP drug product manufacturer for QBiotics. The service performed by Alcami is currently essential for the manufacturing of the drug product for tigilanol tiglate. Alcami is contracted by way of a Master Services Agreement (MSA) and individual work orders to manufacture the drug product for regulatory validation and for ongoing commercial manufacture.

The agreement commenced on 11 May 2018 and continues for an initial term ending on 10 May 2023. The agreement automatically renews thereafter for consecutive two year periods unless terminated by giving 12 months' written notice.

The agreement may be terminated for convenience at any time by either party upon giving 12 months' written notice, whereas a work order may be terminated in whole or in part upon giving 60 days' written notice. Either party may immediately terminate the agreement for an unremedied or irremediable breach, for inability to perform obligations under the agreement for 120 calendar days by reason of force majeure, for a party suffering an insolvency event or ceasing to carry on business or in the event that there is a clinical failure or complete market withdrawal of a product or an individual product is found to infringe a third party's intellectual property.

QBiotics indemnifies and releases Alcami from any product liability or third party claims arising from the provision of services.

Under the MSA, QBiotics owns all intellectual property rights developed through the performance of the services to the extent that such rights are directly and solely related to QBiotics' products. All other intellectual property rights developed are owned by Alcami.

QBiotics and Alcami have also agreed not to disclose any confidential information without the other party's prior written consent. Under the master services agreement, the confidentiality obligations survive termination or expiration of the agreement for a period of ten years.

The MSA and the work orders are governed by the laws of Delaware.

The parties have also entered into a Manufacturing Drug Product Pharmaceutical Quality Agreement for a period of 3 years, commencing on 11 October 2019. The contract allocates the responsibilities of each party with respect to quality assurance and is reviewed by both parties every 3 years.

#### **Master Services Agreement with Avance Clinical**

Avance Clinical is a contract research organisation providing clinical research services, including but not limited to running medical studies of the Company's drug. The Company entered into a Master Services Agreement with Avance Clinical on 9 December 2020 which will continue for five years ending 8 December 2025. The agreement will also automatically renew for further periods of 1 year unless one of the parties terminate with 3 months prior notice.

As a part of the arrangement, the Company issues work orders to Avance Clinical from time to time which are governed by the Master Services Agreement. While either party can terminate for a breach that is not or cannot be remedied, there is no right to terminate for convenience. Avance Clinical indemnifies the Company for all losses, except to the extent that loss arose from the Company's breach, negligence, recklessness or wilful misconduct.

#### **Clinical Collaboration MSD International GmBH**

QBiotics and MSD International GmBH (MSD) have agreed to collaborate in a human clinical trial where QBiotics' tigilanol tiglate and MSD's compound will be dosed in combination to treat certain types of tumours.

The collaboration arrangement was signed on 4 August 2020 and will continue until the delivery of the final study report. The collaboration may end prior to the final study report if:

- Either party believes in good faith that the study has unreasonably affected participant's safety;
- Either party materially breaches the clinical trial collaboration and supply agreement; or
- Either party receives information that a regulatory authority has taken action against the compounds being supplied by each party.

MSD may terminate the collaboration if it believes in good faith that its compound is being used in an unsafe manner.

Clinical data generated by the study will be jointly owned by QBiotics and MSD. Prior to the publication of the clinical data, neither party may disclose this information without the consent of the other party and use of the unpublished clinical data is restricted.

Under the arrangement, QBiotics will indemnify MSD against any loss arising from an investigation by a third party into the study, except to the extent such liability arose from MSD's misconduct or breach.

#### **EMR Associates Pty Ltd**

EMR Associates Pty Ltd (EMR) provide project support for the implementation of the human clinical trial in Australia which is necessary to obtain regulatory approval for tigilanol tiglate as an anticancer treatment. EMR provide services such as project management, liaising with ethics committees, hospital sites and investigators.

The agreement is for a three year term. It commenced on 23 December 2015, was renewed in 2019 and ends on 23 December 2023.

Subject to completion of any uncompleted work orders, the agreement may be terminated by either party as follows:

- For convenience on the giving of 20 business days written notice; or
- In the event of insolvency of the other party, or unremedied or irremediable breach upon giving written notice.

Both parties indemnify each other against all loss and claims attributable to any negligent or wilful act or omission or breach of the agreement by that party.

QBiotics owns all information created by EMR or on its behalf in performing the services under the agreement. Any intellectual property rights in that information will be assigned to QBiotics.

The parties have also signed a confidentiality agreement.

#### Master Services Agreement with Indena S.p.A

QBiotics has engaged Indena S.p.A (Indena) to perform a variety of drug testing and drug manufacture. Indena provides its services under work orders which may be issued by QBiotics from time to time.

The Master Services Agreement between the parties was renewed on 24 March 2020 and will end on 25 June 2021 unless the parties mutually agree to extend the term at least 20 Business Days prior to expiry. The Company intends to, and also believes Indena is likely to, agree to renew this arrangement on identical or substantially the same terms. Should the parties fail to agree the extension or enter into new contracts QBiotics will undertake to engage a similar provider and negotiate terms similar to those in the agreement with Indena.

# Additional Information

Furthermore, either party may terminate the agreement for convenience by giving the other party 20 business days' written notice. However any ongoing work orders survive termination and must be completed.

QBiotics will own all intellectual property rights in any data results, material information or significant improvements to QBiotics' products generated by Indena.

#### **Access Agreement with private land owners**

QBiotics has Access Agreements with the owners of certain private land at which native stands of Fontainea are found. For confidentiality reasons, the details of the land owners has not been disclosed in this Prospectus.

The Access Agreement provides QBiotics with access to the private land to undertake a number of activities including collecting leaf and stem material for genetics research and clonal research, conducting studies to determine the key pollinators of Fontainea, bulk collecting Fontainea fruit and general research and development activities conducted in connection with Fontainea and Fontainea fruit. As consideration, QBiotics will pay a fee to access the private land plus a fee per kilogram of bulk collection of Fontainea fruit.

These agreements are usually for a 5 year period but may be terminated for convenience at any time by either party upon giving 30 days' written notice. These agreements will terminate automatically if the land owner ceases to own the land or, in respect of an individual lot, when it ceases to own that lot. No agreements are expiring in the next 12 months.

QBiotics owns all intellectual property rights in any material created by or on behalf of QBiotics arising out of its activities at the private land and activities undertaken on or in connection with the Fontainea fruit collected from or on the private land. Furthermore, the Fontainea fruit collected from the private land belongs to, and is the property of, QBiotics.

# Contract and Research Collaboration Agreement with the Council of the Queensland Institute of Medical Research

The Council of the Queensland Institute of Medical Research (QIMR Berghofer) is contracted to provide QBiotics with research services in relation to the development of tigilanol tiglate and related compounds. In consideration, QBiotics has agreed to pay QIMR Berghofer \$1,079,325 per year in agreed instalments with a 2.5% increase in the second year to address inflation.

The contract commenced on 25 February 2020 and continues until 10 February 2022. The Company intends to, and also believes QIMR Berghofer is likely to, agree to renew this arrangement on identical or substantially the same terms.

QBiotics and QIMR Berghofer have also entered into a Research Services Agreement commencing 1 November 2020 under which QIMR Berghofer has agreed to provide scientific support to QBiotics as it develops potential neuroprotection compounds towards commercial evaluation and clinical translation. The agreement continues for a period of 18 months and will expire in May 2022. The Company intends to and also believes QIMR Berghofer is likely to, agree to renew this arrangement on identical or substantially the same terms. Should the parties fail to agree the extension or enter into new contracts QBiotics will undertake to engage a similar provider and negotiate terms similar to those in the agreement with QIMR Berghofer. A total of \$824,989 is payable by QBiotics over the 18 month period.

Both agreements may be terminated immediately for an unremedied breach. QIMR Berghofer may also terminate the agreement if due to matters beyond its control it becomes impossible or impractical to provide the services.

Under the first research services agreement QBiotics indemnifies QIMR Berghofer for claims in respect of any loss arising out of use of its intellectual property. Under the second research services Agreement QBiotics indemnifies QIMR Berghofer for loss arising from death, injury, illness or damage, except to the extent that loss arise from QIMR Berghofer's breach, negligence or infringement of intellectual property.

QBiotics owns all intellectual property created in connection with QBiotics' technology and reports created by QIMR Berghofer in performing the services. QIMR Berghofer owns any other intellectual property created in the conduct of the research services.

#### Master Services Agreement with Southern Star Research Pty Ltd

Southern Star Research Pty Ltd (Southern Star) provides contract clinical research services on clinical projects. QBiotics engaged Southern Star on 14 April 2019 to provide these services under a Master Services Agreement which will continue until the later of 13 April 2024 or the last date it takes to complete a work order issued before 13 April 2024. The arrangement can also be extended with the mutual agreement of the parties.

Either party can terminate the Master Services Agreement with 60 days' written notice. QBiotics also indemnifies Southern Star for all loss and claims attributable to QBiotics' neglect, wilful act or omission or breach of the master services agreement, as per the terms outlined in the Master Service Agreement.

#### Master Services Agreement with the University of the Sunshine Coast

The University of the Sunshine Coast (USC) provides anti-bacterial screening services to QBiotics. USC is contracted through a MSA and individual work orders.

The Company has been working with USC since 23 November 2015. USC has been working with the broader group since its first research agreement with EcoBiotics Pty Ltd since 7 December 2010.

The term of the latest agreement commenced on 1 July 2020 and continues until 30 June 2025, and subject to any further extension agreed by the parties in writing. No specific conditions for renewal apply other than 20 business days notice prior to end of term.

Subject to completion of any uncompleted work orders, the agreement may be terminated by either party for convenience by giving 20 business days written notice or immediately upon an insolvency event. The agreement may also be terminated for an unremedied breach. The agreement contains a publication regime. If any students of USC are participating on a project, which is the subject of a terminated work order, QBiotics is also required to pay to USC an amount each calendar month, from the time of termination, in relation to each student, until the time the project would have been completed in the normal course of events, being that amount which was agreed to by the parties.

USC indemnifies QBiotics against all loss and claims relating to a negligent or wilful act or omission or breach of the agreement by USC, other than usual carve outs such as for QBiotics' negligence or breach of law.

QBiotics and USC have also agreed not to disclose any confidential information without the other party's prior written consent. These confidentiality obligations continue indefinitely and are not diminished or terminated by completion or termination of the agreement.

QBiotics owns all intellectual property rights created by USC for QBiotics, arising out of any Work Order. USC receives a licence to use the materials supplied by QBiotics to USC for the purposes of performing the services under the agreement.

QBiotics is also a party to a placement agreement and consultancy agreement with USC. The placement agreement governs the placement of a USC research fellow at QBiotics. It expired on 31 August 2020, however the parties intend to renew the arrangement on substantially the same terms. These terms include the right to terminate for breach, insolvency or unfit performance by the research fellow and that there would be no right to terminate for convenience. Any intellectual property created by the research fellow will be owned by QBiotics.

The consultancy agreement was entered into on 1 January 2020 and will continue for 3 years, ending 31 December 2023. As a part of the arrangement, Dr Ogbourne is engaged to give advice, review documents and assess the appropriateness of commercialising pharmaceutical agents at his hourly or daily rate. QBiotics can terminate this engagement for convenience with 21 days written notice or suspend the engagement. Any intellectual property created by Dr Ogbourne in his capacity as consultant will be owned by QBiotics.

## 10.8 Related party transactions

There are no existing agreements or arrangements and there are no currently proposed transactions, in which the Company was, or is, to be a participant, and in which any related party had or will have a direct or indirect material interest, other than the compensation arrangements with Directors and executive officers, which are described Section 5 of this Prospectus, and the following agreements.

## Additional Information

The Company policy in respect of related party arrangements is that a Director with a material personal interest in a matter that relates to the affairs of the Company is required to give notice to the other Directors. A Director who has a material personal interest in a matter that is being considered at a Board meeting must not be present while the matter is being considered at the meeting or vote on the matter, unless permitted to do so by the Corporations Act.

#### 10.8.1 Lease of premises owned by Drs Reddell and Gordon

The Company leases premises from Drs Reddell and Gordon. The current lease term is for a period of three years from 1 July 2019 to 30 June 2022. The rent is \$37,080 per annum, payable in advance and in equal monthly instalments on the first of each month.

These premises are particularly useful to QBiotics in terms of the facilities and they incorporate optimal flexibility for QBiotics in terms of their duration and the cost to QBiotics of renting them is immaterial. Accordingly, it is reasonable in the circumstances for QBiotics and Drs Reddell and Gordon to be considered to be dealing at arm's length in relation to these arrangements. As such, shareholder approval for these arrangements was not considered necessary nor sought.

#### 10.8.2 Lease of land and service agreement with Banyan View Farm

The Company leases land from Banyan View Farm, an entity related to Dr Ogbourne. The initial lease term was for a period of three years beginning 1 July 2017 and the three year option to renew was exercised in 2020. Accordingly, the current lease term is for a period of three years from 1 July 2020 to 30 June 2023. The rent is \$750 per month, payable monthly and in advance. The lease can be renewed for two additional terms of three years. The rental is adjusted on an annual basis by reference to the consumer price index.

The Company, entered into a service agreement with Banyan View Farm. Under the terms of the agreement, Banyan View Farm will carry out certain services for the Company.

The fees payable under the agreement with Banyan View Farm are calculated based on hourly rates, supplies and incidentals incurred as set out in the agreement.

Banyan View Farm has been paid \$29,000 for the lease of land and service agreement for the period from 1 July 2017 to the date of this Prospectus.

The services agreement may be terminated by either party giving 60 days written notice.

These premises are particularly useful to QBiotics in terms of the facilities and environment for the project they provide, they incorporate optimal flexibility for QBiotics in terms of their duration and the cost to QBiotics of renting them is immaterial. Accordingly, it is reasonable in the circumstances for QBiotics and Dr Ogbourne to be considered to be dealing at arm's length in relation to these arrangements. As such, shareholder approval for these arrangements was not considered necessary nor sought.

### 10.9 Interests of directors

Other than as set out below or elsewhere in the Prospectus, no Director has had, within 2 years before lodgement of this Prospectus with ASIC, any interest in:

- the formation or promotion of the Company;
- property acquired or proposed to be acquired by the Company in connection with its formation or promotion; or
- any property acquired or proposed to be acquired by the Company in connection with the Offer of the Shares under this Prospectus.

Other than as set out in this Prospectus, no benefits or amounts have been paid or agreed to be paid, nor has any benefit been given or agreed to be paid to any Director, to induce them to become or qualify as a Director or for services rendered by the Director in connection with the promotion or formation of the Company or the Offer of Shares under this Prospectus.

## 10.10 Litigation and claims

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

#### 10.11 Tax

#### 10.11.1 General overview

Investors should seek and rely on their own professional taxation advice in relation to any investment in the Company as the tax consequences for any investor will depend on the investor's particular circumstances.

The comments below provide a general overview of the Australian tax implications for Australian tax resident investors who acquire Shares under this Prospectus and hold their Shares on capital account for Australian income tax purposes. This summary is general in nature and is not intended to be an authoritative or complete statement of the applicable law and should not be relied upon by investors.

These comments do not apply to other types of investors, including those that:

- hold their Shares on revenue account or as trading stock (for example investors that carry on a business of trading in Shares), or
- investors that are resident of any jurisdiction other than Australia, or
- entities that may be subject to special tax rules, including banks, insurance companies, tax exempt entities, superannuation funds, temporary residents, or
- investors who are subject to the Taxation of Financial Arrangements (TOFA) rules governed by Division 230 of the Income Tax Assessment Act 1997.

The summary does not take into account the tax laws of countries other than Australia.

The comments below are based on the laws as at the date of this Prospectus including the Income Tax Assessment Act 1997 (Cth), Income Tax Assessment Act 1936 (Cth), the A New Tax System (Goods and Services Tax) Act 1999 (Cth), relevant stamp duty legislation, applicable case law and published Australian Taxation Office and State / Territory Revenue Authority rulings, determinations and statements of administrative practice. The tax implications discussed below do not take into account any change to the tax law after the date of this Prospectus.

The Company and its advisers disclaim all liability to any investor or other party for all costs, loss, damage and liability that the investor or other party may suffer or incur arising from, relating to or in any way connected with the contents of this summary or the provision of this summary to the investor or other party or the reliance on this summary by the investor or other party.

#### 10.11.2 Dividends Received by Australian tax resident Investors

Dividends distributed by the Company to Australian tax resident investors are required to be included in the assessable income of those investors in the year of receipt. Australian tax resident investors are also required to include in their assessable income any franking credits attached to dividends received.

Where a franking credit is included in the investor's assessable income, the investor will generally be entitled to a corresponding tax offset equal to the franking credits attached. To be eligible for the franking credit tax offset, an investor must satisfy the "holding period" rule. This rule requires that an investor holds the Shares "at risk" for a continuous period of not less than 45 days (excluding the days of acquisition and disposal). The holding period rules will not apply to an investor who is an individual whose total franking credits offset entitlements for an income year does not exceed \$5,000.

Investors must also satisfy the "related payments" rule to be eligible for the franking credit tax offset which broadly will be satisfied where the investor continues to hold the shares and is not required to pass on the benefit of the dividend to other persons.

## Additional Information

The franking credit tax offset can be applied to reduce any tax payable by the investor and:

- individuals and complying superannuation funds are entitled to a refund of tax to the extent that the franking credit tax offset exceeds the investor's income tax liability for the income year ("excess franking credits").
- companies will generally have no additional tax to pay when receiving fully franked dividends provided both companies have the same tax and franking rates. Companies may be able to be convert any excess franking credits to a carry forward tax loss (as companies are not entitled to a refund of excess franking credits).

Franked dividends received by corporate investors will generally give rise to a franking credit in the corporate investor's franking account (subject to the corporate investor satisfying the rules outlined above for claiming a franking credit tax offset).

Special rules apply to investors that are trustees (other than trustees of complying superannuation entities) or partnerships. The income tax treatment of dividends and franking credits in the hands of trust beneficiaries or partners will be dependent upon the tax status of those beneficiaries and partners.

Investors should seek their own advice regarding the tax implications of dividends received in respect of their Shares held.

#### 10.11.3 Disposal of Shares by Australian tax resident Investors

The disposal of a Share by an investor will trigger a capital gains tax (CGT) event where the investor holds their Share on capital account. Australian tax resident investors will:

- make a capital gain where the capital proceeds received on the disposal of the Share exceeds the cost base of the Share, or
- make a capital loss where the capital proceeds received on the disposal of the Share are less than the reduced cost base of the Share.

The capital proceeds will generally be equal to the amount received for the disposal of the Share.

Broadly, the cost base and reduced cost base (subject to modifications) of a Share will be equal to the Issue Price of the Share plus any incidental costs of acquisition and disposal (such as brokerage).

If an investor is an individual or complying superannuation entity and has held the Share for at least 12 months before disposal of the Share, the investor will generally be entitled to a "CGT discount" for any capital gain made on the disposal of the Share. Where the CGT discount applies, any capital gain arising (after applying any available capital losses) may be reduced by:

- 50% in the case of individuals, or
- by one-third in the case of complying superannuation entities.

Corporate investors (investors that are companies) are not entitled to a CGT discount.

Where the investor is a trustee of a trust that has held the Share for at least 12 months before disposal, the CGT discount may flow through to the beneficiaries of that trust if those beneficiaries are not companies. Investors that are trustees should seek specific advice regarding the circumstances in which beneficiaries may be eligible to utilise the CGT discount.

Prior to applying the CGT discount, investors may reduce any capital gains by any available capital losses (current year capital losses and carried forward capital losses). Any resulting net capital gain (after also applying the CGT discount) is included in an investor's assessable income.

Where the disposal results in a net capital loss and the investor has no remaining capital gains to offset, the capital loss is carried forward and may be available to be offset against capital gains in future years (subject to the satisfaction of any applicable loss recoupment rules). Capital losses cannot be used to reduce the investor's ordinary assessable income (only capital gains).

#### 10.11.4 Tax file number (TFN) Withholding Tax

Resident investors may, if they choose, notify the Company of their TFN, ABN or a relevant exemption from withholding tax with respect to dividends. In the event the Company is not so notified, tax will automatically be deducted at the highest marginal rate, in addition to where relevant, the Medicare levy from dividends. Resident investors may be able to claim a tax credit in respect of any tax withheld on dividends in their tax returns.

An investor is not required to quote their TFN to the Company. An investor who holds Shares as part of an enterprise may quote its ABN instead of its TFN.

#### 10.11.5 Goods and services tax

The acquisition, redemption or disposal of the Shares by an Australian resident (registered for GST) will be an input taxed financial supply, and therefore is not subject to GST. No GST should be payable in respect of dividends paid to investors. An Australian resident investor (registered for GST) may not be entitled to claim full input tax credits in respect of GST on expenses incurred relating to the acquisition, redemption or disposal of the Shares (e.g. lawyers' and accountants' fees).

Investors should seek their own tax advice on the impact of GST in their own particular circumstances.

### 10.11.6 Stamp duty

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

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

#### 10.12 Consents

Each of the parties named in the table below has consented to being named in this Prospectus in the form and context in which it is named and has not withdrawn such consent prior to the lodgement of this Prospectus with the ASIC:

Capacity in relation to the Company	Consenting party
Australian legal adviser	Thomson Geer
Investigating Accountant	Grant Thornton Corporate Finance Pty Ltd
Patent Attorney	Griffith Hack
Share registry	Link Market Services Limited
Auditor	Grant Thornton Audit Pty Ltd

To the maximum extent permitted by law, each of the parties named above:

- states that it has not authorised or caused the issue of this Prospectus;
- is not taken to have made, or purported to have made, any representation or warranty in relation to the Company either express or implied or any statement in this Prospectus or on which a statement made in the Prospectus is based other than as specified in this Section; and
- expressly disclaims and takes no responsibility for any part of this Prospectus other than as referred to in this Prospectus as having been made by such party.

## **Additional Information**

### 10.13 Interests of experts and advisers

Other than as set out below or elsewhere in this Prospectus, no person named in this Prospectus as providing professional or advisory services in connection with the preparation of this Prospectus or any firm in which any such person is a partner has or had at any time during the two years before lodgement of this Prospectus with ASIC, any interest in:

- The formation or promotion of the Company;
- Property acquired or proposed to be acquired by the Company in connection with its formation or promotion; or
- Any property acquired or proposed to be acquired by the Company in connection with the Offer of the Shares under this Prospectus.

Other than as set out in this Prospectus, no amounts or benefits have been paid or agreed to be paid for services rendered by the person performing a function in a professional, advisory or other capacity with the preparation or distribution of this Prospectus.

It is estimated that the Company will pay the following costs in connection with the preparation and issue of this Prospectus and the making of the Offer (exclusive of GST):

**Table 10.2: Cash Offer Costs** 

Service \$'000	Gross proceeds of \$5 million	Gross proceeds of \$10 million	Gross proceeds of \$12.5 million
Thomson Geer - Legal fees	40	40	40
Grant Thornton Corporate Finance Pty Ltd -			
Investigating Accountant's fees	20	20	20
ASIC fees	3	3	3
Printing and other incremental costs directly related			
to the Offer	40	40	40
Total cash Offer costs	103	103	103

These amounts, and the expenses of the Offer, will be paid by the Company out of funds raised under the Offer or available cash. Further information on the use of proceeds and payment of expenses of the Offer is set out in Section 8.3

## 10.14 Inspection of documents

Copies of the following documents will be available for inspection free of charge at the registered office of the Company for at least 13 months after lodgement of this Prospectus:

- the written consents to the issue of this Prospectus; and
- the Constitution of the Company.

## 10.15 Working capital statement

The Directors believe that, on completion of the Offer, the Company will have sufficient working capital to carry out its objectives as stated in the Prospectus.

## 10.16 Supplementary information

A supplementary prospectus will be issued if the Company becomes aware of any of the following between the issue of this Prospectus and the date the Shares are quoted:

- a material statement in this Prospectus is misleading or deceptive;
- there is a material omission from this Prospectus;

- there has been a significant change affecting a matter included in this Prospectus; or
- a significant new circumstance has arisen and it would have been required to be included in this Prospectus.

### 10.17 Brokerage

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

## 10.18 Governing law

This Prospectus and the contracts that arise from the acceptance of Applications are governed by the law applicable in Queensland, Australia and each Applicant submits to the exclusive jurisdiction of the courts of Queensland, Australia.

### 10.19 Statement of Directors

The Directors report that after due enquiries by them, in their opinion since the date of the reviewed financial statements in Section 7, there have not been any circumstances that have arisen or that have materially affected or will materially affect the assets and liabilities, the financial position, profits or losses or prospects of the Company, other than as disclosed in this Prospectus.

This Prospectus is authorised by each Director of the Company who has consented to its lodgement with ASIC and its issue, and has not withdrawn that consent.



11

Glossary and Technical Terms

## Glossary and Technical Terms

In this Prospectus, the following terms and abbreviations have the following meanings, unless the context otherwise requires:

## 11.1 Glossary

Term	Description
\$	Australian dollars.
AEST	Australian Eastern Standard Time.
Applicant	A person who submits a valid Application Form pursuant to this Prospectus.
Application	A valid application to subscribe for Shares under the Offer pursuant to this Prospectus.
Application Form	The personalised Application Form attached to or accompanying this Prospectus.
Application Monies	Money submitted by Applicants in respect of their Applications.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
ASIC	Australian Securities and Investments Commission.
ASX	ASX Limited (ABN 98 008 624 691) or the securities market it operates, as the context requires.
Board	The board of directors of the Company.
Closing Date	The date that the Offer closes, being 21 June 2021.
Company or QBiotics	QBiotics Group Limited ACN 617 596 139.
Constitution	The constitution of the Company.
Corporations Act	The Corporations Act 2001 (Cth).
Corporations Regulations	The Corporations Regulations 2001 (Cth).
Directors	The directors of the Company.
EBIT	Earnings before interest and tax.
EBITDA	Earnings before interest, tax, depreciation and amortisation
EMA	European Medicines Agency.
Existing Shareholders	Holders of Shares as at 5:00pm on the Prospectus Date.
Existing Shares	The issued Shares immediately prior to the allotment of Shares under the Offer.
Exposure Period	The exposure period for this Prospectus commencing on the Prospectus Date and ending seven days after lodgement, subject to any extension of the period by ASIC.
FDA	Food and Drug Administration of the United States of America.
FDA-CVM	Food and Drug Administration of the United States of America Centre for Veterinary Medicine.
GST	Goods and services tax.
Holding Statement	Document detailing the number of Shares held by the Applicant.
IND	Investigational New Drug.
IP	Intellectual property, or intellectual property rights, as the context requires.
Investigating Accountant	Grant Thornton Corporate Finance Pty Ltd.
Investigating Accountant's Report	The report of the Investigating Accountant contained in Section 7.
Maximum Subscription	The maximum subscription amount being sought by the Company under the Offer (before any Oversubscriptions), being \$10,000,000.
Minimum Subscription	The minimum subscription amount being sought by the Company under the Offer, being \$5,000,000.
Offer	The invitation to apply to subscribe for Shares pursuant to this Prospectus.
Offer Period	The period beginning on the Opening Date and ending on the Closing Date.
Offer Price	\$0.90 per Share.
Online Application Form	Application Forms obtained via the Offer Site at www.gbiotics.com/prospectus
Opening Date	The date that the Offer opens.

Term	Description
Option	An option to subscribe for Shares.
Oversubscription	The Company may (at its sole discretion) accept up to \$2,500,000 over the Maximum Subscription to raise up to \$12.5 million.
Privacy Act	Privacy Act 1988 (Cth).
Prospectus	This prospectus dated 17 May 2021 as modified or varied by any supplementary prospectus issued by the Company and lodged with the ASIC from time to time.
Prospectus Date	The date on which this Prospectus was lodged with ASIC, being 17 May 2021.
Share	A fully paid ordinary share in the capital of the Company.
Share Registry	Link Market Services Limited (ACN 083 214 537).
Shareholder	A holder of Shares.
Shareholding	A shareholding in the Company.
SRN	Security holder reference number.
TFN	Tax file number.
TGA	Therapeutics Goods Administration.
USA	United States of America.
VMD	Veterinary Medicines Directorate

## 11.2 Technical terms

Term	Description
API	Active Pharmaceutical Ingredient.
CMC	Chemistry Manufacturing and Controls - manufacturing research and development of a drug with the intent of meeting regulatory approval for eventual marketing.
Companion Animal	A dog, cat or horse.
DAMPS	Damage-associated molecular patterns are molecules within cells that are a component of the innate immune response released from damaged or dying cells due to trauma or an infection by a pathogen.
Drug Product	A manufactured product that contains a drug (API); there are many forms of drug products including tablets, capsules, solutions and creams; the EBC-46 intralesional drug product is a solution.
Drug Substance	Active Pharmaceutical Ingredient - the active compound or drug for example EBC-46.
EBC-1013	A chronic wound healing treatment in early animal clinical development.
EBC-46	The anticancer drug also known as tigilanol tiglate. EBC-46 is a novel small molecule short-chain diterpene ester from the tigliane class of compounds being developed as a local treatment for a range of solid tumours in humans and animals.
GMP	Good Manufacturing Practice - manufacturing guidelines for a human and veterinary product.
HNSCC	Head and neck cancer squamous cell carcinoma.
Human Clinical Phase I Trial	Testing of an experimental drug in healthy humans to determine safety parameters of the drug.
Human Clinical Phase I/II Trial	Testing of an experimental drug in patients with the target disease to assess the drug's safety and effectiveness.
Human Clinical Phase II Trial	Treating patients with the target disease to examine an experimental drug's effectiveness and determine optimum dosing regime. Human Clinical Phase II Trial may include Human Phase IIA (dosing confirmation) and IIB (efficacy)

# Glossary and Technical Terms

Term	Description
Human Clinical Phase III Trial	Treating patients with the target disease to confirm optimum dosing regime of a drug in development; this is the final efficacy study prior to application for registration.
MCT	Mast Cell Tumour – a tumour common in dogs accounting for 16% to 21% of cutaneous tumours.
Pivotal Field Efficacy Study	A veterinary study treating animal patients with the target disease to confirm optimum dosing regime of a drug in development; this study and a Target Animal Safety Study are the final studies undertaken prior to applying for registration of a veterinary pharmaceutical with the FDA-CVM in the USA.
Preclinical	Laboratory and animal studies to understand the safety and initial effectiveness of an experimental drug to treat the target disease, the drug's mechanism of action and exploration of methods to manufacture the drug.
R&D	Research and development - discovering new knowledge about products (for example molecules) and applying that knowledge to improve the products.
SCC	Squamous Cell Carcinoma - is a type of skin cancer that begins in the squamous cells. Squamous cells are the thin, flat cells that make up the epidermis, or the outermost layer of the skin.
STS	Soft Tissue Sarcomas - a type of cancer that begins in the soft tissues of your body.
Target Animal Safety Study	A veterinary study to examine the safety parameters of a drug in the target species; this study and a Field Efficacy Study are the final studies undertaken prior to applying for registration of a veterinary pharmaceutical with the FDA-CVM in the USA.
Tigilanol tiglate	The anticancer drug also known as EBC-46. Tigilanol tiglate is a novel small molecule short-chain diterpene ester from the tigliane class of compounds being developed as a local treatment for a range of solid tumours in humans and animals
VLU	Venus leg ulcer





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Application Forms

## Corporate Information

Company Headquarters Taringa Central Suite 3A, Level 1, 165 Moggill Road TARINGA QLD 4068 Tel: + 61 7 3870 8933

#### Legal Adviser

Thomson Geer Level 14, 60 Martin Place SYDNEY NSW 2000

### Patent Attorney

Griffith Hack Level 10, 161 Collins Street MELBOURNE VIC 3000

#### Auditor

Grant Thornton Audit Pty Ltd Level 18, 145 Ann Street BRISBANE QLD 4000

#### Share Registry

Link Market Services Limited 680 George Street SYDNEY NSW 2000

### **Investigating Accountant**

Grant Thornton Corporate Finance Pty Ltd Level 17, 383 Kent Street SYDNEY NSW 2000



