

# PROSPECTUS

Offering 14 million new Shares at \$0.50 per Share

in Anatara Lifesciences Limited ACN 145 239 872













#### IMPORTANT NOTICES

#### General

This Prospectus is dated 4 September 2014. A copy of this Prospectus was lodged with ASIC on that date. Neither ASIC nor ASX takes any responsibility for the contents of this Prospectus or the merits of the investment to which this Prospectus relates. No Shares will be allotted or transferred on the basis of this Prospectus after the expiry date. This Prospectus expires on 4 October 2015.

No person is authorised to give any information or make representations about the Offer, which is not contained in this Prospectus. Information or representations not contained in this Prospectus must not be relied on as authorised by the Company, or any other person, in connection with the Offer.

This Prospectus provides information for investors to decide if they wish to invest in Anatara. Read this document in its entirety. Examine the assumptions underlying the financial information and the risk factors that could affect the financial performance of Anatara. Consider these factors carefully in light of your personal financial circumstances. Seek professional advice from your stockbroker, accountant or other professional adviser before deciding whether to invest. The Offer does not take into account the investment objectives, financial situation or needs of particular investors. An investment in Anatara should be considered speculative.

#### Australian and New Zealand residents only

The Offer is available to Australian and New Zealand residents having a registered address in those jurisdictions. The distribution of this Prospectus in jurisdictions outside Australia or New Zealand may be restricted by law. Seek advice on and observe any restrictions. This Prospectus is not an Offer in any place where, or to any person to whom, it would not be lawful to make the Offer.

#### Special notice to New Zealand Resident investors

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 and Regulations (Australia). In New Zealand, this is Part 5 of the Securities Act 1978 and the Securities (Mutual Recognition of Securities Offerings-Australia) Regulations 2008.

This Offer and the content of the prospectus are principally governed by Australian rather than New Zealand law. In the main, the Corporations Act and Regulations (Australia) set out how the Offer must be made.

There are differences in how securities are regulated under Australian law. For example, the disclosure of fees for collective investment schemes is different under the Australian regime.

The rights, remedies, and compensation arrangements available to New Zealand investors in Australian securities may differ from the rights, remedies and compensation arrangements for New Zealand securities

Both the Australian and New Zealand securities 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, Wellington, New Zealand. The Australian and New Zealand regulators will work together to settle your complaint.

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

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 securities is not New Zealand dollars. The value of the securities 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 securities 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 securities are able to be traded on a securities market and you wish to trade the securities through that market, you will have to make arrangements for a participant in that market to sell the securities on your behalf. If the securities 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 securities and trading may differ from securities markets that operate in New Zealand.

#### Defined terms

Some terms used in this Prospectus are defined in the Glossary.

#### **Electronic prospectus**

This Prospectus is available electronically at http://anataralifesciences.com. The Application Form attached to the electronic version of this Prospectus must be used within Australia or New Zealand. Electronic versions of this Prospectus should be downloaded and read in their entirety. Obtain a paper copy of the Prospectus (free of charge) by telephoning 1300 850 505 (within Australia) or +61 3 9415 4000 (outside Australia). Applications for Shares may only be made on the Application Form attached to this Prospectus or in its paper copy form downloaded in its entirety from http://anataralifesciences.com.

#### **Exposure** period

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

#### Privacy

If you complete an Application Form you will be giving Anatara personal information. The Company and the share registry collect, hold and use that personal information to assess your application and to communicate and provide services to you as a Shareholder. The Company may disclose information to its agents, service providers (such as the share registry) and government bodies. The Company's privacy policy sets out how you may access, correct and update the personal information that we hold about you (by contacting the share registry), how you can complain about privacy related matters and how the Company responds to complaints.

#### Currency

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

#### Photographs and diagrams

Photographs used in this Prospectus without descriptions are only for illustration. The people shown are not endorsing this Prospectus or its contents. Diagrams used in this Prospectus may not be drawn to scale. The assets depicted in photographs in this Prospectus are not assets of the Company unless otherwise stated.

# Table of contents

Letter from the Chairman 6		
1	Investment overview	9
2	Business overview	17
3	Ownership, management and corporate governance	35
4	Financial information	53
5	Risk factors	63
6	Investigating accountant's report and financial services guide	73
7	Intellectual property report	79
8	Material agreements	93
9	Details of the offer	105
10	Additional information	111
11	Glossary	117
Application form		120
Corporate directory		

#### Letter from the Chairman

#### Dear Investor

On behalf of the Board, it is my pleasure to invite you to invest in Anatara Lifesciences Ltd (Anatara).

Anatara is developing Detach<sup>TM</sup>, a natural, plant-based product that prevents and treats diarrhoea in production animals. Detach<sup>TM</sup> has been proven to be safe and effective on commercial pig farms where, in addition to reducing the incidence of diarrhoea, it was shown to improve farming economics, animal health and meat yields, and reduce the use of antibiotics.

There is now an urgent need to reduce the use of antibiotics in humans and animals because of the emergence of antibiotic resistance in bacteria. Antimicrobial resistance is a serious worldwide problem for both humans and animals, and is an issue that governments around the world are grappling with. Up to an estimated 80%¹ of antibiotics used worldwide are not used to treat humans, but are instead added to animal feed to promote growth of farm animals and prevent diseases, such as diarrhoea.

What would appear a logical use of antibiotics has unfortunately led to a rise in superbugs – or antimicrobial resistance – where bacteria no longer respond to these life-saving drugs. Inadvertently, humans have created an expensive, debilitating and in some cases, life threatening health problem. A recent study in humans concluded that antimicrobial resistance causes 23,000 deaths in the USA each year<sup>2</sup>. Accordingly there is an urgent need to find new non-antibiotic solutions for the treatment of both humans and animals<sup>3</sup>.

Detach<sup>TM</sup> can potentially make a significant contribution to reducing reliance upon the use of antibiotics for the control of diarrhoea in farm animals. By preventing bacteria from attaching to the lining of the gut, Detach<sup>TM</sup> can both prevent and treat diarrhoeal disease. Its anti-secretory and anti-inflammatory properties deliver additional benefits – enabling animals to stay healthy and gain weight.

Detach™ is a new formulation of a previous product that was sold and marketed to pig producers in Australia in 1991 by Ciba-Geigy (now Novartis) and quickly established significant market uptake. Profitability for farmers who bought the product was driven by the increased weight and health status of their herds, and a reduction in antibiotic use. Detach was removed from the market due to corporate restructure activity, not because of efficacy or safety issues.

Subject to successful field trials and regulatory approval, Anatara plans to re-launch Detach™ in Australia in 2016, with the European and US markets targeted to follow in 2017. Anatara is initially targeting use in the pork industry, where diarrhoea is a major problem for the circa 1.6 billion piglets born worldwide every year, affecting piglet growth and often causing death. In order to expeditiously return the product to market:

<sup>2009</sup> Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, FDA, Dec. 9, 2010

US Centers for Disease Control and Prevention, 2013. Antibiotic Resistance Threats in the United States. http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

The World Health Organisation 'Antimicrobial resistance: global report on surveillance 2014' http://www.who.int/drugresistance/documents/surveillancereport/en/

- Anatara will undertake field trials of the new formulation of Detach™, to reprove its efficacy and safety. Successful trials and regulatory approval will establish Detach™ as a safe and effective alternative to antibiotics that will allow pig producers to maintain animal health and improve growth and profitability.
- Anatara has lodged a patent application for the new formulation of Detach™
  and is confident of its ability to scale up manufacturing for commercial supply to
  Australia and to the global market.

Given the prior history of the old formulation of Detach in the market place, along with successful field trials conducted in 2012, and a well mapped out regulatory plan, the Directors believe that Detach<sup>TM</sup> can be rapidly progressed to re-launch.

Anatara is delighted to have secured the support of the Pig Health and Research Unit at the Victorian Department of Environment and Primary Industries, who will work with the Company to get Detach<sup>TM</sup> ready for the Australian marketplace by 2016. Anatara is also in the process of establishing a potential strategic development partnership with Australia's Pork Cooperative Research Centre (CRC) to further support the development of Detach<sup>TM</sup>.

Funds raised under this Prospectus, in addition to existing funds, will provide Anatara with working capital to pursue the launch of Detach<sup>TM</sup> in Australia, the EU and the USA; and to further develop Detach<sup>TM</sup> for the treatment and prevention of diarrhoea in humans. Further details on the proposed use of funds are set out in section 9.3.

Under this Prospectus, Anatara is offering for subscription up to 14 million new Shares at \$0.50 each to raise up to \$7 million (before Offer costs). The Offer is fully underwritten by the Lead Manager and Underwriter, subject to the terms and conditions of the Underwriting Agreement contained in section 8.3.

This Prospectus contains more detailed information regarding Anatara's operations, financial position, management and future plans. It outlines Anatara's business model and key dependencies relevant to the business model. I encourage you to read and understand the Prospectus, and seek independent professional advice as necessary, before making an investment decision.

In particular, the risks of investing in an early stage company must be considered in full and the key risks for Anatara are set out in section 5. Any investment in Anatara should be considered speculative.

The Detach™ technology provides an important alternative to antibiotic use and we believe it has significant growth potential through expansion into other geographic markets in the pig industry and as a treatment in other production animals, such as calves and chickens. We therefore believe this is an exciting offer for investors and on behalf of the Board, it gives me great pleasure to present you with the opportunity to invest in Anatara Lifesciences Limited

Dr Mel Bridges

Chairman

Anatara Lifesciences Limited



Chapter 1

# Investment Overview

#### 1. Investment overview

#### Offer details

Offer Price per Share	\$0.50
Total number of Shares on issue before the Offer*	23,750,000
Total number of Shares offered under this Prospectus	14,000,000
Total number of Shares on issue following the Offer**	37,750,000
Amount to be raised under the Offer	\$7 million
Market capitalisation at the Offer Price	\$18,875,000

<sup>\*</sup> Subject to shareholder approval of a 1:5 subdivision of Shares at a general meeting of the Company scheduled for 11 September 2014.

### Important dates

Event	Date
Prospectus date	4 September 2014
Offer opens	18 September 2014
Offer closes	3 October 2014
Anticipated date of allotment	16 October 2014
Shareholding statements expected to be dispatched	20 October 2014
Anticipated commencement of ASX trading	21 October 2014

All dates and times are subject to change and are indicative only. All times are Australian Eastern Standard Time. The Company, with the consent of the Lead Manager and Underwriter, reserves the right to vary these dates and times without notice. The Company may close the Offer early, withdraw the Offer, or accept late applications.

<sup>\*\*</sup> The Company has implemented an ESOP with current capacity to issue up to 5% of the issued share capital of the Company as options. However, as at the date of this Prospectus, no options or other securities convertible to shares are on issue.

#### INTRODUCTION

# Anatara's aim and objectives

Anatara's mission is to develop oral solutions for gastrointestinal diseases in production animals and humans. Its initial focus is the development and commercialisation of  $Detach^{TM}$ , a non-antibiotic therapy that prevents and treats diarrhoea (also known as scour) in piglets.

section 2.1

to traditional antibiotics to control scour, that will allow pig producers to maintain animal health and growth aspects of production, without contributing to the problem of antimicrobial resistance and the stigma associated with their use.

Anatara believes that Detach™ will be a safe and effective alternative

#### Market Opportunity

The development of non-antibiotic alternatives in livestock production is a major commercial opportunity for Anatara because there is now significant pressure to reduce antibiotic use in production animals. Overuse of antibiotics has led to a global health problem where increasing numbers of antibiotic resistant bacteria are making bacterial infections more difficult to treat.

sections 2.1 and 2.3

#### BUSINESS MODEL.

# Anatara's lead product in development – Detach™

Detach<sup>TM</sup> is a natural, non-antibiotic therapy for the prevention and treatment of scour in piglets and is made from bromelain, an extract from pineapple stems.

section 2.2

Detach<sup>TM</sup> is a new formulation of a previously successful product, with proven safety, efficacy and economic value on commercial pig farms. This earlier formulation, also called Detach, was launched, marketed and distributed in Australia in 1991 by Ciba Geigy (now Novartis) and used on several thousands of pigs. It was well received by farmers, where profitability was driven by increased weight and health of the herd. Detach was removed from the market as a result of corporate restructure activity, not because of efficacy or safety issues.

# Detach™ – pathway to market

Anatara has a well mapped out pathway to market for the new formulation of Detach™ for pigs in Australia which can be summarised as follows:

sections 2.4 and 2.5

Manufacture – Anatara has contracted the services of Sphere Healthcare, a contract manufacturing organisation (CMO). Sphere will manufacture Detach™ for the Australian field trials and has the capacity to scale up its manufacture for commercial supply to the Australian, and global markets.

Field trials – Anatara has entered into an agreement with the Department of Environment and Primary Industries (DEPI) Victoria which will conduct field trials of Detach<sup>TM</sup> in piglets, to re-confirm its safety and efficacy.

# Detach<sup>™</sup> – pathway to market

Registration – The new formulation of Detach<sup>TM</sup> will be subject to approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). In conjunction with its regulatory consultants Anatara has confirmed with the APVMA the product application category, and aims to re-launch Detach<sup>TM</sup> for use in scour for piglets in Australia in 2016.

sections 2.4 and 2.5

**Distribution and sales** – Following the launch of Detach™ for use in pigs in Australia, Anatara will then seek to launch Detach™ in the EU and the USA in 2017.

Anatara plans to partner with Australian distributors who directly supply pig farmers in the Australian market. For international markets, Anatara plans to partner with large, multinational veterinary companies to sell and distribute Detach<sup>TM</sup>. Anatara will also seek to partner with larger pharmaceutical and biotechnology companies to progress the development of Detach<sup>TM</sup> for diarrhoea in other production animals, such as calves and chickens, as well as in humans.

Revenue will be earned through Detach<sup>TM</sup> sales, licensing, milestone payments and royalties.

The key dependencies for the commercialisation of Detach<sup>TM</sup> include there being no major regulatory or development hurdles, successful field trials, ongoing contractual arrangements with its contract manufacturer, securing commercially meaningful intellectual property protection and, ultimately, take up by end consumers.

### BENEFITS AND RISKS

# Key investment highlights

Key investment highlights include:

2.2 and 2.3

sections

- (a) Clear pathway to medium term product launch Anatara expects launch of its lead product Detach™ by mid-2016.
- (b) Proven product Detach™ is based on a previously registered and launched product. Anatara is leveraging the significant earlier data to fast track the registration application.
- (c) Detach™ is a non-antibiotic treatment. Orally active, with long-lasting effects. A single dose of Detach™ provides several days of protection against diarrhoea.
- (d) Strong regulatory support Many governments have called for severe restrictions on the use of antibiotics and are providing support for potential alternative solutions.
- (e) Consumer driven demand Growing public concern and awareness are also driving change in how antibiotics are used in animal production. Consumers are increasingly indicating that they do not want antibiotics in their food and there is a social trend towards organic and antibiotic free food.

(f) Excellent safety profile - Detach™'s active components are purified from plants that are already well known to regulatory authorities and has GRAS (generally regarded as safe) status in the USA.

sections 2.2 and 2.3

- (g) Experienced management The Directors of Anatara have excellent track records in building successful businesses.
- (h) World class research Detach™'s efficacy is supported by scientific research at world class institutions and peer-reviewed publications.
- (i) Diarrhoea is a global health problem Diarrhoea affects billions of animals and people each year.
- (j) Strong potential pipeline Anatara has the potential to develop  $\mathsf{Detach^{TM}}$  for other production animals such as calves and chickens, as well as humans.

Key risks to Anatara's business The key specific risks associated with Anatara's business are:

section 5

- (a) Detach<sup>TM</sup> is in development and not approved for commercial sale the new formulation of Detach<sup>TM</sup> is still in development and has not yet generated any product sales for the Company. Product revenues are not anticipated for at least two years and there is no guarantee that, following development, Detach<sup>TM</sup> will be commercially successful and achieve sufficient sales.
- (b) Field trial risk approval for Detach<sup>TM</sup> is dependent on Anatara's ability to conduct successful field trials in pigs, which depend on the availability of field trial sites and regulatory approvals. There is no guarantee these trials will return efficacious results.
- (c) Regulatory risk Anatara's ability to manufacture and sell its products is dependent upon regulatory approvals in target markets, for which there is no guarantee of securing such approvals in a timely and cost effective manner.
- (d) *Delay risk* the potential for delay of any of Anatara's key milestones presents a number of risks (including achieving revenue within anticipated timeframes and potential cost overruns). Delays may be caused by various factors, including delays in completing successful field trials and obtaining regulatory approval for the new formulation of Detach<sup>TM</sup>.
- (e) Intellectual property Anatara's ability to leverage its innovation and expertise is dependent on the Company successfully protecting its intellectual property. Detach is currently protected by a US provisional patent and as a trade secret. There is no guarantee Detach will be capable of further legal protection. It may also be subject to unauthorised disclosure or be unlawfully infringed.
- (f) Competition the life sciences industry is competitive and subject to rapid and significant change. Other companies may be pursuing the development of products that target the same conditions Anatara is pursuing and may be better resourced or develop superior products. This risk may be increased by the current focus on the issue of antimicrobial resistance and need for non-antibiotic alternatives.

#### Key risks to Anatara's business

(g) Dependence on key relationships and personnel - Anatara depends on the performance of its commercial partners, and the retention of key consultants and personnel, to successfully grow its business. The loss of any such relationships may have a material adverse effect on the Company.

section

The Anatara business is also subject to general risk factors.

The specific risks identified above and additional general risks associated with Anatara are set out in further detail in section 5.

Any investment in Anatara should be considered speculative.

#### PROPOSED USE OF FUNDS AND FINANCIAL INFORMATION

#### Use of funds

Anatara plans to fund the development and re-launch of Detach™ in piglets in Australia using existing cash.

section 9.3

The Offer will raise new capital for Anatara which will be used to fund the development and launch of Detach<sup>TM</sup> in the EU and the USA, intellectual property protection, R&D initiatives, and working capital.

The Offer proceeds will be applied as follows:

Use of proceeds	\$ raised
Registration of Detach™ for pigs in	From pre-existing
Australia	funds
Registration of Detach™ for pigs in EU	1,055,000
Registration of Detach™ for pigs in USA	730,000
Detach™ for humans – further	392,000
development	
Patent costs	300,000
General administration costs	2,287,000
Personnel costs	1,425,000
Transaction costs	811,000
Total funds raised	7,000,000

This use of funds represents the current intentions of the Company based on its current business plan and business conditions. The amounts and timing of the actual expenditure may vary and will depend upon numerous factors, including the timing and success of the development programs and field trials the Company is proposing to undertake.

# Anatara's financial position

The Company's financial position is set out in detail in section 4 of this Prospectus.

section

As Detach<sup>TM</sup> is in development and not available for sale, the Company does not currently derive any revenue from its operations. To fund its operations, Anatara has relied upon seed capital and has also funded some collaborative research through a research grant. Anatara's material operating expenses include research and development, including regulatory expenses, maintenance and development of intellectual property, costs and professional fees associated with commencing the initial public offer, and general and administrative costs.

#### OTHER DETAILS

# Board and executives

Anatara's Board collectively have significant depth of executive and non-executive board experience in the life sciences industry and early stage companies, combined with publicly listed company, capital market, financial and commercial expertise.

sections 3.1 and 3.2

Director	Position	Independence
Mel Bridges	Non-Executive Chairman	Not independent
David Venables	Chief Executive Officer and Managing Director	Not independent
lain Ross	Non-Executive Director	Independent
Tracie Ramsdale	Non-Executive Director	Independent
Jay Hetzel	Non-Executive Director	Independent

Mel has over 30 years' experience building successful, international life science, diagnostic and medical device companies. Mel is also a director of ASX listed companies ALS Ltd and Tissue Therapies Ltd.

David has a track record in the global biotech product development and manufacturing sectors. This has included the role of CEO for Ark Therapeutics Group plc and COO of Intercell USA Inc.

lain has more than 30 years' experience in the international life science and technology sectors. This has included over 20 years experience of cross-border management in chairman or CEO roles.

Tracie is one of the founders of ASX listed Alchemia Ltd and led the company as CEO from 1998 to 2007, in addition to serving as a director since mid-2003.

Jay co-founded Genetic Solutions Pty Ltd to develop genomics technology in livestock (later sold to Pfizer Animal Health in 2008). He is currently chairman of ASX listed Leaf Energy Ltd.

The Company Secretary is Stephen Denaro. Stephen is an experienced Company Secretary and Chief Financial Officer of various ASX listed companies and with major chartered accountancy firms in Australia and the United Kingdom.

# Board and executives

Key executives, in addition to David Venables as CEO, include:

sections 3.1 and 3.2

#### Tracey Mynott - Chief Scientific Officer

Tracey is one of the inventors of the Detach™ technology. She has held senior management positions in academia as well as ASX listed and private Australian and UK biotechnology companies.

#### Alan Dowling - Group Accountant

Alan has owned and managed a number of private companies, having previously worked for PwC in private and commercial tax.

#### Hayley van der Meer - Commercial Manager

Hayley specialises in sales and marketing, commercialisation of new technology, technology transfer, intellectual property management and project management, working with ASX listed companies.

Further details on the experience and qualifications of each of the Directors and key executives are set out in section 3.

#### Related party transactions and benefits for other parties

Other than the usual contractual arrangements (i.e. executive employment contract with David Venables, appointment letters with other Directors, and deeds of access, insurance and indemnity), as set out in further detail in section 10, there are currently no material arrangements between Anatara and its Directors, or other related parties.

sections 8.8, 8.9 and 10.7

# Advisers and other service providers are entitled to fees for services as set out in this Prospectus.

# How to participate in the Offer

To participate in the Offer, please complete the Application Form attached to this Prospectus and return it to your broker or, if not received from a broker, the share registry with payment of the Application Money before the Closing Date. For further details see section 9.

section 9.5 and Application Form

#### Important notice

This section is not intended to provide full details of the investment opportunity. Investors must read this Prospectus in full to make an informed investment decision. The Shares offered under this Prospectus carry no guarantee of return of capital, return on investment, payment of dividends or on the future value of the Shares.



Chapter 2

# Business Overview

# 2.1 Anatara's mission

Anatara's mission is to develop oral solutions for gastrointestinal diseases in food production animals and humans. Its initial focus is the development and commercialisation of Detach™, a natural, plant-based, nonantibiotic therapy that prevents and treats diarrhoea in pigs. Subject to meeting current regulatory and development hurdles, it is anticipated that Detach™ will be launched in the Australian market in 2016, with the European and US markets planned to follow in 2017.

# ANTIBIOTIC RESISTANCE



# AN EMERGING ISSUE FOR THE WORLD

Antibiotic resistance in bacteria is a growing worldwide problem for both humans and animals.

Bacteria that cause infections can develop ways to survive antibiotics that are meant to kill them. The spread of bacteria that are resistant to antibiotics or "superbugs" is driven by overuse of these drugs — and not just in people. Up to 80% of all antibiotics used are in livestock production. Many farmers around the world feed antibiotics to their animals, not only to prevent and treat infections, but also as growth promotants - to make them grow faster. This leads to drug-resistant bacteria in the animals, and this resistance can spread to the bacteria that infect humans<sup>4</sup>. More than 23,000 people in the United States die each year because of infection by antibiotic resistant bacteria.

# MOVES TO STOP USE OF ANTIBIOTICS AS GROWTH PROMOTANTS IN ANIMALS

The World Health Organisation (WHO) has called for a worldwide ban on the use of antibiotics as growth promotants in feed of all livestock, as well as restrictions on the use of antibiotics in people. Many countries have responded and placed restrictions on the use of several classes of antibiotics in animals. In Europe, a total ban is in place on growth promoting antibiotics in animal feed.

# CONSUMERS ARE SEEKING MEAT FREE FROM ANTIBIOTICS



Growing public concern and awareness are adding to the need to reduce the use of antibiotics in animal production. Consumers want assurance that the meat they consume is safe and antibiotic free.



# GOVERNMENTS ARE RAISING FOOD STANDARDS

Countries such as Korea have legislated that their meat must be labelled as either "antibiotic free" or "organic".

Other Asian countries, such as Japan and Singapore, the world's largest importers of pork, are following suit, prompting countries such as the USA to investigate the trade implications of not withdrawing antibiotics from animal production.



# POPULATION GROWTH INCREASES DEMAND FOR MEAT

Global population growth means the world needs to produce 50% more meat by 2030 and 100% more by 2050 to satisfy increased demand. With the increased intensification of agriculture, and without the routine use of antibiotics, it will be more difficult to maintain animal health and protect animal welfare. It will therefore become more difficult to sustain economic food production.

# THE SEARCH FOR **ALTERNATIVES TO ANTIBIOTICS** IS ON



The majority of antibiotics added to livestock feed are used as growth promotants and as prophylactics or preventatives to stop diseases like scour. Scour is one of the most common problems in pig farming, causing poor health, reduced weight gains, high cost of treatment and death. With governments around the world issuing stricter guidelines for the use of antibiotics, the search for alternatives is growing. Detach<sup>TM</sup> is a safe and effective alternative that will allow pig producers to maintain current levels of animal health, efficiency and profitability.

### 2.2 Product Overview - Detach™

#### About Detach™

Detach<sup>TM</sup> is based on 25 years of scientific research, supported by peer-reviewed publications, world-renowned medical researchers and business executives, experienced in the successful commercialisation of drugs and building life science businesses.

Detach<sup>TM</sup> is a modified release formulation of bromelain, a natural extract from pineapple stems. It is formulated with various ingredients to allow its efficient delivery to the small intestine.

Detach<sup>TM</sup> is easily administered by mouth to the piglet via a measured dosing applicator. It is a single dose treatment, saving labour and management and can be given at a predictable and convenient time.

To prevent scour, Detach™ is given as a once only oral dose just before the expected onset of scour with no need for changes in on-farm management practice. To prevent early post-weaning scour, it is administered when the piglets are moved to the weaner pens. For scour in suckers (unweaned piglets), a single dose of Detach™ is administered at 2 days of age to protect piglets over the 2-5 day of age vulnerable period. A repeat dose at weaning is recommended for farms that have both a sucker and a weaner problem. As a treatment, a single dose is administered as soon as the symptoms of scour appear.

Anatara has lodged a US provisional patent for the new formulation of Detach<sup>TM</sup> and is confident of its efficacy, safety and in its ability to scale up manufacture following regulatory approval. The new Detach<sup>TM</sup> formulation has improved cost of goods and more convenient packaging for farmers.

# Product History

Detach™ is a new formulation of a former product (also called Detach) that was previously launched and marketed in Australia by Ciba Geigy (now Novartis) in the 1990s. In early field trials Detach was proven to be safe and effective in several thousand piglets where it reduced scour, improved weight gains and reduced the number of antibiotic treatments.

Following the launch of Detach in 1991, it quickly secured significant market uptake with major pig producers in New South Wales and Victoria, both key pig production areas, but was removed from the market, not because of efficacy or safety issues, but because of corporate restructure activity.

The previous success of the former Detach product provides Anatara with confidence in the potential of its new formulation of Detach<sup>TM</sup>. Anatara owns all the rights to the former product and all of the former data and registration documents, which allows Anatara to fast track the registration application of the new formulation of Detach<sup>TM</sup> with the APVMA.

In preparation for the re-launch of Detach<sup>TM</sup> in 2012 Anatara completed successful field studies in Europe on commercial pig farms and demonstrated that this new formulation of Detach<sup>TM</sup> is as effective as the former version was in 1991 (see below).

The re-launch of Detach<sup>TM</sup> is timely because of the mounting pressure to reduce antibiotic use in production animals. Detach<sup>TM</sup> is expected to be a safe and effective alternative to traditional antibiotics to control scour. It will allow pig producers to maintain animal health and growth aspects of production without contributing to the problem of antimicrobial resistance and the stigma associated with antibiotic use, and hence represents a major commercial opportunity for Anatara.

#### Economic Benefit of Detach™

Detach™ improves pig health and provides economic advantages to pig farmers.

Table 1 below shows a summary of field trials conducted on the earlier formulation of Detach. The key performance indicators include improved average daily weight gain of both sucker and weaner piglets (by 12.7% and 8.6%, respectively), reduced mortality by over 40%, and a reduction in antibiotic use by 31% to 67.4%<sup>5</sup>.

The weight gain data was analysed using an AUSPig analysis, a computer program developed by the CSIRO<sup>6</sup> to calculate a commercial benefit. The analysis showed that Detach could increase returns at slaughter by up to \$5.18 per pig, an increase in 45% net revenue per pig<sup>5</sup>. No adverse effects due to Detach were observed.

These benefits do not include labour saved in treating pigs with antibiotics, the cost of the antibiotics or the feed saved based on improved feed conversion ratios (FCR)<sup>7</sup>.

Table 1: Summary of Detach (old formulation) field trials conducted from 1988-1991<sup>5</sup>

Detach™ trial summary	Suckers	Weaners
Number of trials	11	8
Number of piglets	4,752	2,880
Improved average daily weight gain	12.7%	8.6%
Reduction in mortality	42.4%	41%
Reduction in antibiotic use	67.4%	31%
\$ Benefit/100 head*	\$526	\$299

<sup>\*</sup> AUSPig linear programming analysis performed by the Victorian Department of Agriculture, Australia.

<sup>5</sup> Lindsay, L. 1991. Auspig model indicates new scours treatment could boost returns by \$5.18 a pig. Milne's Pork Journal. 13:32-33.

<sup>6</sup> The Commonwealth Scientific and Industrial Research Organisation.

Feed conversion ratio (FCR) is a measure of an animal's efficiency in converting its food into animal protein. For the farmer, this means the difference between how much it costs to feed a pig versus the amount of meat the farmer gains in return.

The new formulation of Detach<sup>™</sup> has been trialled in weaner pigs in new field studies in 2012 on commercial pig farms in Europe. Like the earlier Detach, the new formulation of Detach<sup>™</sup> improved piglet health and piglet performance. Compared to untreated pigs, Detach<sup>™</sup> reduced the incidence of post weaning scour (by 40%), improved average daily weight gains (by 22%) and reduced antibiotic use (by 55%).

An added benefit of Detach<sup>M</sup> in these recent trials, is that it also improved FCR. The improvements in FCR add to the commercial case for Detach<sup>M</sup>, enabling pig farmers to capture more profits from more efficient meat production.

In one trial of 267 weaner pigs, Detach™ improved FCR by up to 33%, when compared with piglets treated with colistin (an antibiotic) added to feed. In another trial of 216 piglets, Detach™ improved FCR by 4.2% compared to piglets administered with zinc oxide (an antimicrobial). Table 2 shows a summary of these field trials. These data show that Detach™ has a potentially superior benefit on FCR over products currently used to control scour in piglets.

**Table 2**: Summary of Detach<sup>™</sup> (new formulation) field trials conducted in 2012 showing improvements in FCR.

Field Study	Comparisons	Improvement in FCR (%)
Spain	Detach™ vs ZnO	4.2%
	Detach™ vs No treatment	2.7%
France	Detach™ vs Colistin	33%
	Detach™ vs No treatment	7%

The improved performance in FCR by Detach™ is significant as the cost of feed is the major cost to pork production. Every improvement in the feed conversion ratio will reduce feed costs and improve profitability for pig producers.

It has been estimated by Australian Pork Limited that a 0.1% improvement in grower feed conversion efficiency can improve the profitability of a 200-sow unit by approximately \$6,000 per annum<sup>8</sup>.

#### Detach - how it works

The mechanism of action of Detach™ and its active ingredient bromelain is well validated and published in leading international scientific journals, including Gastroenterology, GUT, the Journal of Immunology and Infection and Immunity9. In these studies, Detach™ was shown to demonstrate efficacy against the most common cause of scour, enterotoxigenic E. coli (ETEC), as well as other agents.

Australian Pork Limited Fact Sheet, December 2008

Mynott, T.L. et al. 1997. Bromelain prevents secretion caused by Vibrio cholerae and Escherichia coli enterotoxins in rabbit ileum in vitro. *Gastroenterol*. 113:175-184.

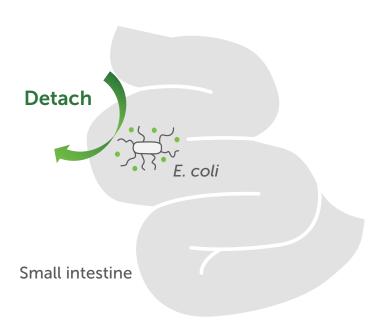
Mynott, T.L. et al. 1999. Bromelain, from pineapple stems, proteolytically blocks activation of extracellular regulated kinase-2 in T cells. *J. Immunol*. 163:2568-2575.

Chandler and Mynott. 1998. Bromelain protects piglets from diarrhoea caused by oral challenge with K88 positive enterotoxigenic Escherichia coli. *Gut* 43:196-202.

Mynott, T.L. et al., 1991. Efficacy of enteric-coated protease in preventing attachment of enterotoxigenic Escherichia coli and diarrheal disease in the RITARD model. *Infect. Immun*. 59:3708-3714.

Scour is caused by many different organisms, including bacteria, viruses and protozoan parasites. This diversity makes diarrhoea a difficult illness to treat and there are currently no products available to treat all causes.

Detach<sup>™</sup> has broad spectrum activity. Detach<sup>™</sup> not only prevents the diarrhoea-causing organism from attaching to the small intestine in the first place, but it also blocks the inflammatory and secretory action of toxins, the underlying cause of diarrhoea.



# Figure 1a. Detach prevents attachment of bacteria to the small intestine.

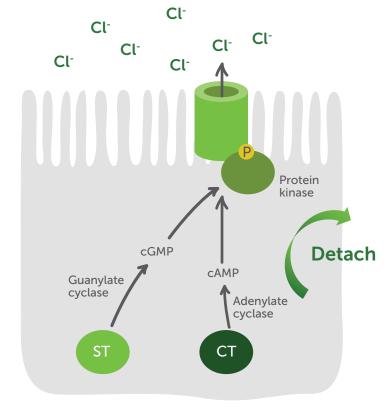
Many bacteria, such as enterotoxigenic E. coli, need to attach to the small intestine to cause diarrhoea. Once they attach, they deliver their toxins (see below).

Detach prevents bacteria from attaching to the intestine, so they then pass through the gut without causing disease.

# Figure 1b. Detach blocks intestinal secretion

Diarrhoea is a result of Cl<sup>-</sup> (chloride) secretion by cells that line the small intestine. Cl- secretion is stimulated through the activation of cyclic AMP (cAMP), cyclic GMP (cGMP) or Ca<sup>2+</sup> (calcium) signalling molecules. Many bacterial toxins activate these signalling molecules in different ways. For example, cholera toxin (CT) produced by Vibrio cholerae stimulates cAMP, while heat stable (ST) toxin from E. coli stimulates cGMP. Other organisms, such as cryptosporidia and rotavirus cause diarrhoea by the production of inflammatory mediators, such as TNF, that also activate signalling molecules.

Detach blocks the cell signalling pathways, and therefore prevents diarrhoea.



Intestinal Cell

As Detach<sup>TM</sup> acts on the underlying mechanisms of diarrhoea, it has a significant advantage over current treatments, such as antibiotics or vaccines, and therefore it could be effective against most causes of diarrhoea. That is, unlike antibiotics and vaccines that only target specific types of pathogen, Detach<sup>TM</sup> is likely to be effective against a range of different causes of diarrhoea, making it a single product solution.

### 2.3 Industry Overview

### Market opportunity

Anatara believes the market for Detach™ will be driven by:

- The need to improve economics of pork production;
- New legislation restricting the use of antibiotics;
- Increasing incidences of scour;
- · Intensification of pig production;
- The need for non-antibiotic alternatives:
- Increasing demand for pork; and
- · Rising consumer awareness about animal welfare and food safety.

Pork is the most consumed meat in the world. A growing global population with a high demand for pork makes the pig farming market a logical first target. It is estimated that by 2050, 100% more meat will be required to feed the growing population<sup>10</sup>. Also, increased wealth is driving meat consumption. With reduced land available and the increased intensification of agriculture, and without the routine use of antibiotics, it is important that new treatments for scour are brought to market, to maintain the health and welfare of production animals.

The map below indicates the market opportunity for Anatara. Anatara is initially focused on distributing Detach™ within Australia, followed by the significant pig farming regions of the USA and the EU.

The Australian market is relatively insignificant in the global context. However it is a logical market for Anatara to target for its initial roll out of Detach<sup>TM</sup>. given that the product was developed in Australia, and the previous formulation was successfully marketed here in the past. Anatara will seek to leverage similarities in the regulatory environments between Australia, the USA and the EU.

Launching Detach<sup>TM</sup> within the USA and the EU coincides with the mounting pressure in both regions to reduce antibiotic use in production animals. Within the EU, there has been a ban on antibiotic growth promotants in animal feed since 2006. In the USA, the FDA has released guidance around the reduced use of antibiotics, and in 2013, a bill was put before the Senate, designed to address the issue.

Anatara believes it is clear to consumer and meat producers in our three key target markets that a better alternative to antibiotics is required. Anatara will continue to assess opportunities in other markets.

10

Evans, A. 2009. The Feeding of the Nine Billion. Global Food Security for the 21st Century. Chatham House Report.



Number of piglets weaned per year in millions

# Current Market Treatments

Current treatment options for scour in pigs have limitations. These primarily include:

- Microbial resistance and consumer trends in the case of antibiotics;
- Microbial resistance and environmental concerns regarding the use of Zinc Oxide:
- Lack of broad spectrum efficacy for vaccines; and
- Lack of proven efficacy for other treatments.

The potential competitive advantage offered by Detach™ relative to other current treatment options is illustrated below:

# Scour in pigs - Current treatment options and their limitations

#### **Antibiotics**

- Current gold standard for prevention and treatment of scour.
- Overuse has led to the emergence of antibiotic resistant bacteria.

#### Zinc Oxide

- Alternative to antibiotics. High doses added to pig feed just before and after weaning to prevent scour.
- Banned in some countries.
- Is a heavy metal, may lead to antimicrobial resistance and is an environmental pollutant.

#### Copper Sulphate

- Added to pig feed mainly as a growth promotant, but may also have some antibacterial activity.
- May lead to antibiotic resistance and is an environmental pollutant.

# Advantages of Detach<sup>TM</sup>











Detach™ does not target the pathogen, so will not contribute to antimicrobial resistance



is a biodegradable protein. Detach™ is digested in the

Active component in Detach™



piglet gut, and therefore is safe for the environment.



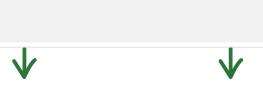
Detach™ does not lead to antimicrobial resistance and has no negative impact on the environment.

#### **Vaccines**

- Oral Vaccines are available for some strains of E. coli.
- There is difficulty in generating immune responses in young animals, and the diversity of strains makes full protection difficult.

#### Other Alternatives

- Phytobiotics (essential oils), organic acids, low protein diets and probiotics (live bacterial cultures) are other proposed alternatives.
- These approaches have mixed success.





Detach<sup>™</sup> is broad spectrum. Its effectiveness does not depend on the cause of scour.



Detach™ is scientifically proven to reduce scour and increase weight gains.

### Key features of Detach<sup>TM</sup>

The key features of Detach can therefore be summarised as follows:

#### **Key features**

- Prevents and treat diarrhoea
- Based on a previously launched and successfully marketed product
- Long acting a single dose will protect for several days
- ✓ Broad spectrum efficacy its effectiveness does not depend on the cause of diarrhoea
- ✓ Safe the active ingredient is obtained from pineapple stems and is categorised as GRAS (Generally Recognised As Safe) by the FDA and is an approved ingredient in other territories
- A naturally derived, non-antibiotic product so will be widely accepted by consumers
- ✓ Stable Detach<sup>™</sup> does not require refrigeration
- ✓ Does not target the organism so unlike antibiotics and vaccines, Detach<sup>™</sup> does not exert selective pressure on them to create resistant strains
- Based on peer-reviewed scientific studies published in high impact journals
- ✓ Both the new and old formulation of Detach<sup>TM</sup> have been proven in previous field trials in piglets

#### Benefits to the farmer

- Decreased susceptibility of piglets to infections
- Reduced piglet mortality and production losses
- Improved piglet health and weight gains
- Improved feed efficiency, leading to lower cost of production and increased profitability
- ✓ Reduction in antibiotic use

#### Benefits to the consumer

- Reduced exposure to antibiotics in food
- May help reduce the creation of antimicrobial resistant bacteria – so called 'superbugs'.
- Increased confidence in food safety and food quality

# 2.4 Detach™ development strategy

#### Overview

Anatara's initial focus is to launch Detach™ for use in pigs in Australia in 2016. Anatara plans to then follow up with launches in the EU and the USA targeted in 2017.

Anatara operates on a low operating cost model where overhead costs are kept to a minimum, with funds concentrated on advancing Anatara's products. Research and development is outsourced to collaborators and/or service providers where applicable.

The route to market for Detach™ can be broadly summarised as follows:

Manufacture Clinical Trials Registration Distribution and Sales

### Key Development Steps

The key development steps are set out in further detail below.

### Manufacturing

The manufacture of Detach™ will be outsourced to Sphere Healthcare Pty Ltd (Sphere) in Sydney, a contract manufacturing organisation licensed with the APVMA. Sphere has the experience and capability to deliver Anatara's complete manufacturing requirements, starting with sourcing and receiving the raw ingredients, through to manufacturing, stability testing, labelling and packaging of the final Detach™ product ready for distribution. A summary of the contract with Sphere is set out in section 8.5.

Sphere has the capacity to scaleup to meet the Australian, EU and US pig markets. It is also licensed with the TGA, so it can also accommodate Anatara's plans to potentially develop a human product.

#### Field Trials

Although the earlier formulation of Detach was trialled successfully in 1991, and the new formulation was trialled successfully in 2012 in the EU, additional field studies are required on the new formulation of Detach<sup>TM</sup> for registration in Australia.

Field trial permit applications have been lodged with the APVMA and Anatara is currently working with the DEPI, and is in discussions with Pork CRC, to identify suitable commercial pig farms in Australia as trial sites.

These trials will investigate the ability of Detach™ to reduce the incidence, severity and duration of scour, and improve health in two age groups of piglets: suckers (unweaned piglets) and weaners (just weaned piglets). Up to six trials are planned comprising a total of 2,400 piglets, which are expected to commence in Q3 2014. Each trial will be

conducted as blinded, controlled, randomised field trials comparing two parallel groups of piglets with at least 200 piglets per treatment group. Following Detach<sup>TM</sup> treatment, piglets will be monitored daily, and scour and general health will be recorded using an agreed scoring system. The number and type of antibiotics or other medications administered throughout the study will be recorded. The weights of piglets will also be recorded at agreed intervals during the study period.

Further trials are also required in the EU and USA before Detach™ is able to be registered in these jurisdictions.

### Registration

Detach was originally registered for use for all forms of scour in suckers and for E. coli scour in weaners. Although the previous formulation of Detach was approved in Australia, a new application to the APVMA is required for registration of the new Detach<sup>TM</sup> formulation. Anatara has engaged experienced APVMA regulatory consultants who have reviewed the earlier data and have advised what additional data may be needed. A meeting to discuss Anatara's approach to registration of Detach<sup>TM</sup> has also been held directly with the APVMA.

While the new Detach<sup>TM</sup> formulation has been improved, Anatara and its regulatory consultants believe that several data waivers may be available from the APVMA, which could simplify the re-registration process. Anatara has sought preliminary advice from the APVMA and submitted a briefing document noting that several waivers to certain sections of the registration application are justified. For example, there is significant data already available supporting animal safety and efficacy, and that Detach<sup>TM</sup> poses no risk to the environment. In addition, since the active ingredient (bromelain) is already listed on the Australian Register of Therapeutic Goods (ARTG), and is generally recognised as safe by the FDA, it poses little risk to humans.

On the assumption that the new trial data supports the existing data, Anatara with the assistance of its regulatory advisors, expects to submit its registration application for Detach<sup>TM</sup> in pigs with the APVMA in early 2015. The APVMA review process is expected to take approximately 9 to 12 months following submission of the application for registration based on current APVMA review times.

#### EU and USA

While the APVMA is reviewing the Australian application, Anatara will prepare the registration applications for Detach<sup>TM</sup> for piglets in the EU and the USA.

As Detach<sup>TM</sup> has not been registered in the EU or the USA, a new application is required. While much of the data generated to support an Australian product approval is applicable, each licensing authority has its own specific regulations and expectations. Anatara has engaged EU and USA regulatory consultants who have reviewed the data and have mapped out the requirements for registration in the EU and the USA.

Pre-submission meetings with the European Medicines Agency (EMA) and the Committee for Veterinary Medicines (USA) will be conducted to clarify their respective requirements for safety, efficacy and manufacturing control of Detach<sup>TM</sup>.

The data requirements for the EU are anticipated to be completed by the end of 2015 leading to a license application to the EMA during the first quarter of 2016. Following a 12 month review, Anatara expects product approval in early 2017 followed by product launch during the first half of 2017.

The US application will follow six months behind the European application, with anticipated approval by mid-2017 and product launch in the second half of calendar 2017.

Anatara has applied for small and medium-sized enterprise (SME) status in the EU, which allows it to qualify for a 90% reduction of the usual regulatory fees. An application for a fee waiver will also be submitted in the USA to qualify for a reduction in the \$101,000 per year Animal Drug User Fee, which is required to be paid during the period when a New Investigational Animal Drug Application (INAD) is open.

#### Sales and Distribution

#### Australia

The Australian pork industry is consolidated, with 50% of pigs produced by 15 companies in just a few locations; northern Victoria, southern New South Wales, south east Queensland and South Australia<sup>11</sup>.

Anatara therefore intends to appoint a Product Development Manager and market Detach<sup>TM</sup> to farmers directly via established distribution networks rather than enter into a commercialisation agreement with another animal health company. This strategy increases the value that Anatara can deliver to shareholders.

#### EU and USA

Due to the size and complexity of the pork industry in the EU and the USA, Anatara's strategy for entering these markets is to enter into a co-development and / or commercialisation agreement with an animal health company (or companies) with an already established significant market presence. The Board believes that, based on the successful demonstration of efficacy in field trials in Australia, a partnership can be developed with appropriate companies on competitive terms.

# Strategic Partners

#### Pork CRC

Anatara is seeking to establish a potential strategic development partnership with the Pork CRC in Australia for field trials and marketing of Detach $^{TM}$ .

The Pork CRC is a Cooperative Research Centre, with funding provided by the Australian Government. The CRC program supports medium to long-term end user driven research collaborations to address major challenges facing Australia. It has recently committed to reducing antibiotic use in the pig industry by 50%.

The Pork CRC is made up of participants from the Australian pork industry, research organisations and universities. The key objectives of the Pork CRC are to provide and adopt new and novel technologies that reduce feed costs, improve herd feed conversion efficiency and increase the range and functionality of pork products.

Many of the participants in the Pork CRC are also pig farmers, the end users of Detach<sup>TM</sup>, which if Anatara is successful in establishing a partnership with the Pork CRC, should assist in facilitating rapid uptake by the industry.

<sup>11</sup> http://www.depi.vic.gov.au/agriculture-and-food/livestock/plg,-goat-and-deer-industry-profile. Accessed 5 March 2014.

# Department of Environment and Primary Industries (DEPI), Victoria

Anatara is also entered into a technical services agreement with the Pig Health and Research Unit (PHRU) at the DEPI for field trials and regulatory support. The PHRU is located near Bendigo in Victoria, in close proximity to approximately 85% of Victoria's pig farms, the second largest production area for pigs in Australia. The PHRU also assisted with the earlier field trials and registration of Detach in 1991. A summary of the agreement with the DEPI is set out in section 8.4.

The PHRU is partly funded by pig producer levies. The unit conducts pig disease surveillance and develops vaccines and other therapies to control disease. They also assist pig producers to understand, implement and comply with APIQ™, the Australian Pork Industry Quality Assurance Program on their farms. By implementing this program, it allows farmers to export their pigs and allows them to demonstrate to their customers that they follow acceptable standards for management, food safety, biosecurity, traceability and animal welfare.

A key objective of the DEPI is to reduce the use of antibiotics on farms. Anatara expects  $Detach^{TM}$  will help them achieve this objective.

# 2.5 Licensing, Partnering & Co-development

### Detach™ products for other production animals

There is the potential to develop Detach™ for the prevention and treatment of scour in other production animals, such as calves and chickens. Anatara will be seeking to partner with companies to progress the development of Detach™ for other production animals.

Calf scour causes more financial loss to cow-calf producers than any other health problem in their herds. Calf scour costs the Australian dairy industry alone approximately \$52 million each year, or \$26 for every cow<sup>12</sup>. The types of organisms that cause scour in calves, are similar to those that cause scour in piglets.

Vaccination programs are only partially effective, because of the various different organisms that cause scour, so antibiotics are widely used. The dairy and beef industries are under the same pressure as the pork industry to reduce the use of antibiotics.

In preliminary field studies on six dairy farms, the earlier version of Detach was shown to be effective against scour in calves. Detach reduced death from 25% to 4%, the number of days of scouring (from 2.33 days to 1.46 days), and the use of antibiotics by 66%.

### Detach™ products for humans

Anatara also has the potential to develop  $Detach^{TM}$  to prevent diarrhoea in humans and will seek to partner with large pharmaceutical / biotechnology companies for human applications of  $Detach^{TM}$ .

<sup>12</sup> Reported by Coopers Animal Health. Average Herd Size - Dairy Australia Industry Statistics 2008/09, Average calving - University of Adelaide Agri business resources, Treatment costs - Based on Industry standard prices June 2010, Economics of heifer rearing Richard Moss QDPI.

Novel, safe and non-antibiotic treatments are urgently needed to control the several billion episodes of diarrhoea that occur each year in humans. Diarrhoea is the second largest cause of death in the developing world and kills nearly one million<sup>13</sup> children annually. It is also a major cause of illness for travellers - affecting more than 40 million tourists, business travellers and military personnel.

Diarrhoea also affects people with inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS), as well as those undergoing cancer and HIV treatments.

The anti-secretory and anti-inflammatory mode of action of Detach™ provides Anatara and its commercial partners with the potential to develop a range of anti-diarrhoea products based on Detach™.

Anatara has already shown that a modified version of Detach™ can reduce IBD in mouse models that represent human disease. IBD constitutes a range of clinical conditions affecting the digestive tract, including Crohn's disease, and ulcerative colitis (UC). Patients with IBD experience abdominal pain and cramping, bloating, blood and mucus in the stool, loss of appetite and persistent diarrhoea. The Crohn's and Colitis Foundation of America estimates as many as 1.4 million Americans have IBD¹⁴, while another 2.3 million are affected in Europe and Australia¹⁵.

A Phase I study on a tablet form of Detach has been conducted previously which confirmed its safety. Anatara intends to:

- Undertake a detailed market assessment on the human applications of Detach<sup>TM</sup>.
- Engage with key opinion leaders, key influencers of policy, as well as strategic partners, to develop the target product profile.

Following this assessment a product development strategy will be developed to maximise return from each of the key markets comprising travellers, military and the developing world.

Anatara will be seeking non-dilutive grants to fund further research and development. Such grants include those awarded by the Gates Foundation, PATH (Program for Appropriate Technology in Health), an international non-profit organisation; and the World Health Organisation (WHO).

### 2.6 Intellectual property

Anatara owns the exclusive proprietary rights to the old formulation of Detach along with all the previous registration, field trial data, safety and manufacturing documents.

Anatara also exclusively owns all the rights to the new formulation of Detach™.

This new formulation is an improved version of the original Detach and is superior to bromelain, the active ingredient, alone. A US provisional patent application on this formulation has been filed. This application seeks protection for both animal and human uses of  $\mathsf{Detach}^\mathsf{TM}$ .

<sup>13</sup> http://www.cdc.gov/healthywater/pdf/global/programs/Globaldiarrhea508c.pdf.

<sup>14</sup> http://www.csfa.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed 13 August 2014.

Molodecky, N.A., et al., 2012. Increasing incidence and prevalence of the inflammatory bowel diseases with time, based on systematic review. Gastroenterology, 142:46-54

Anatara intends to file complete patent applications in major commercial territories, such as the EU, US, China, Korea, Brazil, Canada, Russia, Mexico, India and Australia within 12 months.

Further patents will be filed on data obtained from a research collaboration with Monash University. The Australian Research Council awarded a grant of \$290,000 for a research collaboration between Monash University and Anatara which is currently being used to support Anatara's intellectual property protection strategy. This research is directed at solving key structural and functional characteristics of components of Detach<sup>TM</sup>. This collaboration will help Anatara understand why Detach<sup>TM</sup> molecules display "drug-like" activity and therefore assist in identifying new intellectual property. Intellectual property generated from this program is solely owned by Anatara.

For further details on Anatara's intellectual property see the intellectual property report in section 7.

## 2.7 Key Dependencies

#### The key dependencies for the commercialisation of Detach™ are:

- No major regulatory or development hurdles arising and the successful completion of all required field trials by the Company.
- Ongoing contractual arrangements with the Company's contract manufacturer, Sphere Healthcare Pty Ltd, to produce Detach™ for field trials and, following the development phase, in sufficient quantities for sale to Anatara's customers.
- Finalising the Company's intellectual property portfolio (including registering final patents for Detach™) in various jurisdictions.
- Following the development phase, take up of Detach™ by customers at commercially sufficient levels to support the ongoing operations of Anatara and further product development and sales.



Chapter 3

Ownership, management and corporate governance

# 3.1 Board and Company Secretary

In addition to David Venables (see details in section 3.2 below), the Board comprises:

# Mel Bridges, BSc Chemistry, PhD, FAICD Non-Executive Chairman

Mel has over 30 years' experience building successful, international lifescience, diagnostic and medical device companies and commercialising a wide range of Australian technology. He holds a Bachelor of Science and a Doctorate from the Queensland University of Technology. Mel is also a Fellow of the Australian Institute of Company Directors (AICD) and is also on their Council. Mel is responsible for numerous commercial and M&A transactions and liquidity events.

Mel has received numerous prestigious national and state business awards including the 2005 AusBiotech Chairman's Industry Medal and 2004 Queensland Entrepreneur of the Year. Mel has successfully founded and developed veterinary and human lifescience companies, including the recent sale of Peptech Animal Health to Virbac in 2011, and Catapult Genetics to Pfizer Animal Health in 2008.

Mel is currently a director of ASX 100 company ALS Ltd, and a director of Tissue Therapies Ltd, where he is also the chair of the audit  $\vartheta$  risk committee.

#### lain Ross, BSc Biochemistry, CDir Non-Executive Director

lain is a biochemistry graduate of London University, and is an experienced businessman with more than 30 years' experience largely in the international life sciences and technology sectors. Following a career with multi-national companies, including Sandoz AG, Fisons plc, Hoffman La Roche, Celltech plc and Reed International plc, for the past 18 years he has undertaken a number of company turnarounds and start-ups as a board member on behalf of banks and private equity groups.

lain's track record includes multiple financing transactions as well as extensive experience of divestments and strategic restructurings and more than 20 years in cross-border management as a Chairman and CEO. He has led and participated in four initial public offerings, and has direct experience of M&A transactions in Europe, USA and Pacific Rim. Currently he is non-executive Chairman of Ark Therapeutics plc, Biomer Technology Ltd, and Amarantus BioScience Holdings, Inc. He is a non-executive director of Benitec Biopharma Limited, Novagen Limited and Tissue Therapies Limited all of which are listed in Australia. He is a qualified Chartered Director and Vice-Chairman of the Council of Royal Holloway, London University.

# Tracie Ramsdale, B App Sc, M Pharm, PhD, FTSE, MAICD Non-Executive Director

Tracie holds a PhD in Biochemistry from the University of Queensland, a Master of Pharmacy from the Victorian College of Pharmacy and a Bachelor of Applied Science (Chemistry) from the Royal Melbourne Institute of Technology. Tracie has more than 25 years experience in drug discovery and development, having held research positions at the Victorian College of Pharmacy, Bond University and the University of Queensland. In 1995, she co-founded Alchemia Limited, an ASX-listed biotechnology company, and

served as its Chief Executive Officer until 2007. Tracie is an adjunct Professor at the School of Chemical and Molecular Biosciences, University of Queensland, a member of the Australian Federal Government Advisory Council on Intellectual Property, a Fellow of the Australian Academy of Technological Sciences and Engineering, and a member of the Australian Institute of Company Directors.

Tracie is currently a non-executive director of Alchemia Limited and a director of Life Sciences Queensland. She currently provides independent consulting advice to the biotechnology industry, academia and government.

#### Jay Hetzel, B Agr Sci (Hons), PhD, FTSE, FAICD Non-Executive Director

Jay holds a Bachelor in Agricultural Science (Honours) (University of Melbourne) and a PhD in Animal Genetics (University of Sydney). He had a distinguished scientific career with CSIRO for over 20 years in the field of animal genetics. In 1998, he co-founded Genetic Solutions Pty Ltd to commercialise genomics technology in livestock and held positions of Managing Director and Scientific Director. The company was sold to Pfizer Animal Health in 2008. Jay has served on a number of industry and government advisory groups including the Queensland Biotechnology Advisory Council, Australian Government Gene Technology Technical Advisory Committee and the Life Sciences Queensland Steering Committee. Jay is a Fellow of the Australian Academy of Technological Sciences and Engineering and a Fellow of the Australian Institute of Company Directors. He is currently chairman of ASX listed Leaf Energy Ltd.

# Stephen Denaro, B Bus, CA, MAICD Company Secretary

Stephen has extensive experience in mergers and acquisitions, business valuations, accountancy services, and income tax compliance gained from positions as Company Secretary and Chief Financial Officer of various public companies and with major chartered accountancy firms in Australia and the United Kingdom. He provides company secretarial services for a number of start-up technology and ASX listed and unlisted public companies.

Stephen has a Bachelor of Business in Accountancy, Graduate Diploma in Applied Corporate Governance and is a member of the Institute of Chartered Accountants in Australia and the Australian Institute of Company Directors.

# 3.2 Management team

The key management team comprises:

David Venables, BSc Microbiology (Hons), PhD Chief Executive Officer & Managing Director

David has a PhD in Mammalian Cell Fermentation from Surrey University. He joined Medeva plc in 1995 where he spent 5 years as Group Leader, Process Development. In 1998 David was appointed Head of Biotechnology at Covance and then in 2002 he moved to Q1 Biotech Ltd as Director of Operations, Biomanufacturing. Following the acquisition of Q1 Biotech by BioReliance (subsequently acquired by Invitrogen in 2003), David was appointed Director of Market Development and Global Manufacturing at Invitrogen. In 2004 he became Director of Operations at BioReliance

Europe before joining Intercell in 2007. At Intercell, he was responsible for building Intercell's manufacturing capabilities in Europe and the USA, as Site Head for vaccine manufacturing operations in the UK, followed by Chief Operating Officer of Intercell USA Inc. based in Maryland, USA.

As CEO of Ark Therapeutics he has been responsible for leading the company through a transition to a viral contract development and manufacturing service model. David has an outstanding track record in the global biotech product development and manufacturing sectors, and has extensive operational and international business development experience.

# Tracey Mynott, B Agr Sc. (Hons), PhD Chief Scientific Officer

Tracey is one of the inventors of the Detach<sup>TM</sup> technology, being involved with its development in the 1990's, and more recently with the development of the new formulation. Tracey has a PhD in the pathogenesis of enteric infections with a particular focus on the Detach<sup>TM</sup> concept and enterotoxigenic *E. coli* infections. She has conducted post-doctoral studies at The Center for Vaccine Development at the University of Maryland in USA, The Division of Gastroenterology within The Royal College of Physician's and Surgeons at Columbia University in New York, The Digestive Diseases Research Centre at The Medical College of St. Bartholomew's Hospital in London UK and in The Department of Biochemistry, Imperial College in London.

Tracey is the former Head of Business Development at The Queensland Institute of Medical Research, one of Australia's most prestigious research facilities. She has also held senior management positions in public and private Australian and UK biotechnology companies, where she has successfully discovered and patented several technologies, devised and directed drug development and clinical programs, developed and implemented business strategies, including licensing, acquisitions, capital raising and marketing.

#### Alan Dowling, BBus Group Accountant

Alan completed his BBus at the University of Southern Queensland and spent his early career in private accountancy firms before moving to PwC where he worked in private and commercial tax. Alan has owned and managed a number of successful private companies before moving to Anatara as Group Accountant.

#### Hayley van der Meer, B Biomed Sc, Grad Dip Marketing Management Commercial Manager

Hayley has extensive experience in the medical diagnostics and agricultural biotechnology industries, holding positions in both Australia and the USA with ASX listed diagnostics manufacturer, Panbio Limited, the former Molecular Plant Breeding Cooperative Research Centre (MPB CRC), and most recently with ASX listed Leaf Energy Ltd. Hayley specialises in sales and marketing, commercialisation of new technology, technology transfer, intellectual property management and project management.

Hayley holds a Bachelor of Biomedical Science from Griffith University and a Graduate Diploma in Marketing Management from Central Queensland University.

# 3.3 Organisational structure

Sarantis is a wholly owned subsidiary of Anatara. Sarantis is the registered holder of certain intellectual property. Anatara does not intend to use Sarantis as an operating company other than to maintain intellectual property rights already held in its name. Anatara intends to have a simple corporate structure and will operate in its own capacity until such time as operating needs or geographic expansion make it appropriate to have a broader group structure.

# 3.4 Responsibility of the Board

The Board is responsible for the Company's proper corporate governance. To carry out this obligation, the Board must act:

- (a) honestly, conscientiously and fairly;
- (b) in accordance with the law:
- (c) in the interests of Anatara's shareholders (with a view to building sustainable value for them); and
- (d) in the interests of employees and other stakeholders.

The Board's broad function is to:

- (a) chart strategy and set financial targets for the Company;
- (b) monitor the implementation and execution of strategy and performance against financial targets; and
- (c) appoint and oversee the performance of executive management and generally to take and fulfil an effective leadership role in relation to the Company.

Power and authority in certain areas is specifically reserved to the Board – consistent with its function described above. These areas include:

- (a) providing leadership and setting the strategic objectives of the Company;
- (b) composition of the Board itself including the appointment and removal of the Chairman or deputy chairman (if applicable);
- (c) oversight of the Company including its control and accountability system;
- (d) appointment and removal of senior management (including the CEO or equivalent) and the Company Secretary;
- (e) reviewing, ratifying and monitoring the risk management framework and setting the risk appetite within which the Board expects management to operate;
- (f) approving and formulating company strategy and policy;

- (g) approving and monitoring operating budgets and major capital expenditure;
- (h) overseeing the integrity of the Company's accounting and corporate reporting systems, including the external audit;
- (i) monitoring industry developments relevant to the Company and its business;
- (j) developing suitable key indicators of financial performance for the Company and its business:
- (k) overseeing corporate strategy and performance objectives developed by management;
- (I) overseeing the Company's compliance with its continuous disclosure obligations;
- (m) approving the Company's remuneration framework;
- (n) monitoring the overall corporate governance of the Company (including its strategic direction and goals for management, and the achievement of these goals); and
- (o) oversight of the Company's various committees.

## 3.5 Composition of Board

The Board is comprised of five directors. At least half of the Board are non-executive directors independent from management. The chairman of the Board is a non-executive director.

## 3.6 Board charter and policy

The Board has adopted a charter which formally recognises its responsibilities, functions, power and authority and composition. This charter sets out other things which are important for effective corporate governance including:

- (a) a detailed definition of 'independence';
- (b) a framework for the identification of candidates for appointment to the Board and their selection (including undertaking appropriate background checks);
- (c) a framework for individual performance review and evaluation;
- (d) proper training to be made available to Directors both at the time of their appointment and on an on-going basis;
- (e) basic procedures for meetings of the Board and its committees including frequency, agenda, minutes and private discussion of management issues among non-executive Directors;
- (f) ethical standards and values (in a detailed code of ethics and values);

- (g) dealings in securities (in a detailed code for securities transactions designed to ensure fair and transparent trading by Directors and senior management and their associates); and
- (h) communications with shareholders and the market.

The purpose of the charter is to 'institutionalise' good corporate governance and to build a culture of best practice both in Anatara's internal practices and its dealings with others.

## 3.7 Audit and risk management committee

The purpose of this committee is to advise on the establishment and maintenance of a framework of internal control and appropriate ethical standards for the management of the Company. Its current members are:

- (a) Tracie Ramsdale (committee chair);
- (b) Jay Hetzel; and
- (c) Iain Ross.

The committee performs functions relevant to risk management and internal and external reporting and reports to the Board following each meeting. The committee's responsibilities include:

- (a) setting Board and committee structures to facilitate a proper review function by the Board;
- (b) internal control framework including management information systems;
- (c) corporate risk assessment (including economic, environmental and social sustainability risks) and compliance with internal controls;
- (d) internal audit function and management processes supporting external reporting;
- (e) review of financial statements and other financial information distributed externally;
- (f) review of the effectiveness of the audit function;
- (g) review of management corporate reporting processes supporting external reporting, including the appropriateness of the accounting judgments;
- (h) review of the performance and independence of the external auditors;
- (i) review of the external audit function to ensure prompt remedial action by management, where appropriate, in relation to any deficiency in or breakdown of controls;
- (j) assessing the adequacy of external reporting for the needs of shareholders;
- (k) reviewing any proposal for the external auditor to provide non-audit services and whether it might compromise the independence of the external auditor; and
- (I) monitoring compliance with the Company's code of ethics.

Meetings will be held at least three times each year. A broad agenda is laid down for each regular meeting according to an annual cycle. The committee invites the external auditors to attend each of its meetings.

# 3.8 Remuneration committee

The purpose of this committee is to assist the Board and report to it on remuneration and related policies and practices (including remuneration of senior management and non-executive Directors). Its current members are:

- (a) Iain Ross (committee chair);
- (b) Mel Bridges; and
- (c) Jay Hetzel.

The committee's functions include:

- (a) review and evaluation of market practices and trends on remuneration matters;
- (b) recommendations to the Board about the Company's remuneration policies and procedures;
- (c) oversight of the performance of senior management and non-executive Directors;
- (d) recommendations to the Board about remuneration of senior management and non-executive Directors; and
- (e) reviewing the Company's reporting and disclosure practices in relation to the remuneration of Directors and senior executives.

Meetings will be held at least once a year and more often as required.

# 3.9 Nominations committee

The purpose of this committee is to assist the Board and make recommendations to it about the appointment of new Directors (both executive and non-executive) and senior management. Its current members are:

- (a) Mel Bridges (Committee Chair)
- (b) Jay Hetzel; and
- (c) Iain Ross.

The committee's functions include:

(a) development of criteria (including skills, qualifications and experience) for Board candidates;

- (b) identification and consideration of possible candidates, and recommendation to the Board;
- (c) ensuring appropriate induction and continuing professional development programs are implemented for Directors;
- (d) review of processes for succession planning for the Board, CEO and other senior executives;
- (e) establishment of procedures, and recommendations to the Chairman, for the proper oversight of the Board and management; and
- (f) ensuring the performance of each Director, and of senior management, is reviewed and assessed each year using procedures adopted by the Board.

Meetings will be held at least once a year and more often as required.

## 3.10 Policies

#### Securities Trading Policy

A securities trading policy (Trading Policy) has been adopted by the Board to provide guidance to Directors, identified employees including senior management, and other employees of Anatara, where they are contemplating dealing in Anatara's securities or the securities of entities with whom Anatara may have dealings. The Trading Policy is designed to ensure that any trading in Anatara's securities is in accordance with the law and minimises the possibility of misperceptions arising in relation to Directors' and employees' dealings in Anatara's securities or securities of other entities.

The Trading Policy is directed at dealing in Anatara's securities by the Directors and employees, dealings through entities or trusts controlled by a relevant person, or in which they have an interest, and encouraging family or friends to so deal. It also extends to addressing dealings in the securities of other entities that may be transacting with, or be counterparties of, Anatara.

Any non-compliance with the Trading Policy will be regarded as an act of serious misconduct. The Trading Policy is available on Anatara's website at http://anataralifesciences.com.

#### Continuous Disclosure Policy

The Board has adopted a continuous disclosure policy (Disclosure Policy), which sets out procedures to be adopted by the Board to ensure Anatara complies with its continuous disclosure obligations to keep the market fully informed of information which may have a material effect on the price or value of the Company's securities and to correct any material mistake or information in the market.

The Board is responsible for determining whether information is such that it would have a material effect on the price or value of Anatara's securities. The Disclosure Policy provides a framework for the Board and officers of Anatara to internally identify and report information which may need to be disclosed and sets out practical implementation processes in order to ensure any identified information is adequately

communicated to ASX and Shareholders. The Disclosure Policy also sets out the exceptions to the disclosure requirements.

Any non-compliance with the Disclosure Policy will be regarded as an act of serious misconduct. The Disclosure Policy is available on Anatara's website at http://anataralifesciences.com.

#### Diversity Policy

Anatara is committed to complying with the diversity recommendations published by ASX and promoting diversity among employees, consultants and senior management, and has adopted a policy in relation to diversity (Diversity Policy).

Anatara defines diversity to include, but not be limited to, gender, age, disability, ethnicity, marital or family status, religious or cultural background, sexual orientation and gender identity.

The Diversity Policy adopted by the Board outlines Anatara's commitment to fostering a corporate culture that embraces diversity and provides a process for the Board to determine measurable objectives and procedures to implement and report against to achieve its diversity goals.

Anatara's Nominations Committee is responsible for implementing the Diversity Policy, setting the Company's measurable objectives and benchmarks for achieving diversity and reporting to the Board on compliance with the Diversity Policy.

As part of its role, Anatara's Remuneration Committee is responsible for formulating and implementing a Company remuneration policy. Under the Diversity Policy, a facet of this role will include reporting to the Board annually on the proportion of men and women in Anatara's workforce and their relative levels of remuneration.

The Board will assess and report annually to Shareholders on Anatara's progress towards achieving its diversity goals.

The Diversity Policy is available on Anatara's website at http://anataralifesciences.com.

# 3.11 Compliance with ASX Corporate governance principles and recommendations

The ASX document, 'Third Edition Principles of Good Corporate Governance and Best Practice Recommendations' (**Guidelines**) were published by the ASX Corporate Governance Council with the aim of enhancing the credibility and transparency of Australia's capital markets. Anatara's corporate governance charter has been drafted in light of the Guidelines.

The Board has assessed Anatara's current practice against the Guidelines and outlines its assessment below:

Compliance

Comply

#### Principle 1 - Lay solid foundations for management and oversight

1.1 Establish the functions expressly reserved to the Board and those delegated to management, and disclose those functions.

The Board is responsible for overall corporate governance of the Company.

Complies.

The role of the Board and delegation to management have been formalised in the Charter which outlines the main corporate governance practices in place for the Company and to which the Board and each Director are committed. The conduct of the Board is also governed by the Constitution, and where there is inconsistency with that document, the Constitution prevails to the extent of the inconsistency. The Charter will be reviewed and amended from time to time as appropriate taking into consideration practical experience gained in operating as a listed company.

1.2 Undertake appropriate checks before appointing a person as a director, and provide shareholders with all material information relevant to a decision on whether or not to elect or re-elect a director.

The Company has completed police checks, insolvency and banned director searches in relation to the existing directors. The Company will conduct appropriate checks for future appointments.

Complies.

1.3 Have a written agreement with each director and senior executive setting out the terms of their appointment.

The Company has entered into written agreements with each director and senior executive.

Complies.

1.4 The company secretary should be accountable directly to the board on all matters to do with the proper functioning of the board.

This is consistent with the Charter and corporate structure of the Company. The Company Secretary has a direct relationship with the Board in relation to these matters and operates independently of the executive.

#### Compliance

#### Comply

1.5 Establish a diversity policy and disclose the policy or a summary of that policy. The policy should include requirements for the Board to establish measurable objectives for achieving gender diversity and for the Board to assess annually both the objectives and progress in achieving them, for reporting against in each reporting period.

The diversity policy for the company has only recently been implemented and accordingly, the Company has not reported on measurable objectives in any annual report to date.

Does not comply, however, in accordance with the policy the Company intends to disclose the measurable objectives for achieving gender diversity in each annual report and the Company's progress in achieving diversity objectives.

1.6 Have a process for periodically evaluating the performance of the Board, its committees and individual directors, and disclose that process and, at the end of each reporting period, whether such performance evaluation was undertaken in that period.

The Board Charter provides for regular performance reviews to be conducted.

Does not comply, however, in accordance with the Charter the Company intends to evaluate performance of the Board and disclose for each reporting period whether an evaluation has been undertaken.

1.7 Have a process for periodically evaluating the performance of the company's senior executives, and disclose that process and, at the end of each reporting period, whether such performance evaluation was undertaken in that period.

The Board's broad function is to chart strategy and set financial targets for the Company, monitor the implementation and execution of strategy and performance against financial targets, appoint and oversee the performance of executive management, and generally to take an effective leadership role in relation to the Company.

The Chairman, with assistance from the Nominations
Committee, annually assesses the performance of Directors and senior executives, and the Chairman's performance is assessed by the other Directors.

#### Compliance

#### Comply

#### Principle 2 - Structure the Board to add value

2.1 The Company should have a nomination committee, which has at least three members, a majority of independent directors and is chaired by an independent director.

The functions and operations of the nomination committee should be disclosed.

has been established with its own Charter and consists of Mel Bridges (committee chair), Jay Hetzel and Iain Ross. The Nominations Committee partially complies with recommendation 2.4, which recommends that the committee have at least three members, the majority of whom must be independent.

A Nominations Committee

Given the current nature and scale of Anatara's activities, the Company considers it appropriate that Mel Bridges chair the Nominations Committee.

2.2 Have and disclose a board skills matrix, setting out what the board is looking to achieve in its membership.

The Company has established charter rules for the Nominations Committee as a guide for Board deliberations. Together, the Directors have a broad range of experience, expertise, skills, qualifications and contacts relevant to the Company and its business.

Does not presently comply, however the Board intends to formalise a skills matrix.

2.3 Disclose the names of the directors that the Board considers to be independent directors, and an explanation of why the Board is of that opinion if a factor that impacts on independence applies to a director, and disclose the length of service of each director.

The Board considers each of the following directors to be independent:

lain Ross (appointed 7 February 2014)

Tracie Ramsdale (appointed 4 August 2014)

Jay Hetzel (appointed 4 August 2014)

The Board notes the following directors are deemed not independent for the purposes of the Guidelines:

Mel Bridges (appointed 15 July 2010) – Mel is a founding shareholder of the Company and has a significant shareholding.

David Venables (appointed 17 February 2014) - David is an executive director.

#### **Principles and Recommendations** Comply 2.4 A majority of the Board should The Company currently has a Complies. be independent directors. 5 member Board, of whom 3 are independent non-executive Directors. 2.5 The chair of the Board should The Chairman, Mel Bridges, Does not comply, however be an independent director and is a non-executive Director, the Board believes the should not be the the CEO. however he is deemed not to be deemed non-independence of the Chairman does not independent. impede proper oversight of the Managing Director by The Company's Managing Director, David Venables, is the Chairman and the Board not the same individual as the which comprises a majority of Chairman. independent directors. 2.6 This is consistent with the There should be a program Complies. for inducting new directors Board Charter and processes and providing appropriate implemented by Anatara. professional development opportunities for directors to develop and maintain the skills and knowledge needed to perform their role as a director effectively.

#### Principle 3 - Act ethically and responsibly

3.1 Have a code of conduct for the Board, senior executives and employees, and disclose that code or a summary of that code.

The Company has adopted a code of conduct, which sets out a framework to enable Directors to achieve the highest possible standards in the discharge of their duties and to give a clear understanding of best practice in corporate governance.

Compliance

Comply

#### Principle 4 - Safeguard integrity in corporate reporting

4.1 The Company should have an audit committee, which consists of only non-executive directors, a majority of independent directors, is chaired by an independent chairman who is not chairman of the Board, and has at least three members.

The functions and operations of the audit committee should be disclosed.

- 4.2 The Board should, before approving financial statements for a financial period, receive a declaration from the CEO and CFO that, in their opinion, the financial records have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the Company, formed on the basis of a sound system of risk management and internal controls, operating effectively.
- 4.3 The Company's auditor should attend the AGM and be available to answer questions from security holders relevant to the audit.

The Company has established an Audit and Risk Management Committee to assist and report to the Board.

The Audit and Risk Management Committee consists of Tracie Ramsdale (committee chair), Jay Hetzel and Iain Ross, all independent Directors and will be chaired by an independent Director who is not the Chairman.

This is consistent with the approach to be adopted by the audit committee and Board.

Anatara's auditor with be requested to attend the AGM and shareholders will be entitled to ask questions in accordance

with the Corporations Act and

these Guidelines.

Complies.

Complies.

Complies.

#### Principle 5 - Make timely and balanced disclosure

5.1 Have a written policy for complying with continuous disclosure obligations under the Listing Rules, and disclose that policy or a summary of it.

Anatara has a written continuous disclosure policy which is designed to ensure that all material matters are appropriately disclosed in a balanced and timely manner and in accordance with the requirements of the ASX Listing Rules.

Compliance

Comply

#### Principle 6 - Respect the rights of security holders

6.1 Provide information about the Company and its governance to investors via its website.

The Board Charter and other applicable policies are available on the Company's website.

Complies.

6.2 Design and implement an investor relations program to facilitate effective two-way communication with investors.

The Company aims to ensure that all Shareholders are well informed of all major developments affecting the Company and that the full participation by Shareholders at the Company's AGM is facilitated.

Does not presently comply, however the Company is consulting with its investor relations adviser to implement an effective program.

6.3 Disclose the policies and processes in place to facilitate and encourage participation at meetings of security holders.

The Company intends to facilitate effective participation in the AGM, as well as the ability to submit written questions ahead of the AGM. The Company intends to adopt appropriate technologies to facilitate the effective communication and conduct of general meetings.

The Company has not disclosed a formal policy or process, but has however engaged recognised and reputable share registry service provider and investor relations consultant to further these objectives.

6.4 Give security holders the option to receive communications from, and send communications to, the Company and its share registry electronically.

The Company has instructed its share registry to facilitate this option for investors, as well as future shareholders at appropriate times.

Complies.

## Principle 7 - Recognise and manage risk

7.1 The Board should have a risk committee which is structured so that it consists of a majority of independent directors, is chaired by an independent director, and has at least three members.

The functions and operations of the risk committee should be disclosed.

The Company has a combined Audit & Risk Committee. See above for independent status of the committee members.

The functions and operations of the Committee are established under the Charter. Does not comply to the extent that the Company does not have a separate risk committee, however the Board has formed the view that the audit and risk committee is appropriately structured and independent from the Chairman and executive to effectively fulfil its role.

Principles and Recommendations		Compliance	Comply	
7.2	The Board or a committee of the Board should review the entity's risk management framework with management at least annually to satisfy itself that it continues to be sound, and disclose, in relation to each reporting period, whether such a review has taken place.	The Charter establishes the role of the committee. the committee will establish the risk management framework.	Does not comply to the extent that the committee has newly formed and not conducted an annual review.	
7.3	Disclose if the Company has an internal audit function, how the function is structured and what role it performs, or if it does not have an internal audit function, that fact and the processes the Company employs for evaluating and continually improving the effectiveness of its risk management and internal control processes.	Due to the Company's limited number of employees and relative nature and scale of its operations, the costs of an independent audit function would be disproportionate. The Company has an external auditor and the audit and risk committee will monitor and evaluate material or systemic issues.	Does not comply due to the nature and scale of operations, however the Board believes it and the audit & risk committee have adequate oversight of the existing operations.	
7.4	Disclose whether the Company has any material exposure to economic, environmental and social sustainability risks and, if it does, how it manages those risks.	The Board does not believe the Company has any such material risks. The Company must operate in accordance with the regulatory and ethical standards prescribed by the APVMA in Australia and other relevant regulators overseas.	Complies.	

#### Compliance

#### Comply

#### Principle 8 - Remunerate fairly and responsibly

8.1 The Board should have a remuneration committee which is structured so that it consists of a majority of independent directors, is chaired by an independent director, and has at least three members.

The functions and operations of the remuneration committee should be disclosed.

The Board has established a Remuneration Committee to assist the Board to discharge its responsibilities in relation to remuneration and issues relevant to remuneration policies and practices, including those for senior management and non-executive Directors.

The remuneration committee consists of Iain Ross (committee chair), Mel Bridges and Jay Hetzel. It consists of a majority of independent directors, is chaired by an independent director who is not the Chairman, and has at least three members.

The composition and role of the Remuneration Committee is set out in the Remuneration Committee charter.

8.2 The policies and practices regarding the remuneration of non-executive directors, and the remuneration of executive directors and other senior executives, should be separately disclosed.

The Company intends to adopt remuneration policies which comply with the Guidelines including separately disclosing the remuneration of non-executive directors, and the remuneration of executive directors and other senior executives.

No senior executive is involved directly in deciding their own remuneration.

Complies.

Does not presently comply, however the company intends to disclose these policies in its future annual reports.



Chapter 4

# Financial information

#### 41 Introduction

This financial information section summarises Anatara's selected consolidated financial data derived from audited consolidated financial statements for the years ended 30 June 2012, 30 June 2013, and 30 June 2014, and in addition to a pro forma balance sheet as at 30 June 2014.

The financial information has been prepared in Australian Dollars and in accordance with Australian Accounting Standards (including Australian Accounting Interpretations), other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act.

This section contains the following financial information:

- (a) the Historical Consolidated Statement of Profit or Loss and Other Comprehensive Income for the financial years ended 30 June 2012, 30 June 2013 and 30 June 2014;
- (b) the Historical Consolidated Statement of Cash Flows for the financial years ended 30 June 2012, 30 June 2013 and 30 June 2014; and
- (c) the Historical and Pro Forma Consolidated Statement of Financial Position as at 30 June 2014; which assumes completion of the transactions set out in section 4.7 as at that date, including the Offer under this Prospectus.

The Historical and Pro Forma Financial Information have been reviewed by Grant Thornton Corporate Finance Pty Ltd, whose Independent Limited Assurance Report is contained in section 6.

The information set out in this Section and Anatara's selected consolidated financial information should be read together with:

- management's discussion & analysis set out in sections 1 to 2;
- the risk factors described in section 5;
- the use of funds described in section 9.3;
- the Independent Limited Assurance Report on the Historical and Pro Forma Financial Information set out in section 6; and
- the other information contained in this Prospectus.

In addition, investors should be aware that past performance is not an indication of future performance.

# 4.2 Audited and reviewed financial statements

Anatara's audited consolidated financial statements for the years ended 30 June 2012, 30 June 2013 and 30 June 2014 were audited by Grant Thornton Audit Pty Limited, and unqualified opinions with an emphasis of matter in relation to going concern issued.

# 4.3 Management's discussion & analysis of the historical financial information

# Key components of Anatara's Historical Financial Information

Anatara is still in the early stages of commercialisation and consequently, its operating results predominantly consist of research grants, research expenses, legal costs relating to patent maintenance, costs and professional fees associated with commencing the initial public offering process and general and administrative costs.

No historical costs in relation to its intellectual property development have been capitalised.

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

	FY2012 Audited	FY2013 Audited	FY2014 Audited
	\$	\$	\$
Revenue			
Research grant	110,000	90,000	90,000
Interest income	855	932	12,438
Total Revenue	110,855	90,932	102,438
Overheads			
Research expenses	145,093	130,923	177,439
Employee benefit and director expenses	-	50,000	246,773
Professional fees	-	3,360	180,614
Travel and accommodation	-	49,165	201,461
Patent expense	39,935	39,989	78,678
Other expenses	5,254	2,889	80,329
Total overheads	190,282	276,326	965,294
Profit/(Loss) before income tax	(79,427)	(185,394)	(862,856)
Income tax expense	-	-	-
Profit/(Loss) after tax	(79,427)	(185,394)	(862,856)

The historical consolidated statement of profit or loss and other comprehensive income has been extracted from the audited consolidated financial statements of Anatara for the years ended 30 June 2012, 30 June 2013 and 30 June 2014.

#### Research grant

Anatara owns any intellectual property generated under the three year, ARC awarded Monash University and Anatara research agreement. As such it recognises the benefit of the funding directed to Monash University by the ARC as income. The agreement concludes in November 2014. See sections 2.6 and 8.6 for further details.

# Research and development expenses

Anatara's research costs predominantly relate to costs associated with the Monash University research.

All research and development costs are expensed as incurred. Anatara anticipates that it will continue research and development activities in relation to the re-launch of  $\mathsf{Detach}^\mathsf{TM}$ .

#### Patent costs

Patent spend increased during FY14 to maintain and protect the current intellectual property portfolio.

#### General and administrative expenses

These costs predominantly relate to consultancy fees, travel and administrative overheads in relation to ongoing operations and seeking additional funding. These costs increased during FY13 and FY14 as the Company's activities expanded with the commencement of lain Ross and David Venables.

Other expenses increased during FY14 as Anatara expands the corporate infrastructure with new office space, website development and related costs to support the needs of being a growing public company.

#### Income tax benefit

As Anatara incurs significant research and development expenditure, Anatara is able to access the Federal Government research and development tax incentive grants. As these amounts have yet to be claimed for FY12, FY13 and FY14, these amounts have not yet been recognised in the historical results.

# 4.5 Historical consolidated statement of cash flows

	FY12	FY13	FY14
	Audited	Audited	Audited
Cash Flows from Operating Activities			
Net profit/(loss) before tax	(79,427)	(185,394)	(862,856)
(Increase)/Decrease in trade receivables	(933)	1,178	-
(Increase)/Decrease in other assets	(5,830)	-	2,970
Increase/(Decrease) in trade and other payables	-	6,997	220,620
Net Cash provided by Operating Activities	(86,190)	(177,219)	(639,266)
Cash Flows from Financing Activities			
Proceeds from the issue of shares	-	-	1,750,000
Capital raising costs	-	-	142,934
Proceeds from related party borrowings	125,662	200,297	17,267
Net Cash Flows from Financing Activities	125,662	200,297	1,624,333
Net (decrease)/increase in cash and cash equivalents	39,472	23,078	985,067
Cash at the beginning of the period	3,465	42,937	66,015
Cash at the end of the period	42,937	66,015	1,051,082

The historical consolidated statement of cash flows has been extracted from the audited consolidated financial statements of Anatara for the years ended 30 June 2012, 30 June 2013 and 30 June 2014.

# Cash flow from operating activities

Historically, cash flows from operating activities have been negative due to the significant research and development, selling and general and administrative expenses.

#### Cash flow from financing activities

Finance activities include \$363,000 of funding provided by related parties (see Share Capital note in section 4.6 for further details) and \$1.75 million as part of the pre IPO capital raise.

At 30 June 2014, Anatara had cash and cash equivalents of \$1,051,000.

# 4.6 Historical and pro forma consolidated statement of financial position

The pro forma statement of financial position set out below has been prepared to illustrate the effects of the pro forma adjustments set out below and in section 4.7, as if they had occurred on or before 30 June 2014:

		As at 30 June 2014			
		Audited	Adjustments	Pro forma	
	Notes	\$	\$	\$	
Current Assets					
Trade and other receivables		456	-	456	
Cash and cash equivalents	(a), (b)	1,051,082	6,399,273	7,450,355	
Other assets		2,860	-	2,860	
Total Current Assets		1,054,398	6,399,273	7,453,671	
Total Assets		1,054,398	6,399,273	7,453,671	
Current Liabilities					
Trade and other payables		227,617	-	227,617	
Total Current Liabilities		227,617	-	227,617	
Total Liabilities		227,617	-	227,617	
Net Assets		826,781	6,399,273	7,226,054	
Equity					
Share capital	(a), (b)	1,971,292	6,519,763	8,491,055	
Accumulated losses	(b)	(1,144,511)	(120,490)	(1,265,001)	
Total equity		826,781	6,399,273	7,226,054	

The historical consolidated statement of financial position has been extracted from the audited consolidated financial statements for the year ended 30 June 2014.

The pro forma consolidated statement of financial position as at 30 June 2014 reflects the pro forma transactions, the application of the funds from the Offer less the costs associated with the Offer.

## Share capital

At 14 April 2014, \$341,000 of borrowings payable to Parma Corporation Pty Ltd, a director related entity, was converted to 215 fully paid ordinary shares (which was subsequently subdivided to 322,500 shares following shareholder approval for a 1:1,500 share split). \$22,000 of borrowings payable to Azalea Consulting Pty Ltd, an entity related to a previous director, was also converted to equity.

During FY14, a pre IPO capital raise successfully raised \$1.75 million (1,750,000 fully paid ordinary shares at \$1.00 each).

# 4.7 Pro forma adjustments

The following transactions and events contemplated in this Prospectus, referred to as the Pro forma Adjustments, which are to take place on or before the completion of the Offer are presented as if they together with the Offer had occurred on or before 30 June 2014 and are set out below:

#### Subsequent events

(a) The Company has resolved to subdivide 4,750,000 ordinary shares to 23,750,000 ordinary shares (i.e. five shares for every one existing share).

#### · Pro forma adjustments

- (a) The issue of 14,000,000 fully paid ordinary shares at \$0.50 each, amounting to \$7 million.
- (b) Cash expenses associated with the offer (including advisory, legal, accounting and administrative fees), are estimated to be \$811,000 (inclusive of GST), per Section 9.3. Of this, \$210,000 has already been incurred in the year ending 30 June 2014. Of the remainder \$601,000, \$480,000 has been charged against issued capital, and \$121,000 against accumulated losses. GST in respect of the offer costs has not been recorded as a trade receivable as these may not be claimable from the ATO.

# Pro forma notes and summary of significant accounting policies

# Pro Forma Cash and cash equivalents

The pro forma cash and cash equivalents as at 30 June 2014 reflects the pre IPO capital raise and net proceeds of the Offer as set out below:

		Pro forma
		Subscription
	Note	\$
Cash and cash equivalents at 30 June 2014		1,051,082
Pro forma transactions:		
Proceeds from the shares issued under the Offer	(a)	7,000,000
Payment of the Offer costs	(b)	600,727
Pro forma cash and cash equivalents		7,450,355

#### Pro Forma Share capital

The pro forma cash and cash equivalents as at 30 June 2014 reflects the pre IPO capital raise and net proceeds of the Offer as set out below:

		Pro forma Subscription
	Note	\$
Share capital at 30 June 2014		1,971,292
Subsequent events:		
Share subdivision of five shares for every one existing shares		
Pro forma transactions:		
Proceeds from the shares issued under the Offer	(a)	7,000,000
Capital raising costs	(b)	(480,237)
Pro forma share capital		8,491,055

#### Pro forma Accumulated Losses

The pro forma accumulated losses as at 30 June 2014 reflects the Offer costs allocated to accumulated losses:

		Pro forma Subscription
	Note	\$
Accumulated losses at 30 June 2014		(1,144,511)
Pro forma transactions:		
Offer costs expensed (cash)	(b)	(120,490)
Pro forma accumulated losses		(1,265,001)

# 4.8 Significant accounting policies

#### Basis of presentation and use of estimates

The historical and pro forma financial information included in this Prospectus has been presented in accordance with Australian Accounting Standards (including Australian Accounting Interpretations), other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act.

#### Going concern basis of accounting

The historical and pro forma financial information included in this Prospectus was prepared on a going concern basis that contemplates the realisation of assets and discharge of liabilities in their normal course of business.

The Company has incurred a net loss for the years ended 30 June 2012, 30 June 2013 and 30 June 2014, negative operating cash flows from operations and has accumulated losses, therefore material uncertainty exists regarding going concern. The directors have performed a review of the cash flow forecasts and have considered the cash flow needs of the Company. Management expects operating losses and negative cash flows will continue for the foreseeable future and anticipates that expenses will increase from current levels because of additional expenses related to research and development and commercial activities.

In December 2013 to April 2014, Anatara raised \$1.75 million of seed funding to progress the development of Detach<sup>TM</sup>, its intellectual property, within the Australian market. It intends to raise additional capital to finance the development of Detach<sup>TM</sup> in Europe and the United States as these markets are much larger and profitable for the Company. In the event that capital is not raised, Anatara will need to seek other sources of funding and adjust its expenses from operations.

The historical and pro forma consolidated financial information included in this Prospectus does not include any adjustments to reflect the possible future effects of the recoverability and classification of assets and liabilities that may result from the possible inability to continue as a going concern if the capital raising the subject of this Prospectus or other funding is not successful.

#### Cash and cash equivalents

Cash comprises cash on hand and demand deposits. Cash equivalents are short term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

## Revenue recognition

Grant income is recognised when Anatara determines that it will comply with the conditions attached to the grant and that the grant will be received. The funding is recognised on a systematic basis over periods in which the entity recognises as expenses the costs related to the grant.

## Research and development

Research and development costs are recognised as an expense when incurred.

# 4.9 Dividend policy and forecast distribution

Payment of dividends by the Company depends upon the availability of distributable earnings, and the Company's franking credit position, operating results, available cash flows, financial condition, taxation position, future capital requirements, general business and financial conditions, and other factors the Directors consider relevant. The Directors give no assurances about the payment of dividends, the extent of payout ratios or the future level of franking of dividends.

No dividend is anticipated to be paid in the short to medium term following quotation of the shares in the Company on ASX.



Chapter 5

# Risk factors

# 5.1 Factors influencing success and risk

#### Introduction

This section identifies the major risks the Board believes are associated with an investment in Anatara.

The Anatara business is subject to risk factors, both specific to its business activities, and risks of a general nature. Individually, or in combination, these might affect the future operating performance of Anatara and the value of an investment in the Company. There can be no guarantee that Anatara will achieve its stated objectives or that any forward-looking statements will eventuate. An investment in the Company should be considered in light of relevant risks, both general and specific. Each of the risks set out below could, if it eventuates, have a material adverse impact on Anatara's operating performance and profits, and the market price of the Shares.

Before deciding to invest in the Company, potential investors should:

- (a) read the entire Prospectus;
- (b) consider the assumptions underlying the risk factors that could affect the financial performance of Anatara;
- (c) review these factors in light of their personal circumstances; and
- (d) seek professional advice from their accountant, stockbroker, lawyer or other professional adviser before deciding whether to invest.

# 5.2 Specific investment risks

# New formulation of Detach™ is in development and not approved for commercial sale

Anatara's ability to achieve profitability is dependent on a number of factors, including its ability to complete successful field trials and obtain regulatory approval for the new formulation of Detach $^{\text{TM}}$ , and successfully commercialise Detach $^{\text{TM}}$ . There is no guarantee that Detach $^{\text{TM}}$  will be commercially successful.

The new formulation of Detach<sup>TM</sup> is still in development. It has not generated any product sales for the Company, with product revenues not anticipated for at least two years. Although the previous formulation of Detach<sup>TM</sup> was marketed and sold in 1991, the new formulation requires significant additional development, including field trial testing and regulatory approval prior to commercial use, and there is no guarantee that the new formulation will obtain regulatory approval, perform as anticipated, or, if successful, be manufactured in commercial quantities at reasonable costs.

As field trials on both the new and old formulation of Detach<sup>TM</sup> have been focused on the application to pigs (with a limited trial in calves), there is also no supporting data to show that  $Detach^{TM}$  will have successful application to other animals or humans.

There are many reasons why initially promising products fail to be successfully commercialised. For example, field trials may be suspended for safety or efficacy reasons, following development it may prove difficult or impossible to manufacture  $\mathsf{Detach}^\mathsf{TM}$  on a large scale, or during the period of development competitors (including those with greater resources) may emerge with competing or alternative treatments.

#### Market failure

The Company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales, to fund sufficient revenues for continued operations and growth, may not be achieved.

#### Field trial risk

The development of therapeutic products is inherently risky and subject to factors beyond Anatara's control. The industry is highly regulated, subject to competition and reliant on the timely availability of field trial sites. Anatara may be unable to secure necessary approvals from regulatory agencies and other collaborators to conduct field trials.

There is also no assurance that products developed using Anatara's technology will prove to be safe and efficacious in field trials, or that the regulatory approval to manufacture and market its products will be received. Field trials might also potentially expose Anatara to product liability claims in the event its products in development have unexpected effects in the field or on persons handling Detach<sup>TM</sup> during field trials.

#### Regulation

The research, development, manufacture and sale of products using Anatara's technology, particularly to the extent such technology is to be used in products for human consumption, are subject to varying degrees of regulation by a number of government authorities in Australia and overseas, including but not limited to the APVMA, EMA and FDA.

The regulatory framework differs from location to location, which requires a tailored approach in each jurisdiction. The need to adjust the approach may result in delays to the commercialisation of  $Detach^{TM}$ .

All governments reserve the right to amend their policies in relation to drug development. The regulatory environment may be subject to change in one or more jurisdictions and require the Company to adjust its approach, resulting in delays or, in the worst case, preventing the commercialisation of Anatara's products.

The applicable legislative regime which applies to the APVMA, as the relevant regulatory authority for approval of Detach™ in Australia, is subject to changes which came into effect from 1 July 2014. This means that some requirements and processes have not been fully tested and may give rise to the risk of uncertainty, delay or further cost being incurred if the regulatory pathway is different to that anticipated.

In addition, a regulator (in one or more jurisdictions) may decline approval for Anatara to conduct field trials of Detach<sup>TM</sup> (or other products) or impose unfavourable

conditions for ongoing field trials and commercialisation. This would result in significant delays and, potentially, prevent Anatara marketing  $Detach^{TM}$  (or other products) in a particular region.

#### Intellectual property

Anatara's business is to a large extent reliant upon the nature of its to-be registered intellectual property rights, and the Company's success will depend in part on its ability to obtain commercially valuable patent claims and to protect its intellectual property.

Although the Company has registered a US provisional patent for the new formulation of Detach<sup>TM</sup>, additional patent applications will be filed to provide more extensive intellectual property protection. Examination of patents may be expensive and time-consuming, with no guarantee that lodged patent applications will result in issued patents. It may also take longer than expected for patents to issue and, if successful, the claims of any patents that are issued may not provide meaningful protection.

Although the Company has itself conducted patent searches on 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 in non patent literature cannot be searched systematically.

If letters patent are not issued to Anatara, then the value of the Company's intellectual property rights may be significantly diminished. Further, any information contained in patent applications will become part of the public domain, and so will not be protected as confidential information.

The Company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or Anatara may incur substantial costs in asserting or defending its intellectual property rights. Such disputes could substantially delay the development and commercialisation of Detach $^{\mathsf{TM}}$ .

# Commercial manufacturing and distribution capability

New formulation Detach<sup>TM</sup> has not yet been produced on a large scale. Anatara's success is dependent upon its ability, and the ability of its commercial partners, to manufacture Detach<sup>TM</sup> (following regulatory approval) on a commercial scale, with continuity of supply and in accordance with current Good Manufacturing Practices, prescribed by the APVMA and other regulatory authorities. In the event that Anatara or any of its commercial partners discontinue operations or have insufficient capacity, for any reason, this may result in substantial cost and delay.

The Company may also not be able to secure sufficient quantities of the raw products (including bromelain) to manufacture Detach<sup>TM</sup>. This may be due to problems with the supply chain or unforseen events that impact on the quality or quantity of the raw product (pineapple stems) at critical times.

Anatara only has operations in Australia and, therefore, faces potential difficulties in managing and controlling the commercialisation of its products in other countries.

#### Product liability and insurance

In carrying out its work Anatara will potentially face contractual and statutory claims, or other types of claim from customers or suppliers. In addition, Anatara is exposed to potential product liability risks that are inherent in the manufacturing of pharmaceutical products. Consumers, healthcare producers or persons selling products based on Anatara's technology may be able to bring claims against Anatara based on the use of such products in field trials and the sale of products based on Anatara's technology.

As Anatara's business exposes it to potential product liability and professional indemnity risks, which are inherent in the process development and manufacturing of pharmaceutical products, it will be necessary for Anatara to secure certain levels of insurance. There can be no assurance that any future necessary insurance cover will be available to Anatara at an acceptable cost, if at all, or that, in the event of any claim, the level of insurance carried by Anatara now or in the future will be adequate or that a product liability or other claim would not have a material adverse effect on Anatara's profitability and financial condition.

#### Dependence upon key personnel

Anatara depends on the talent and experience of its personnel as its primary asset. There may be a negative impact on Anatara if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel of the Company who leave to work for a competitor may adversely impact the Company. Increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.

#### Risk of delay and continuity of operations

Anatara may experience delay in achieving a number of critical milestones, including securing commercial partners, completion of field trials, obtaining regulatory approvals, manufacturing, product launch and sales. Any material delays may impact adversely upon the Company, including the timing of any revenues under milestone or sales payments.

Anatara may also experience business continuity problems arising from extreme events. As with most businesses, Anatara is reliant on IT systems in its day-to-day operations. An inability to operate such systems would impact the business. This might result, for example, from a computer virus or other cyber attack or from a physical event at its offices.

#### Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. A number of companies, both in Australia

and abroad, may be pursuing the development of products that target the same markets that Anatara is targeting.

Given the current focus on the issue of antimicrobial resistance and need for non-antibiotic alternatives, potential competitors may identify the non-antibiotic market as a growth opportunity and focus greater resources on such activities than may have been the case in the past. Some of these companies may have, or develop, technologies superior to Anatara's own technology, and any such companies may also have substantially greater financial, technical and/or human resources than Anatara to pursue the development of those products.

#### Arrangements with third-party collaborators

Anatara may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of Detach<sup>TM</sup>. These collaborators may be asked to assist with funding or performing field trials, manufacturing, regulatory approvals or product marketing. There is no assurance that Anatara will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals. If Anatara is unable to find a partner, it would be required to develop and commercialise Detach<sup>TM</sup> (and other potential products) at its own expense. This may place significant demands on the Company's internal resources and potentially delay the commercialisation of Detach<sup>TM</sup> (and other products).

#### Special interest groups and adverse public opinion

Government bodies and regulatory agencies require that potential pharmaceutical products are subject to pre-clinical studies, including animal testing, prior to conducting human trials. Such work can be subject to adverse public opinion and has attracted the attention of special interest groups, including those of animal rights activists. There can be no assurance that such groups will not, in the future, focus on Anatara's activities or those of its customers, licensees or collaborators, or that any such public opinion would not adversely affect Anatara's operations.

The pharmaceutical industry is frequently subject to adverse publicity on many topics, including corporate governance, product recalls and research and discovery methods, as well as to political controversy over the impact of novel techniques and therapies on humans, animals and the environment. Adverse publicity about Anatara, its collaborators, its products, or any other part of the industry may hurt Anatara's public image, which could harm its operations, cause its share price to decrease or impair its ability to gain market acceptance for its services.

#### Anatara may need to raise additional funds

The Company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or that it will be able to raise that capital on satisfactory terms. If Anatara is unsuccessful in obtaining funds when required, it may need to delay or eliminate its research and development, commercialisation or manufacturing activities, or other aspects of its business, have to license or sell its technologies on unfavourable terms, or scale down or cease operations. If Anatara raises funds by issuing shares, it may dilute the ownership of existing shareholders.

#### Grant funding

Anatara and its partners may from time to time receive government grants (such as the grant awarded to Monash University and Anatara by the Australian Research Council). These grant monies are typically payable on achievement of certain scientific and commercial milestones. If those milestones are not achieved, grant monies may be suspended. Anatara may also be required to repay some or all of the grant monies if it breaches the terms of the grant, or if it obtains additional funding for the relevant activities from other sources, and in other circumstances. The laws and policies that apply to grant funding are constantly under review. If these laws and policies change, Anatara's access to grant funding may be reduced or cease.

#### Capital structure risk

Following completion of the Offer, the Directors and management team, will retain a significant holding in Anatara and will therefore have a significant influence over the Company, including in relation to resolutions requiring the approval of Shareholders. This collective interest may also have an impact on liquidity (particularly having regard to the escrow arrangements referred to below), as well as acting as a potential deterrent to corporate transactions.

#### Escrow arrangements

Certain shareholders of the Company will be subject to escrow requirements, designed to protect the integrity of the market and allow the Company to develop a track record. This means that certain Shareholders (including the Directors and management team) will not be able to deal with escrowed Shares for a period of up to 24 months. At the end of the escrow period, these Shares will be released from escrow at the same time, which may impact the Company's share price if relevant persons seek to trade their Shares at that time.

## Limited operating history

An investment in Anatara should be evaluated in light of the risks and difficulties often encountered by emerging companies and particularly by such companies in a rapidly evolving and technologically advanced life sciences environment. As there is limited operating history, there is low visibility and predictability of demand for products offered by Anatara within Australia and in any expansion to other countries.

## Speculative nature of investment

Any potential investor should be aware that subscribing for Shares involves various risks. The Shares to be issued pursuant to the Offer carry no guarantees with respect to the payment of dividends, return of capital or market value. The success of the Company is dependent on regulatory processes in Australia and other countries, commercialisation of Detach $^{TM}$  (and other potential products), and market adoption of those products. An investment in Anatara should therefore be considered speculative in nature.

#### 5.3 General investment risks

#### Share market investments

Before the Offer there has been no public market for the Shares. It is important to recognise that, once the Shares are quoted on ASX, their price might rise or fall and they might trade at prices below or above the Offer Price. There can also be no assurance that an active trading market will develop for the Shares.

Factors affecting the price at which the Shares are traded on ASX could include domestic and international economic conditions. In addition, the prices of many listed entities' securities are affected by factors that might be unrelated to the operating performance of the relevant company. Those fluctuations might adversely affect the price of the Shares.

#### General economic conditions

Anatara's operating and financial performance is influenced by a variety of general economic and business conditions including the level of inflation, interest rates and government fiscal, monetary and regulatory policies. Prolonged deterioration in general economic conditions, including an increase in interest rates, could be expected to have a corresponding adverse impact on the Company's operating and financial performance.

#### Accounting standards

Australian accounting standards are set by the Australian Accounting Standards Board (AASB) and are outside the Directors' and Anatara's control. Changes to accounting standards issued by AASB could materially adversely affect the financial performance and position reported in Anatara's financial statements.

#### Taxation risks

Changes to the rate of taxes imposed on Anatara (including in overseas jurisdictions in which Anatara operates now or in the future) or tax legislation generally may affect Anatara and its Shareholders. If the R&D tax rebate is reduced or qualifying conditions are changed, this would have an adverse impact on the Company and may delay the commercialisation of Detach<sup>TM</sup>. In addition, an interpretation of Australian taxation laws by the Australian Taxation Office that differs to Anatara's interpretation may lead to an increase in Anatara's taxation liabilities and a reduction in Shareholder returns.

Personal tax liabilities are the responsibility of each individual investor. Anatara is not responsible either for taxation or penalties incurred by investors.

#### No guarantee of dividend

The ability of Anatara to pay dividends in the future is dependent on many factors, and in particular the outcome of Anatara's field trials and commercialisation of Detach™. This, together with a number of other factors, will impact on the Company's ability to pay a dividend. The Board cannot give any assurance regarding the payment of dividends in the future.

## Litigation

There is a risk that the Company may in future be the subject of or required to commence litigation. There is, however, no litigation currently underway or threatened.

# 5.4 Cautionary statement

Statements contained in this Prospectus may be forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking terminology such as, but not limited to, 'may', 'will', 'expect', 'anticipate', 'estimate', 'would be', 'believe', or 'continue' or the negative or other variations of comparable terminology. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. The Directors' expectations, beliefs and projections are expressed in good faith and are believed to have a reasonable basis, including without limitation, based on the examination of historical operating trends, data contained in the Company's records and other data available from third parties. There can be no assurance, however, that their expectations, beliefs or projections will give the results projected in the forward-looking statements. Investors should not place undue reliance on these forward-looking statements.

Additional factors that could cause actual results to differ materially from those indicated in the forward-looking statements are discussed earlier in this section.



## Chapter 6

Investigating
Accountant's Report
and Financial
Services Guide



Board of Directors Anatara Lifesciences Ltd 433 Logan Road Stones Corner Brisbane, QLD 4120

4 September 2014

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Dear Directors

### INDEPENDENT LIMITED ASSURANCE REPORT ON THE HISTORICAL AND PRO FORMA FINANCIAL INFORMATION AND FINANCIAL SERVICES GUIDE

#### Introduction

We have prepared this Independent Limited Assurance Report at the request of the Directors of Anatara Lifesciences Ltd ("Anatara") for inclusion in a Prospectus ("Prospectus") to be dated on or about 4 September 2014 to be issued by Anatara, in respect of the planned initial public offering on the Australian Securities Exchange.

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

#### Scope

Grant Thornton Corporate Finance has been requested to prepare this report on the following financial information:

#### **Historical Financial Information**

The Historical Financial Information of Anatara, as set out in **Section 4** of the Prospectus comprises the following:

- The consolidated statement of comprehensive income for the years ended 30 June 2012, 30 June 2013 and 30 June 2014;
- The consolidated statement of cash flows for the years ended 30 June 2012, 30 June 2013 and 30 June 2014;
- The consolidated statement of financial position as at 30 June 2014;

(hereafter, the 'Historical Financial Information').

Grant Thornton Corporate Finance Pty Ltd ABN 59 003 265 987 a subsidiary or related entity of Grant Thornton Australia Ltd ABN 41 127 556 389

Holder of Australian Financial Services Licence No. 247140

Grant Thornton Australia Limited is a member firm within Grant Thornton International Ltd. Grant Thornton International Ltd and the member firms are not a worldwide partnership. Grant Thornton Australia Limited, together with its subsidiaries and related entities, delivers its services independently in Australia.



2

The Historical Financial Information has been extracted from the audited financial statements for the years ended 30 June 2012, 30 June 2013 and 30 June 2014, which were audited by Grant Thornton Audit Pty Ltd.

#### **Pro forma Financial Information**

The Pro forma Financial Information as set out in **Section 4.6** of the Prospectus comprises the pro forma consolidated statement of financial position as at 30 June 2014 assuming completion of the Offer and includes the Pro forma Adjustments ("Pro forma Adjustments") as at that date as disclosed in **Section 4.7**,

(hereafter, the 'Pro forma Financial Information').

(collectively the 'Financial Information').

The Financial Information has been prepared in accordance with the stated basis of preparation being the recognition and measurement principles contained in Australian Accounting Standards and the Company's adopted accounting policies. The Financial Information is also presented 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.

This report has been prepared for inclusion in the Prospectus. Grant Thornton Corporate Finance disclaim any assumption of responsibility for any reliance on this report or on the Financial Information to which this report relates for any purpose other than the purposes for which it was prepared. This report should be read in conjunction with the Prospectus.

### **Directors Responsibility for the Historical and Pro Forma Financial Information**

The Directors have prepared and are responsible for the preparation and presentation of the Historical and Pro forma Financial Information. The Directors are also responsible for the determination of the Pro forma Adjustments as set out in **Section 4.7** of the Prospectus. This includes responsibility for such internal controls as the directors determine are necessary to enable the preparation of historical and pro forma 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 Historical and Pro forma Financial Information based on the procedures performed and evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagement ASAE 3450 Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information. Our procedures consisted of reading relevant Board minutes, reading relevant contracts and other legal documents, enquiries of management personnel and the Directors, and analytical and other procedures applied to Anatara's accounting records.



3

#### An instinct for growth

These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance provided is less than that given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion on the Financial Information

#### **Conclusion Statements**

#### Review conclusion on the Financial Information

Based on our independent review, which is not an audit, nothing has come to our attention which causes us to believe that:

- a The Historical Financial Information does not present fairly the Historical Financial Information in accordance with the measurement and recognition (but not all of the presentation and disclosure requirements) of applicable Accounting Standards in Australia;
- b The Pro forma Adjustments do not provide a reasonable basis for the Pro Forma Financial Information;
- c The Pro Forma Financial Information has not been prepared on the basis of the assumptions set out in **Section 4.7** of the Prospectus; and
- d The Pro forma Financial Information does not present fairly the pro forma consolidated statement of financial position as at 30 June 2014 in accordance with the measurement and recognition (but not all of the presentation and disclosure requirements) of applicable Accounting Standards in Australia as if the Pro forma Adjustments set out in **Section 4.7** of the Prospectus had occurred at 30 June 2014.

#### **Independence and 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 report.

#### **Financial Services Guide**

We have included our Financial Services Guide as **Appendix A** to this report. The Financial Services Guide is designed to assist retail clients in their use of any general financial product advice in this report.

Yours faithfully

GRANT THORNTON CORPORATE FINANCE PTY LTD

**NEIL COOKE** 

Partner

MICHAEL CUNNINGHAM
Partner – Audit & Assurance

76



#### **Appendix A (Financial Services Guide)**

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Level 17, 383 Kent Street

This Financial Services Guide is dated 4 September 2014.

#### 1. About us

Grant Thornton Corporate Finance Pty Ltd (ABN 59 003 265 987, Australian Financial Services Licence no 247140) ("Grant Thornton Corporate Finance") has been engaged by Anatara Lifesciences Ltd ("Anatara") to provide a report in the form of Independent Limited Assurance Report for inclusion in a Prospectus dated on or about 4 September 2014 ("the Prospectus") relating to the offer of shares in the Company ("the Issue"). 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 to 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.

#### 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 Licence to assist you in this assessment.



5

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

Grant Thornton Corporate Finance charges fees to produce reports, including this report. These fees are negotiated and agreed with the entity who 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 our fees are charged on a fixed basis. Partners, Directors or employees of Grant Thornton Corporate Finance, Grant Thornton Australia Ltd, or other associated entities, may receive dividends, salary or wages from Grant Thornton Australia Ltd.

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Grant Thornton Corporate Finance has an internal complaint handling mechanism and is a member of the Financial Ombudsman Service (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 the Financial Ombudsman Service who can be contacted at:

PO Box 579 – Collins Street West Melbourne, VIC 8007 Telephone: 1800 335 405

Grant Thornton Corporate Finance is only responsible for this 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.

#### 8. 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



Chapter 7

## Intellectual Property Report

www.LicensingLaw.Net

55 Madison Avenue, 4th floor Morristown, NJ 07960-7397 USA Practice limited to Domestic & International Pharmaceutical Patent law and licensing

25 August 2014

The Board of Directors of Anatara Lifesciences Limited 433 Logan Road, Stones Corner Brisbane QLD 4120 AUSTRALIA

Re: Patent Attorneys' Report on DETACH<sup>TM</sup> 125 - Anatara Lifesciences Limited

Dear Directors:

We provide the following Report on behalf of Anatara Lifesciences Ltd (hereinafter referred to as "the Company"). The report provides details of (i) Australian and foreign patent applications which have been prepared and filed by Pharmaceutical Patent Attorneys, LLC on behalf of the Company, and (ii) Australian and foreign patent applications and issued patents which have been acquired by the Company (items (i) to (ii) here referred to collectively as "the Company Patent Applications").

This report about the Company is provided for information purposes only, and the status summary provided herein is correct to the best of our knowledge at the date of this Report.

#### **Background**

Pharmaceutical Patent Attorneys, LLC was established in 1997. All partners were trained in the internal legal department of at least one major international pharmaceutical manufacturer. All partners are fully qualified to litigate patent cases before The United States Patent & Trademark Office's Patent Trial & Appeal Board and at least one Federal court. Our practice is limited to the pharmaceutical and related industries: animal drugs, vaccines, dietary supplements, medical devices and Active Pharmaceutical Ingredient and Finished Dosage Form manufacturing. Neither Pharmaceutical Patent Attorneys, LLC nor any of its partners has, or is, entitled to any shares in the Company. Pharmaceutical Patent Attorneys, LLC has no other interests in the promotion of the Company. This report has been prepared at the request of the Company, and Pharmaceutical Patent Attorneys, LLC is charging commercial rates for the preparation of this report.

On information and belief, Pharmaceutical Patent Attorneys, LLC has been responsible for the Company's patent filings since the Company's inception, and has prepared and filed, or

PHARMACEUTICAL PATENT ATTORNEYS, LLC +1 (973) 984 6159

reviewed, the patent applications set out in the appended Schedules. Pharmaceutical Patent Attorneys, LLC has prepared all specifications to the best of its abilities based on the information provided, including information provided by the inventors in relation to their knowledge of the prior art.

The members of Pharmaceutical Patent Attorneys, LLC do not claim to have extensive experience in jurisdictions foreign to those in which they hold professional license to practice. To prosecute patent applications in foreign jurisdictions, Pharmaceutical Patent Attorneys, LLC utilizes the services of firms of foreign patent attorneys and agents to assist in the handling of patents and patent applications in countries outside those in which Pharmaceutical Patent Attorneys, LLC attorneys are licensed.

#### **Patents**

Patents are an intellectual property right. Patents are granted by legal jurisdiction (generally by country) for "inventions." Patents grant the patent owner a limited right to exclude others from practicing (importing, making, using, offering to sell or selling) the invention described in the legal "claims" set forth in the patent. A patent right is valid throughout the relevant jurisdiction, and is granted in exchange for a full disclosure to the public (via the patent publication) of a previously-confidential invention.

Patents grant the patentee a right to exclude others from practicing: a patent does not grant the patentee the right to practice. Thus, a patentee may obtain a valid patent on a new invention, yet be unable to legally sell that invention due to blocking patent rights held by a third party. Thus, in planning a new product, it is important to not only plan for filing patents (to prevent unauthorized copying), but also to perform a thorough and reliable search of third party patents (to assure the new patent is not blocked from launch by third-party rights).

Patents may be granted in respect of new or improved products, compositions or processes. Patents are applicable to almost all areas of current scientific and industrial activities, including genetic engineering, diagnostics and therapeutics, including animal and human drug products and methods for treating livestock (medical methods for treating human beings are patentable in many, but not all, commercially-important jurisdictions).

Patents have a finite term. In many countries, the term runs for 20 years from the date of the filing of a complete patent application, subject to the payment of regular maintenance, renewal or annuity fees. In the United States, animal drug patents may qualify for patent term "restoration." "Patent Term Restoration" is an extension of patent term beyond the normal 20 year term. This extension is intended to compensate human drug and animal drug manufacturers for the significant (often years-long) patent term lost due to delay in receiving medicines agency marketing authorization.

As the holder of a patent gains exclusive rights sanctioned by the relevant jurisdiction, patent owners have the rights, subject to the provisions of each jurisdiction's national law, to use their patents to stop competitors from infringing on the exclusive rights to the invention claimed by the patent's legal claims. A patent owner also has the power to grant a third party a license to use the patented invention; often this is done in exchange for the payment of royalties to the patent owner. Determining infringement simply requires comparing the allegedly-infringing product to the patent claims. If the allegedly-infringing product has each and every element

enumerated in the relevant patent claim, then the product infringes that patent claim. (This generally remains true even where the allegedly-infringing product also includes further features not expressly mentioned in the legal claim) If, however, the allegedly-infringing product lacks even a single element enumerated in the relevant patent claim, then the product does not infringe.

Remedies to the patent owner for infringement of a patent vary by country. These include money damages and equitable remedies such as injunctions against the manufacture or importation of infringing goods. Money damages may be calculated as a "reasonable" royalty (a royalty the patentee would have accepted in an arm's-length licensing transaction to license the infringing product). Alternatively, money damages may be calculated as the patentee's lost profits (i.e., profits the patentee would have made, but for the existence of the competing infringing product). Because a patentee ostensibly should enjoy monopoly pricing power, a patentee's unit profit may likely exceed an infringer's unit profit, and indeed may exceed it by a significant margin. Lost profits damages are therefore important because a potential infringer may be liable for paying more than its total profit earned. In the case of generic pharmaceuticals, the patentee's lost profits are often greater than the infringer's top-line Sales.

Injunction against the importation of imported goods is particularly important where the patentee can have the allegedly-infringing products impounded by the national customs agency at the start of patent infringement litigation, and held pending resolution of the litigation. For products with a long shelf life (machinery), such seizure can disrupt an accused infringer's supply chains and customer relationships. For products with a shorter shelf life (animal drugs), the mere act of impounding a product for several years of litigation may result in complete loss of that inventory.

Patents are property rights which, like real property, are capable of sale, conditional transfer (as e.g., collateral for a secured loan), license and the like. A patent and patent application may be in the name of one or more entities; this may be the result of more than one inventor being responsible for the invention, and may result in more than one owner each owning an undivided interest in the entire patent. In most of the world, applications are filed in the name of the assignee owner (typically, a company or employer). In the United States of America, the inventor(s) are the applicants for, and recipients of, patents, but can contractually assign their ownership rights to their employer. Generally, absent specific agreement to the contrary, joint patent owners are considered to hold equal undivided interests in a patent.

Patents need to be obtained in each country where rights are required; there is no such thing as a "World Patent" or "international patent." However, an international treaty (the Paris Convention) mandates that all convention countries recognize as a valid priority date the priority date established by the initial patent application filed in any convention country. (Australia is a signatory to The Paris Convention).

Further, a system administered by The United Nations' World Intellectual Property Office ("WIPO") and established under the Patent Cooperation Treaty (PCT) allows for the central filing and examination of patent applications; after a PCT application has been examined by WIPO, copies of that file may be filed in any signatory State(s) for registration as a national patent in that State(s).

In Europe, the European Patent Convention allows for a single European patent application which covers a wide range of countries in Europe including countries both within the

European Community and outside. Patents often take a long time before they are granted under the above system.

Before grant, a patent is considered to be "pending."

Patents in Australia are granted under the Patents Act 1990, which is a Commonwealth Act and is applicable throughout Australia. The Patents Act requires that the invention is novel and inventive at the priority date of the patent application.

In most jurisdictions, before a patent is granted the application must undergo examination by a national authority, or by a nationally-approved authority (such as WIPO), to ensure that it complies with the laws of that jurisdiction. Thus, there can be no assurance when a patent application is filed in any particular jurisdiction of the scope of its legal monopoly upon grant, the validity of the patent granted, or indeed whether it will be granted at all. The laws governing patents vary somewhat from country to country. Because of differences in patent laws, examination and local practices, the claims granted in one country may be different to those granted in another. While an Australian patent does not provide worldwide rights, the filing of a patent application in Australia (or any other Paris convention signatory) establishes a basic date from which one may define legally-competent prior art. If equivalent patent rights are applied for overseas, the same priority date can apply, provided that the overseas filings are made nationally, or under the PCT, within twelve months from the Paris convention application.

#### **Intellectual Property Strategy**

The nature of the Company's business renders it amenable to protection using several different types of intellectual property. The most commercially-important of these are patents, trade marks, trade secrets and data exclusivity. We discuss each in turn.

#### **Patents**

this time period the provisional filing lapses.

The Company's approach to patent applications includes the initial lodgment of a "provisional" patent disclosure in order to obtain an initial priority date recognized by all Paris convention signatories. The Company intends to file provisional disclosures in The United States Patent & Trademark Office, because in addition to the general benefits available by filing in any Paris Convention signatory state, provisional disclosures filed in The United States enable those disclosures to be effective as prior art against competing third party patent applications as of the provisional filing date. That is, a provisional disclosure filed in the United States may under United States law become effective as prior art upon filing - before the provisional disclosure is published. A provisional disclosure has a lifespan of 12 months, and at the end of

The next step in the patenting procedure is to file an international (Patent Cooperation Treaty, or"PCT") application or one or more national applications, or both. If filed within the one-year life span of a provisional disclosure, then these later filed patent applications may be related to the provisional application by a legal assertion of "priority." The priority claim means the subsequent national or international applications are, for any information which is included in

To learn more about such "secret prior art," *see Federal Circuit Expands Prior Art*, 201 NEW JERSEY LAW JOURNAL 997 (Sept. 27, 2010).

the provisional disclosure, accorded the filing date of the provisional application as the effective filing date. The filing date is relevant for defining the universe of legally-competent prior art, and thus is relevant for assessing the novelty and inventive step of the subject matter of the applications. Thus, the subsequent national or international applications replace the earlier provisional disclosure, whilst retaining the earlier provisional filing date for material which was included in the provisional filing.

The Company intends to file PCT international applications claiming priority from provisional applications. The PCT system normally provides for an international search report and examination process to be undertaken over a period of 18 months after the filing of the PCT patent application. At the end of the 18 month international examination process, national and regional-phase applications may be filed in countries / regions of interest. On information and belief, the Company intends to file applications in Australia, Europe, the United States, Canada, Mexico, Brazil, Japan, The People's Republic of China and South Korea, as well as Russia, Ukraine, Vietnam and the Philippines. Note that these are major pork-producing countries.

European Patents are examined by the European Patent Office (EPO), pursuant to the European Patent Convention (EPC). The following countries are members of the EPC: Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Hellenic Republic, Hungary, Estonia, Spain, Finland, France, United Kingdom, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Malta, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, and, Turkey.

A patent application favorably reviewed and approved in one jurisdiction may be accorded expedited approval in other jurisdictions. For example, if a patent application is approved by The United States Patent & Trademark Office, then the Australian Patent Office, the Canadian Patent Office, the European Patent Office and the Russian Patent Office may expedite their review and issue equivalent patent claims on an expedited basis.

#### **Trade Secrets**

Patent protection requires public disclosure; trade secrets protection requires the opposite - an explicit and conscious effort to retain confidentiality, which in fact keeps the information confidential. The advantage of trade secrets protection is that it is relatively easy to achieve: as long as the Company and its agents and employees keep information confidential it will remain so. The weakness of trade secrets is the ease in which this protection is lost: public disclosure, even if in violation of a trade secrets contract, can destroy trade secrets protection. For example, if an employee presents a conference poster which inadvertently discloses confidential information, that information will likely be deemed non-secret, and thus no longer eligible for legal protection as a trade secret.

The Company advises that a number of aspects of the DETACH<sup>TM</sup> 125 reformulation work are difficult to reverse engineer. These aspects do not bar competition, but make manufacturing a competing product more difficult. The Company intents to maintain such information as trade secret.

Page 6

#### **Trade Marks**

Trade marks are a mechanism for consumer protection; trade marks show consumers who made the product at issue, so consumers can form a reasonable expectation of the product's quality. The nature of the Company's animal health product indicates that trade mark protection could be quite valuable in retaining consumer loyalty. The Company has applied to register the trademarks ANATARA, DETACH and Anatara Lifesciences (in stylized form) for animal and human drugs and dietary supplements and related goods. *See* attached <u>Schedule I</u>. These applications have been accepted in Australia and, contingent on no third party opposing, should be registered in Australia by the end of this calendar year.

Pharmaceutical industry best practices for new product planning entails selecting product and company names, world-wide searching to assure that those names are available for exclusive use in the relevant States, and registering the trademarks in the relevant States.

#### **Regulatory Market Exclusivity and Data Exclusivity**

In The European Community, a new animal drug receives eight (8) years of data exclusivity and a further two (2) years of market exclusivity, for an effective total of ten years. In The United States of America, new animal drug receives four (4) or five (5) years of data exclusivity and a further one (1) year of market exclusivity, for an effective total of 5-6 years. In The United States, simply having a patent will add another 1.5 years of market exclusivity. Thus, in the United States, an animal drug patent may be worth 1.5 years of product profit even if the patent has legal claims so narrow as to provide little market share protection.

#### **Patentability and Patent Validity**

#### Company Applications

Set out below in <u>Schedule II</u> are details of pending patent applications owned by the Company. Set out below in <u>Schedule III</u> are details of previously-granted patents owned by the Company. The portfolio of patents and patent applications listed below in the Schedules is divided by individual patents and applications and, where appropriate, the resultant family of corresponding foreign and international patents or applications based on the same priority document(s).

As noted above, a patent is granted in exchange for a full public disclosure (via a published patent application) of an invention not previously disclosed by anyone to the public. New patent protection is therefore not available for the version of DETACH<sup>TM</sup> which was commercially sold in the past. Similarly, new patent protection is not available for the inventions disclosed in the published patent applications describing various aspects of that publicly-available product.

In contrast, the Company's recent improvements to that old formulation are potentially patentable, provided the patent office finds these improvements provide an "inventive step" (*i.e.*, an unexpected advantage) *viz* the prior art.

Similarly, the Company's next generation products will use unique enzymatic blends that were not used in the old on-market Detach<sup>TM</sup> product. The old version of Detach<sup>TM</sup> not having this new blend of enzymes in it, this improvement is potentially patentable, provided the patent

office finds this new change provides an "inventive step" (i.e., an unexpected advantage) viz the prior art.

Delaying patent filing offers several advantages and at least one disadvantage. The advantages include slowing competition, and maximizing the proportion of patent term which is used for its highest-value use.

Regarding slowing competition, a patent application is, generally speaking, published 18 months after it is filed. Delaying the publication date of a patent application may delay the date competitors can study the Company's technology. This may slow competitors' efforts to design and develop a competitive product.

Regarding patent term allocation, patents generally expire 20 years from the date the first related patent application was filed. Delaying filing the original patent application, thus delays the expiration date of the resulting patent estate. For products which are on-market when the patent is filed, immediate issuance of the patent may prevent competitors from launching competitive products. In contrast, for products (like DETACHTM 125) which enjoy some period of regulatory data exclusivity, that data exclusivity prevents competing product launches for some period of time. During a data exclusivity period, patent protection provides little incremental commercial benefit. Thus, a patentee's limited period of patent protection would, in an economically-optimal scenario, start the day data exclusivity expires, not before. While this optimal scenario is in practice difficult to achieve, manufacturers can approach this optimal scenario by delaying patent filing until the estimated patent issue date roughly coincides with the estimated expiration of regulatory data exclusivity.

Delaying patent filing, however, also carries a key disadvantage: the risk that in that delay period, a third party may publish art which bars the later-filed patent application. Balancing the advantages and disadvantages of filing delay requires familiarity with the regulatory process (to estimate the likely timing of approval and consequent data exclusivity expiration) and familiarity with the rate of innovation in the field (to provide some sense of the risk of an intervening third-party publication).

In the instant case, the Company has filed the patent application(s) on the current DETACH<sup>TM</sup> 125 formula described in <u>Schedule II</u>, while delaying for some time patent applications on the next-generation product with a new enzymatic blend.

As is the case with any patent application, there can be no assurance that the patent application(s) listed in <u>Schedule II</u> will result in the grant of a patent, or that the scope of protection provided by any patent which is granted will be valid or identical to the scope of the currently pending applications.

Information regarding the status of the various patent applications and issued patents referred to in <u>Schedule II</u> and <u>Schedule III</u> was obtained directly from our in-house computer docket database or, if expressly noted, was obtained from publicly-available or proprietary third-party databases.

#### **Examination Results**

Unless otherwise specified in the Schedule, the applications are still pending and awaiting the outcome of the examination procedure.

#### **Infringement by Third Parties**

Eunjin International Biotechnology, Ltd. currently offers for sale PINEX® brand bromelain extract for swine and cattle farming. The Company is currently investigating how to enforce its intellectual property rights against this product.

#### **Infringement of Third Party Rights**

As stated above, a patent grants the patentee a right to exclude others: it does not grant the patentee the right to practice. The exploitation of the inventions described and claimed in the Company's patent applications could conceivably infringe third party rights. Similarly, the use of the Company trademarks outside their registration jurisdiction(s) could infringe third party rights. We would be happy to perform systematic, structured "freedom to operate" searches for potentially relevant third party rights, as and when the Company believes it appropriate.

Sincerely,

PHARMACEUTICAL PATENT ATTORNEYS, LLC

Mark Pohl, Esq.

+1 (973) 984-6159 x 304

**SCHEDULE I : Trademark Registrations** 

Trade Mark	Case Status
ANATARA, in Class 005	Early Notice of Acceptance of Serial No. 1613994 issued 28 April 2014.
	Acceptance should be advertised late August 2014.
	Provided not opposed, and registrations fees paid, mark should be registered in November 2014.
DETACH, in Class 005	Early Notice of Acceptance of Serial No. 1613993 issued 29 April 2014.
	Acceptance should be advertised late August 2014.
	Provided not opposed, and registrations fees paid, mark should be registered in November 2014.
Anatara Lifesciences (stylized), in Class 005	Early Notice of Acceptance of Serial No. 1613992 issued 28 April 2014.
	Acceptance should be advertised late August 2014.
	Provided not opposed, and registrations fees paid, mark should be registered in November 2014.

The Company intends to apply to register the ANATARA trade mark and the Anatara Lifesciences logo worldwide, and the DETACH trade mark in major pork producing countries including, e.g., China, The European Union, USA, Brazil, Japan, Russia, Mexico, Canada, South Korea, Ukraine and India, and perhaps Vietnam, Thailand, Malaysia and The Philippines.

#### SCHEDULE II

#### Pending patent applications owned by the Company

IYNOTT, Tracey L., *Anti-Diarrhea Formulation Which Avoids Antimicrobial Resistance*, rovisional patent disclosure Serial No. US62/041,175, filed 25 August 2014, discloses an oral rmulation of bromelain effective to treat and prevent diarrhea caused by pathogenic bacteria. his formulation does not kill pathogenic bacteria, and thus does not facilitate the proliferation f antibiotic-resistant pathogenic bacteria. An example of this new formulation includes romelain, formulated with BlanonseT sodium carboxymethyl cellulose, citric acid, EpikuronT 35F lecithin oil and EDTA.

an oral formulation of bromelain which prevents certain types of diarrhoea in humans and nimals, while avoiding the risk appurtenant to antibiotic treatment of preferentially selecting for ntibiotic-resistant bacteria. An example of this new formulation includes bromelain formulated ith a proprietary combination of excipients.

Within one year after the provisional application filing date, the Company intends to file ne or more counterpart international patent applications under the Patent Cooperation Treaty.

Pharmaceutical Patent Attorneys, LLC is highly confident that it can, on behalf of the ompany, obtain an issued patent claiming one or more aspects of the aforementioned rovisional patent disclosure.

#### SCHEDULE III

#### Previously-granted patents owned by the Company

MYNOTT, Tracey L., *Use of Enzymes, Especially Bromelain, In the Treatment of Diarrhoea*, Patent Cooperation Treaty Application No. PCT/GB93/01374 (WO94/000147), discloses the use of enzymes, especially proteolytic enzymes such as bromelain, to inhibit the action of heat-labile toxin produced by enterotoxigenic *Escherichia coli*. This patent teaches that the mode of action of *Escherichia coli* heat-labile toxin is virtually identical to that of *Vibrio cholerea* cholera toxin. This patent teaches that these enzymes are therefore useful in the prophylaxis, management and treatment of diarrhoea in humans (e.g., traveler's diarrhoea). This patent provides general legal claims covering the use of enzymes to prevent diarrhoea, and more specific legal claims covering the use of bromelain to prevent diarrhoea.

This patent application was issued as a patent in the following States or, where the patent number below is qualified by an "A" suffix, was applied for without issuance of a final patent.

Australia Patent No. 672986 (B2), claiming priority from Australia patent application No. 4507493 (A)

Austria Patent No. 184200

Canada Patent application No. 2137674

Denmark Patent No. 0671943

European Patent No. 671943

German Patent No. 69326351

Greece Patent No. 3031961

Hong Kong patent application No. 1004193

Japan patent application No. H08503691

New Zealand patent application No. 253748

Singapore patent application No. 42846

Spain Patent No. 2138625

United States Patent No. 5928640, issued 27 July 1999.

Except as specifically noted above, each of these national filings has expired. This information has been compiled using a third-party database of patent status information, without incurring the additional expense needed to make an inquiry to each agent in each State where the patent was filed. This limited inquiry is believed adequate because of the relatively short remaining lifetime of each of these patents.

This patent application was, when originally filed, owned by Cortecs Limited. The Company advises that ownership of and title to this patent family has been transferred from Cortecs Limited to the Company by an Assignment contract.

Page 12

YING, Kai So Thomas, *Microgranular Preparation Useful In The Delivery Of Biologically Active Materials To The Intestinal Regions Of Animals*, Patent Cooperation Ttreaty Application No. PCT/AU87/00270, discloses a microgranular preparation having a core comprising a biologically active material in an immobilised form, the core being encapsulated within a water soluble film and coated with enteric coating comprising an alkali soluble, acid insoluble polymer (i.e., an enteric polymer like Eudragit<sup>TM</sup> copolymers) or a high molecular weight polymer, whose structure is substituted with or contains windows of fatty acids or other material capable of being solubilized by intestinal juices. The patent also teaches methods for increasing animal growth and methods for the treatment of scour in piglets which comprise the administration of an effective amount of the aforementioned microgranular preparation. This animal drug formulation is in certain aspects similar to our own new formulation.

This patent application was issued as a patent in the following States or, where the patent number below is qualified by an "A" suffix, was applied for without issuance of a final patent.

Australia Patent No. 4507493 (A), 672986 (B2).

Austria Patent No. 106242.

Canada Patent No. 1314217.

China Patent No. 1035801 (from China application No. 87106794 A.

Denmark Patent application No. DK236388 (A).

European Patent No. 321481.

German Patent No. 3789965.

Greece Patent application Nos. GR87/1331 (A1) and GR87/1332 (A1).

Hong Kong patent No. HK85096 (A).

Japan patent No. 2798248, claiming priority from Japan published patent application No. JPH02500838 (A).

New Zealand patent No. 221575.

Norway Patent Nos. 300991 and 300252, claiming priority from Norway patent application Nos. NO881755 A and NO944301 A.

Singapore patent No. 42846.

Spain Patent No. 2138625.

This patent application was, when originally filed, owned by Enzacor Technologies Limited. The Company advises that ownership of and title to this patent family has been transferred to the Company by an Assignment.

Except as specifically noted above, each of these national filings has expired. This information has been compiled using a third-party database of patent status information, without incurring the additional expense needed to make an inquiry to each agent in each State where the patent was filed. This limited inquiry is believed adequate because of the relatively short remaining lifetime of each of these patents.



Chapter 8

## Material agreements

#### 8.1 Key documents

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

#### 8.2 Constitution

Below is a summary of the key provisions of Anatara's Constitution. This summary is not exhaustive, nor does it constitute a definitive statement of a Shareholder's rights and obligations.

#### Shares

The Directors are entitled to issue and cancel Shares in the capital of Anatara, grant options over unissued shares and settle the manner in which fractions of a Share are to be dealt with. The Directors may decide the persons to whom, and the terms on which, Shares are issued or options are granted as well as the rights and restrictions that attach to those Shares or options.

The Constitution also permits the issue of preference shares on terms determined by the Directors.

Anatara may also sell a Share that is part of an unmarketable parcel of shares under the procedure set out in the Constitution.

#### Variation of class rights

The rights attached to any class of Shares may, unless their terms of issue state otherwise, only be varied with the consent in writing of members holding at least three-quarters of the Shares of that class, or with the sanction of a special resolution passed at a separate meeting of the holders of Shares of that class.

#### Restricted securities

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

#### Share certificates

Subject to the requirements of the Corporations Act, the Listing Rules or the ASX Settlement Operating Rules, Anatara need not issue share certificates if the Directors so decide.

#### Calls

The Directors may, from time to time, call upon Shareholders for unpaid monies on their shares. The Directors must give Shareholders notice of a call at least 30 business days before the amount called is due, specifying the time and place of payment. If a call is made, Shareholders are liable to pay the amount of each call by the time and at the place specified.

A call is taken to have been made when a Directors' resolution passing the call is made or on any later date fixed by the Board. A call may be revoked or postponed at the discretion of the Directors.

#### Forfeiture and lien

Anatara may forfeit Shares to cover any call, or other amount payable in respect of Shares, which remains unpaid following any notice to that effect sent to a Shareholder. Forfeited Shares become the property of Anatara and the Directors may sell, reissue or otherwise dispose of the Shares as they think fit.

A person whose Shares have been forfeited may still be required to pay Anatara all calls and other amounts owing in respect of the forfeited Shares (including interest) if the Directors so determine.

Anatara has a first and paramount lien for unpaid calls, instalments and related interest and any amount it is legally required to pay in relation to a Shareholder's Shares. The lien extends to all distributions relating to the Shares, including dividends.

Anatara's lien over Shares will be released if it registers a transfer of the Shares without giving the transferee notice of its claim.

#### Share transfers

Shares may be transferred by any method permitted by the Corporations Act, the Listing Rules or the ASX Settlement Operating Rules or by a written transfer in any usual form or in any other form approved by the Directors. The Directors may refuse to register a transfer of Shares where it is not in registrable form, Anatara has a lien over any of the Shares to be transferred or where it is permitted to do so by the Listing Rules or the ASX Settlement Operating Rules.

#### General meetings

Each Shareholder, Director and auditor is entitled to receive notice of and attend any general meeting of Anatara. Two Shareholders must be present to constitute a quorum for a general meeting and no business may be transacted at any meeting except the election of a chair and the adjournment of the meeting, unless a quorum is present when the meeting proceeds to business.

#### Voting rights

Subject to any rights or restrictions attached to any Shares or class of shares, on a show of hands each Shareholder present has one vote and, on a poll, one vote for each fully paid Share held, and for each partly paid Share, a fraction of a vote equivalent to the proportion to which the Share has been paid up. Voting may be in person or by proxy, attorney or representative.

#### Remuneration of Directors

Each Director is entitled to remuneration from Anatara for his or her services as decided by the Directors but the total amount provided to all Directors for their services as Directors must not exceed in aggregate in any financial year the amount fixed by Anatara in general meeting (see section 10.7). The remuneration of a Director (who is not the managing Director or an executive Director) must not include a commission on, or a percentage of, profits or operating revenue.

Remuneration may be provided in the manner that the Directors decide, including by way of non-cash benefits. There is also provision for Directors to be paid extra remuneration (as determined by the Directors) if they devote special attention to the business of Anatara or otherwise perform services which are regarded as being outside of their ordinary duties as Directors or, at the request of the Directors, engage in any journey on Anatara's business.

Directors are also entitled to be paid all travelling and other expenses they incur in attending to Anatara's affairs, including attending and returning from general meetings or Board meetings, or meetings of any committee engaged in Anatara's business.

#### Interests of Directors

A Director who has a material personal interest in a matter that is being considered by the Board must not be present at a meeting while the matter is being considered nor vote on the matter, unless the Corporations Act allows otherwise.

#### Election and retirement of Directors

There must be a minimum of three Directors and a maximum of 12 Directors unless Anatara in general meeting resolves otherwise.

Where required by the Corporations Act or Listing Rules, Anatara must hold an election of directors each year. No Director, other than the managing director, may hold office without re-election beyond the third annual general meeting following the meeting at which the Director was last elected or re-elected. A Director appointed to fill a casual vacancy, who is not a managing Director, holds office until the conclusion of the next annual general meeting following his or her appointment. If there would otherwise not be a vacancy, and no Director is required to retire, then the director who has been longest in office since last being elected must retire.

If a number of Directors were elected on the same day, the Directors to retire is (in default of agreement between them) determined by ballot.

#### Dividends

If the Directors determine that a final or interim dividend is payable, it is (subject to the terms of issue on any Shares or class of Shares) paid on all Shares proportionate to the amount for the time being paid on each Share. Dividends may be paid by cash, electronic transfer or any other method as the Board determines.

The Directors have the power to capitalise and distribute the whole or part of the amount from time to time standing to the credit of any reserve account or otherwise available for distribution to Shareholders. The capitalisation and distribution must be in

the same proportions which the Shareholders would be entitled to receive if distributed by way of a dividend.

Subject to the Listing Rules, the Directors may pay a dividend out of any fund or reserve or out of profits derived from any source.

#### Proportional takeover bids

Anatara may prohibit registration of transfers purporting to accept an offer made under a proportionate takeover bid unless a resolution of Anatara has been passed approving the proportional takeover bid under the provisions of the Constitution.

The rules in the Constitution relating to proportional takeover bids cease on the third anniversary of the adoption of the Constitution, or the renewal of the rules, unless renewed by a special resolution of Shareholders.

#### Indemnities and insurance

Anatara must indemnify current and past Directors and other executive officers (Officers) of Anatara on a full indemnity basis and to the fullest extent permitted by law against all liabilities incurred by the Officer as a result of their holding office in Anatara or a related body corporate.

Anatara may also, to the extent permitted by law, purchase and maintain insurance, or pay or agree to pay a premium for insurance, for each Officer against any liability incurred by the Officer as a result of their holding office in Anatara or a related body corporate.

#### 8.3 Underwriting agreement

Anatara and the Lead Manager and Underwriter have entered into the Underwriting Agreement. In accordance with the terms of the Underwriting Agreement, the Underwriter has agreed to manage the Offer and to underwrite the application for new Shares under the Offer by subscribing for any Shares the subject of the Offer for which valid applications are not received. The Underwriter may also appoint sub-underwriters.

#### Fees and costs

Anatara must pay the Lead manager and Underwriter a fee of 5% (comprising an underwriting fee of 4% and a management fee of 1%) of the underwritten Offer proceeds (\$7 million).

In addition to the fees described above, Anatara has agreed to pay the Underwriter for reasonable out of pocket expenses (including legal fees) in relation to the Offer up to \$30,000.

The Lead Manager and Underwriter has agreed to pay Peloton Capital Pty Ltd 3% of the Offer proceeds co-managed by it (\$2 million). The Company has also agreed to pay a 2% fee to Peloton Capital Pty Ltd of the Offer proceeds managed by it (\$2 million).

#### Termination

As is normal for agreements of this nature, the Underwriter may terminate its obligations under the Underwriting Agreement if certain events occur before the Shares are issued ('Unqualified Termination Events'). In respect of the occurrence of certain other events, the Underwriter's ability to terminate is limited to circumstances in which the Underwriter is of the opinion that the event has had or could be expected to have a material adverse effect on certain factors including (but not limited to) the financial condition of Anatara, the ability of the Underwriter to market or promote the Offer or the price or likely price at which the Shares are likely to trade on ASX ('Qualified Termination Events').

The Unqualified Termination Events include (but are not limited to):

- (a) (index fall) the S&P/ASX 200 Index published by ASX on any trading day before completion of the Offer closes at 10% below its level as at the close of ASX trading on the trading day before lodgment of the Prospectus;
- (b) (supplementary prospectus) the Underwriter forms the view (acting reasonably) that a supplementary prospectus must be lodged with ASIC and Anatara does not lodge the supplementary prospectus as required;
- (c) (material adverse change) a material adverse change, or any development involving a prospective material adverse change occurs in relation to Anatara and its related bodies corporate in the reasonable opinion of the Underwriter, including a change that could result in the success of the Offer being affected to a material degree;
- (d) (offer documents) there is:
  - (i) a material omission from the Prospectus or any supplementary prospectus of material required by the Corporations Act to be included;
  - (ii) an Offer Document (defined in the Underwriting Agreement to mean any documents issued or published by or on behalf of the Company in respect of the Offer, including the Prospectus, the Application Forms, any supplementary prospectus, any written materials that are presented or provided to prospective investors (including roadshow presentations) and any Publication (defined in the Underwriting Agreement to include media statements, announcements and other similar materials)) contains a statement which is misleading or deceptive (whether by inclusion or omission); or
  - (iii) an Offer Document (as defined above) does not contain all information required to comply with Chapter 6D and Chapter 7 of the Corporations Act.
- (e) (conduct) Anatara or any of its Directors or officers engage in any fraudulent conduct or activity or breach the Corporations Act;
- (f) (insolvency) Anatara or any of its related bodies corporate becomes insolvent: and
- (g) (material change) there is a change in the material terms of the Offer as set out in the Prospectus (or any supplementary prospectus) without the prior written approval of the Lead Manager and Underwriter;

The Qualified Termination Events include (but are not limited to):

- (a) (hostilities) in respect of any one or more of Australia, the United States of America, any member state of the EU, or the People's Republic of China:
  (i) hostilities not presently existing commence, (ii) a major escalation in existing hostilities occurs, or (iii) a terrorist act is perpetrated;
- (b) (material adverse change in financial markets) any of the following occurs:
  - (i) any material adverse change or disruption to the political conditions or financial markets of Australia, the United Kingdom, or the United States of America, or a general moratorium on commercial banking activities is declared in those countries; or
  - (ii) trading on ASX, the London Stock Exchange, or the New York Stock Exchange is suspended or limited in a material respect for one day on which that exchange is open for trading,
- (c) (conduct) Anatara or any of its Directors or officers engage in any fraudulent conduct or activity or breach the Corporations Act;
- (d) (timetable) any event specified in the Offer timetable is delayed for more than one business day without the prior written approval of the Underwriter;
- (e) (material contracts) any contract, deed or other agreement which is material to the making of an informed investment decision in relation to the Shares, as referred to in the Prospectus, is terminated or breached by Anatara or a related body corporate; and
- (f) (legal proceedings) the commencement of legal proceedings against Anatara or any Director or any regulatory inquiry or public action against a Director or announcement that such action may be taken.

#### Representations, warranties and undertakings

The Underwriting Agreement contains various representations and warranties made by Anatara and the Underwriter, which are customary in such an agreement. Anatara also provides certain undertakings under the Underwriting Agreement regarding the conduct of Anatara prior to, and for limited periods of time following, the Shares being issued.

#### Indemnity

Anatara agrees to indemnify the Underwriter, each of its related bodies corporate and affiliates and each of its officers, directors, employees, representatives, agents and advisers against all losses, liabilities, claims, damages, costs, charges and expenses whatsoever (including reasonable legal costs on a full indemnity basis) incurred or suffered directly or indirectly arising out of or in connection with the Offer or the Underwriting Agreement, other than losses caused directly by the gross negligence, wilful default, wilful misconduct or fraud of any indemnified party or the Underwriter, except to the extent that the breach is caused or contributed to by Anatara, its related bodies corporate or their directors, officers, advisers, agents or employees.

#### 8.4 DEPI Agreement

Anatara entered into a technical services agreement with the DEPI on 20 August 2014 for the conduct of field trials of Detach™ on commercial pig farms. The DEPI provided a project proposal to Anatara on 20 May 2014, and it was agreed that the DEPI would perform the field trials for Anatara on this basis. Specialist pig veterinarians of the DEPI will perform the trials, and will also be members of the management committee. The management committee will make all decisions regarding the conduct of the research, including the milestones, and must make all decisions unanimously. Dr Tracey Mynott and Dr David Venables from Anatara will also be members of the management committee. Funds for the research project will be payable by Anatara in four equal instalments upon various milestones occurring. All intellectual property created during the course of the project will be owned by Anatara. Usual warranties, limitations of liability and confidentiality provisions are also provided.

#### 8.5 Sphere Agreement

On 5 August 2014 Anatara entered into a manufacturing agreement with Sphere Healthcare Pty Ltd ACN 054 309 705 (Sphere) for the manufacture and supply of the Detach<sup>TM</sup> product. The term of this agreement is for an initial period of 36 months. Sphere may terminate the agreement for convenience by providing twelve months written notice to Anatara, and must then assist with the handover to another manufacturer. Anatara is required to submit purchase orders to Sphere three months in advance, as well as providing twelve month rolling forecasts of its monthly demand for the supply of the product. Subject to Sphere's cost of goods increasing, the prices for the manufacture and supply of the Detach<sup>TM</sup> product to Anatara are valid for each twelve month period of the term. Anatara has the right to access and inspect Sphere's records to verify compliance with this agreement. All existing intellectual property rights of Anatara, as well as any new intellectual property rights created in the course of performing the agreement are owned by Anatara. Usual representations and warranties regarding the performance of the agreement and compliance with laws and regulations (including Good Manufacturing Practice standards) are provided by Sphere.

## 8.6 2011 ARC Linkage Projects Research Agreement

On 22 August 2011, Sarantis, Anatara's wholly owned subsidiary, entered into a research agreement with Monash University to conduct a project titled "Characterisation of plant cysteine proteases with therapeutic potential". The ARC separately entered into a funding agreement with Monash University to provide funding totalling up to \$290,000 for the performance of the project.

Usual representations and warranties are given under the research agreement, and Sarantis indemnifies Monash University against any loss by Monash University resulting from a breach of the funding agreement caused by Monash University's reliance on any

warranty given by Sarantis. New intellectual property rights derived from the project are owned by Sarantis, however Sarantis grants Monash University a non-transferable, royalty-free, non-exclusive right to use the intellectual property for research and educational purposes.

The agreement will expire on 1 November 2014, unless otherwise agreed by the parties.

#### 8.7 Escrow arrangements

Certain Existing Shareholders have been asked to enter into both mandatory restriction deeds (to comply with requirements under the Listing Rules) and voluntary restriction deeds with the Company, restricting them from dealing in the Shares held by them at the date of this Prospectus, until 8 May 2015 or the date which is 24 months from the date of the Company's listing on ASX (depending on the relationship of the Existing Shareholder with the Company).

12,926,095 Shares (which will represent 34.2% of the Shares on issue following completion of the Offer) held by Directors, other related parties, and persons who have received shares from these parties, are subject to escrow for 24 months from the date of Anatara's listing on the ASX. A further 8,170,000 Shares (which will represent 21.6% of the Shares on issue following completion of the Offer) held by other unrelated seed investors are subject to escrow until 8 May 2015.

The restriction deeds are in a form consistent with the Listing Rules and restrict applicable Existing Shareholders from disposing of, creating any security interest in or transferring effective ownership or control of, the restricted Shares.

#### 8.8 Executive service contracts

The Company has entered into executive service agreements with key executives, which contain standard terms and conditions for agreements of this nature, including confidentiality, restraint on competition and retention of intellectual property provisions. The agreements are expressed to cover periods specific to individual appointments, but may generally be terminated by notice by either party, or earlier in the event of certain breaches of the terms and conditions.

In the case of Anatara's Managing Director, David Venables, total salary will be \$250,000. Dr Venables will also be eligible to participate in the companies ESOP.

Details of Directors' fees payable to the other Directors are set out in section 10.7.

#### 8.9 Deeds of indemnity and access

The Company has entered into standard deeds of access, insurance and indemnity with the Directors.

The Company has undertaken, consistent with the Corporations Act, to indemnify each Director in certain circumstances and to maintain Directors' and Officers' insurance cover in favour of the Director for seven years after the Director has ceased to be a Director.

The Company has further undertaken with each Director to maintain a complete set of the Company's Board papers and to make them available to the Director for seven years after the Director has ceased to be a Director.

In addition, Anatara has entered into standard deeds of insurance and indemnity on similar terms to those offered to the Directors, with two of its key officers, being its Chief Scientific Officer, Tracey Mynott, and Company Secretary, Stephen Denaro.

#### 8.10 Employee Share Option Plan (ESOP)

#### Eligibility criteria

The ESOP will be open to eligible participants (including full-time and part time employees, executives, Directors and consultants) of the Company or any of its subsidiaries who the Board designates as being eligible.

#### Grant of options

All options are to be offered to participants for no consideration. The offer must be in writing and specify, amongst other things, the number of options for which the participants may apply, the period within which the options may be exercised and any conditions to be satisfied before exercise, the option expiry date (as determined by the Board) and the exercise price for the options.

#### Exercise

The options may be exercised, subject to any exercise conditions, by the participant giving a signed notice to the Company and paying the exercise price in full. The Company will apply for official quotation of any Shares issued on exercise of any options.

#### Lapse

The options shall lapse upon the earlier of the date specified by the Board or events contained in the ESOP rules, including termination of employment or resignation, redundancy, death or disablement.

#### Rights of participants

Once Shares are allotted upon exercise of the options, the participant will hold the Shares free of restrictions. The Shares will rank for dividends declared on or after the date of issue but will carry no right to receive any dividend before the date of issue.

Should the Company undergo a reorganisation or reconstruction of capital or any other such change, the terms of the options will be correspondingly changed to the extent necessary to comply with the Listing Rules. In the event of a change of control, the Board shall have discretion to deal with the options, including allowing accelerated vesting or the issue of options in the substituted corporation. A holder of options is not entitled to participate in a new issue of Shares or other securities made by the Company to Shareholders merely because he or she holds options.

#### Quotation

The Company must apply for official quotation of any Shares issued.

#### Assignment

The options are not transferable or assignable without the prior written approval of the Board.

#### Administration

The ESOP will be administered by the Board which has an absolute discretion to determine appropriate procedures for its administration and resolve questions of fact or interpretation and formulate special terms and conditions (subject to the Listing Rules) in addition to those set out in the ESOP.

#### Termination and amendment

The ESOP may be terminated or suspended at any time by the Board. The ESOP may be amended at any time by the Board except where the amendment reduces the rights of the holders of options.

#### Outstanding options

At the date of this Prospectus, no options have been offered under the ESOP. The Company therefore has capacity to issue up to 5% of the issued share capital of the Company as options.

## 8.11 Documents available for inspection

Copies of the following documents are available for inspection during normal office hours at the registered office of the Company for 13 months after the date of this Prospectus:

- (a) the constitution of Anatara; and
- (b) the consents to the issue of this Prospectus.



Chapter 9

# Details of the Offer

#### 9.1 Description of the Offer

The Offer comprises a capital raising of \$7 million, by way of an issue of 14 million new Shares at \$0.50 per Share.

The process for applying for Shares under the Offer is set out in section 9.5 below.

Applications must be for a minimum of 4,000 Shares (\$2,000) and in multiples of 1,000 shares (\$500) for amounts above the minimum.

The Shares will rank equally in all respects with the shares held by the Existing Shareholders. The rights and liabilities attaching to all Shares are detailed in the Company's constitution. A summary of the constitution is set out in section 8.2.

#### 9.2 Underwriting

The Offer is underwritten by Wilson HTM Corporate Finance Ltd.

Further details of the Underwriting Agreement, including the circumstances in which the Lead Manager and Underwriter may terminate its obligations, are set out in section 8.3.

## 9.3 What will the proceeds of the Offer be used for?

The table below sets out the proposed use of the proceeds from the Offer. This represents current intentions of the Company based on its current business plan and business conditions. The amounts and timing of the actual expenditure may vary and will depend upon numerous factors, including the timing and success of the pre-clinical work programs and field trials the Company is proposing to undertake.

Use of proceeds	\$ raised
Registration of Detach™ for pigs in Australia	From pre-existing funds
Registration of Detach™ for pigs in EU	1,055,000
Registration of Detach™ for pigs in USA	730,000
Detach™ for humans – further development	392,000
Patent costs	300,000
General administration costs	2,287,000
Personnel costs	1,425,000
Transaction costs	811,000
Total funds raised	7,000,000

The Company has sufficient working capital to carry out its objectives, as detailed in this Prospectus.

#### 9.4 Allocation of Shares

The Lead Manager and Underwriter, after consultation with the Company will allocate Shares to Applicants under the Offer at its discretion.

It is intended that all Shares will be allocated via a broker firm offer. However, the Company may also seek to raise funds as part of a general public offer.

Given the nature of the underwriting arrangements, and intention to achieve the listing of Anatara on ASX, it is not anticipated that any allocation will have a material effect on the control of Anatara.

Where no allocation is made to a particular Applicant or the number of Shares allocated is less than the number applied for by an Applicant, surplus Application Money will be returned to that Applicant. No interest is paid on refunded Application Money. Any interest earned on Application Money is the property of the Company.

Successful Applicants are given written notice of the number of Shares allocated to them as soon as possible after the Closing Date. It is the responsibility of Applicants to confirm the number of Shares allocated to them before trading in Shares. Applicants who sell Shares before they receive notice of the Shares allocated to them do so at their own risk.

If the Company's application for admission to ASX is denied, or for any reason this Offer does not proceed, all Application Money will be refunded in full without interest.

#### 9.5 How to apply

Applications may only be made on the Application Form attached to or accompanying this Prospectus or in its paper copy form as downloaded in its entirety from http://anataralifesciences.com/. Detailed instructions on how to complete the Application Form are set out on the reverse of the Application Form.

The Offer Price is \$0.50 per Share. Applications must be for a minimum of 4,000 Shares (\$2,000) and in multiples of 1,000 shares (\$500) for amounts above the minimum.

Unless received from your broker (see below), you need to complete a paper copy of the Application Form (the Company does not accept Application Forms electronically) and send it, with payment in Australian currency, by the Closing Date to:

Computershare Investor Services Pty Limited GPO Box 52 Melbourne, Victoria 3001

Cheques or bank drafts must be made payable to 'Anatara – Share Offer' and should be crossed and marked 'Not Negotiable'.

Applicants with questions on how to complete the Application Form, or who require additional copies of the Prospectus, can contact the share registry on 1300 850 505 (within Australia) or +61 3 9415 4000 (outside Australia) or visit the website http://anataralifesciences.com/ to download a copy of the Prospectus.

#### Broker firm Applicants

If you have received a firm allocation of Shares from your broker, your application and payment procedures differ in two important respects from those described above:

- (a) your application cheque must be made payable to the broker (not to 'Anatara Share Offer'); and
- (b) your completed Application Form and cheque must be delivered to the broker directly (not to the share registry).

Applicants who receive a firm allocation of Shares must lodge their Application Form and Application Money with the relevant broker under the relevant broker's directions in order to receive their firm allocation. Your broker acts as your agent in submitting your application.

The Company, the share registry and the Lead Manager and Underwriter take no responsibility for any acts or omissions by your broker in connection with your Application, Application Form or Application Money.

The procedure should be explained to you in further detail by your broker. If you have a firm allocation of Shares and are in any doubt about what action to take, you should immediately contact the broker who has made you the firm offer.

#### Investor Directed Portfolio Service

An investor directed portfolio service (IDPS) is an investment reporting service offered by an operator. People who invest through an IDPS are indirect investors.

Investors who gain exposure to the Company through an IDPS master trust or wrap account do not themselves become Shareholders in the Company. It is generally the operator of the investing IDPS (or its custodian or nominee) that becomes a Shareholder. It then exercises its rights as Shareholder under its arrangements with the investor.

Indirect investors complete the application form for the IDPS and receive reports from the operator, not the Company.

When investing through an IDPS master trust or wrap account, indirect investors must complete the documents required by the operator of these services. They are not required to complete the Application Form. Enquiries should be directed to the IDPS operator.

#### Validity of Application Forms

An Application Form may only be distributed with, attached to or accompany a complete and unaltered copy of this Prospectus.

By completing and lodging an Application Form received with this Prospectus, the Applicant represents and warrants that the Applicant has personally received a complete and unaltered copy of this Prospectus before completing the Application Form.

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

An Application Form is an irrevocable acceptance of the Offer.

# 9.6 ASX listing

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

It is expected that trading of the Shares on ASX will commence on or about 21 October 2014.

If permission is not granted for official quotation of the Shares on ASX within three months of the date of this Prospectus, all Application Money received is refunded without interest as soon as practicable under the requirements of the Corporations Act.

### 9.7 CHESS

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

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

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

# 98 Withdrawal

The Company reserves the right to withdraw the Offer, at any time before the allotment of Shares. If the Offer does not proceed, the Application Money is refunded. No interest is paid on any Application Money refunded as a result of the withdrawal of the Offer.

# 99 Taxation considerations

The taxation consequences of an investment in the Company depend upon the investor's particular circumstances. Investors should make their own enquiries about the taxation consequences of an investment in the Company. If you are in doubt as to the course you should follow, you should consult your accountant, stockbroker, lawyer or other professional adviser.

# 9.10 Foreign selling restrictions

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

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

Each Applicant warrants and represents that:

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



Chapter 10

# Additional information

# 10.1 Rights attaching to Shares

The rights attaching to Shares in Anatara are set out in the constitution and summarised in section 8.2 of this Prospectus.

# 10.2 Shareholding qualifications

Directors are not required under the constitution to hold any Shares.

# 10.3 Options

No employee share options or other securities have currently been issued under the terms of the ESOP as summarised in section 8.10. The Company has capacity to issue up to 5% of the issued share capital of the Company as options under the ESOP.

# 10.4 Litigation

To the best of the Director's knowledge and belief, no litigation is currently underway or threatened against the Company.

# 10.5 Consents and disclaimers of responsibility

None of the parties referred to below has made any statement that is included in this Prospectus or any statement on which a statement made in this Prospectus is based, except as specified below. Each of the parties referred to below, to the maximum extent permitted by law, expressly disclaims, and takes no responsibility for, any part of this Prospectus, other than the reference to its name and a statement included in this Prospectus with the consent of that party, as specified below.

Wilson HTM Corporate Finance Ltd has given, and has not withdrawn, its written consent to be named as Lead Manager and Underwriter to the Offer in the form and context in which it is named.

Peloton Capital Pty Ltd has given, and has not withdrawn, its written consent to be named as co-manager to the Offer in the form and context in which it was named.

McCullough Robertson has given, and has not withdrawn, its written consent to be named as lawyers to the Company in the form and context in which it is named.

Grant Thornton Corporate Finance Pty Ltd has given, and has not withdrawn, its written consent to be named as Investigating Accountant, in the form and context in which it is

named and for the inclusion of its Investigating Accountant's Report in section 6 of this Prospectus in the form and context in which it is included.

Grant Thornton Audit Pty Ltd has given, and not withdrawn, its consent to be named as Auditor in the form and context in which it is named.

Pharmaceutical Patent Attorneys, LLC has given, and not withdrawn, its consent to be named in the form and context in which it is named.

Fisher Adams Kelly has given, and not withdrawn, its consent to be named in the form and context in which it is named.

Computershare Investor Services Pty Limited has given, and not withdrawn, its written consent to be named as share registrar in the form and context in which it is named.

# 10.6 Interests of experts and advisers

Except as set out in this Prospectus, no person named in this Prospectus as performing a function in a professional, advisory or other capacity in connection with the preparation or distribution of this Prospectus:

- (a) has any interest or has had any interest during the last two years, in the formation or promotion of Anatara, or in property acquired or proposed to be acquired by Anatara in connection with its formation or promotion, or the Offer of the Shares; and
- (b) no amount has been paid or agreed to be paid, and no benefit has been given, or agreed to be given, to any of those persons in connection with the services provided by the person in connection with the formation or promotion of Anatara, or the Offer of the Shares.

Wilson HTM Corporate Finance Ltd has acted as Lead Manager and Underwriter to the Offer. Wilson HTM Corporate Finance Ltd will be paid a management and underwriting fee, details of which are disclosed in section 8.3 of this Prospectus.

Peloton Capital Pty Ltd has has acted as co-manager to the Offer. Peloton Capital Pty Ltd will be paid a fee, details of which are disclosed in section 8.3 of this Prospectus.

McCullough Robertson has acted as legal adviser to the Company in relation to the Offer and has been involved in undertaking due diligence enquiries and providing legal advice on the Offer. McCullough Robertson will be paid an amount of \$140,000 (GST exclusive) for these services.

Grant Thornton Corporate Finance Pty Ltd has acted as Investigating Accountant to the Offer and has prepared the Investigating Accountant's Report in section 6 and performed work on due diligence enquiries. Grant Thornton Corporate Finance Pty Ltd will be paid an estimated fee of \$20,000 for these services. Further amounts may be paid to Grant Thornton Corporate Finance Pty Ltd in accordance with their normal time-based charges.

Grant Thornton Audit Pty Ltd has acted as Independent Auditor to the Company. Grant Thornton Audit Pty Ltd will be paid an estimated fee of \$44,000 (GST exclusive) for the audit of the financial report for the years ended 30 June 2012, 30 June 2013 and 30 June 2014. Further amounts may be paid to Grant Thornton Audit Pty Ltd in accordance with their normal time-based charges.

Pharmaceutical Patent Attorneys, LLC has prepared the Intellectual Property Report on behalf of the Company. Pharmaceutical Patent Attorneys, LLC will be paid an estimated fee of USD25,000 for its work in connection with the Intellectual Property Report. Further amounts may be paid to Mr Pohl in accordance with his normal time-based charges.

# 10.7 Interests of Directors

Other than set out above or elsewhere in this Prospectus:

- (a) no Director or proposed Director of Anatara has, or has had in the two years before lodgement of this Prospectus, any interest in the formation or promotion of Anatara, or the Offer of Shares, or in any property proposed to be acquired by Anatara in connection with information or promotion of the Offer of the Shares; and
- (b) no amounts have been paid or agreed to be paid and no benefit has been given or agreed to be given, to any Director or proposed Director of Anatara either to induce him or her to become, or to qualify him or her as a Director, or otherwise for services rendered by him or her in connection with the promotion or formation of Anatara or the Offer of Shares

# Shareholdings

The Directors or their associates have a beneficial interest in the following Shares in the Company at the date of this Prospectus:

		CI II						
Director	Shareholder	Shares*						
Mel Bridges	Parma Corporation Pty Ltd ACN 057 992 462	5,596,730 Shares						
David Venables	David Venables	1,125,000 Shares						
lain Ross	lain Ross	1,225,000 Shares						
Tracie Ramsdale	Not applicable	None						
Jay Hetzel	Genetic Horizons Pty Ltd ACN 080 568 449 ATF JJ Hetzel Super Fund	404,495 Shares						
Tracey Mynott (former director)	Myeng Pty Ltd ACN 151 016 483	5,002,635 Shares						

<sup>\*</sup> Subject to shareholder approval of a 1:5 subdivision of Shares at a general meeting of the Company scheduled for 11 September 2014.

Accordingly, assuming the Directors do not take up Shares under the Offer, the Directors or their associates (together with Tracey Mynott) will have an aggregate voting power of 35.37% in the Company (following completion of the Offer).

The Directors reserve the right to apply for further Shares under the Offer.

# Transactions with related parties

Except as otherwise set out in sections 8 and 10, there are currently no arrangements between Anatara and its Directors, or other related parties.

# Payments to Directors

The constitution of Anatara provides that the Directors may be paid, as remuneration for their services, a sum set from time to time by Anatara's Shareholders in general meeting, with that sum to be divided among the Directors as they agree.

The maximum aggregate amount for payment to the Directors is \$500,000 per annum<sup>16</sup>. The current fees for each non-executive director is \$50,000 per annum (plus a further \$5,000 per annum for acting as chair of a Board committee) and the fee for the Chairman is \$80,000 per annum.

# 10.8 Expenses of the Offer

The total estimated expenses of the Offer payable by the Company including ASX and ASIC fees, underwriting fees, accounting fees, legal fees, share registry fees, printing costs, public relations costs and other miscellaneous expenses are estimated to be approximately \$811,000.

# 10.9 Electronic Prospectus

16

This Prospectus is available in electronic form at http://anataralifesciences.com/. Any person receiving this Prospectus electronically will, on request, be sent a paper copy of the Prospectus by Anatara free of charge during the period of the Offer.

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

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

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

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

# 10.10 Privacy

When applying for Shares in the Company, Applicants will be asked to provide personal information to Anatara directly, and through the share registry, such as name, address, telephone and fax numbers, tax file number and account details. The Company and the share registry collect, hold and use that personal information to assess Applications, provide facilities and services to Applicants and undertake administration. Access to information may be disclosed by the Company to its agents and service providers on the basis that they deal with the information under the *Privacy Act 1988* (Cth). If the personal information provided is incomplete or inaccurate applications may not be processed. The Company's privacy policy sets out how Applicants may request access to and correction of their personal information held by or on behalf of the Company (by contacting the share registry), how Applicants can complain about privacy related matters and how the Company responds to complaints.

# 10.11 Authorisation

This Prospectus is issued by the Company. Each Director has consented to the lodgement of the Prospectus with ASIC.

Dated 4 September 2014

Dr Mel Bridges

Chairman



Chapter 11

# Glossary

Applicant	a person or entity who submits an	Directors	the directors of the Company.
	Application Form.	EMA	European Medicines Agency.
Application Form	an application form attached to this Prospectus.	Existing Shareholders	the holders of Shares before the date of this Prospectus.
Application Money	the money received by the Company under the Offer, being	FCR	feed conversion ratio.
	the Offer Price multiplied by the number of Shares applied for.	FDA	the US Food and Drug Administration.
APVMA	Australian Pesticides and Veterinary	GRAS	generally regarded as safe.
	Medicines Authority.	IBD	inflammatory bowel disease.
ASIC	Australian Securities and Investments Commission.	IBS	irritable bowel syndrome.
ASX	ASX Limited ACN 008 624 691 or the securities exchange operated	INAD	investigational animal drug application.
	by it (as the case requires).	Lead Manager and	Wilson HTM Corporate Finance Ltd
ASX Settlement	ASX Settlement Pty Ltd ACN 008 504 532.	Underwriter	ACN 057 547 323.
ASX	the ASX Settlement Operating	Listing Rules	the listing rules of ASX.
Settlement Operating	Rules, being the operating rules of the Settlement Facility for the	Offer	the offer of Shares under this Prospectus.
Rules	purposes of the Corporations Act.	Offer Price	\$0.50 per Share.
Board	the board of directors of the Company.	PHRU	pig health and research unit.
cAMP	adenosine 3', 5' – cyclic monophosphate.	Prophylactic	a medicine or course of action used to prevent a disease.
cGMP	guanosine 3', 5' – cyclic	Prospectus	this prospectus.
	monophosphate.	Sarantis	Sarantis Pty Ltd ACN 117 683 084.
CHESS	Clearing House Electronic Subregister System, operated by	Settlement Facility	has the meaning specified in the ASX Settlement Operating Rules.
	ASX Settlement.	Shareholders	holders of shares in Anatara.
Closing Date	the date on which the Offer closes, as stated in section 1, or another	Shares	fully paid ordinary shares in Anatara.
	date nominated by the Company in	SME	small and medium-sized enterprise.
	consultation with the Lead Manager and Underwriter.	suckers	unweaned piglets.
Company or Anatara	Anatara Lifesciences Limited ACN 145 239 872.	TGA	the Therapeutic Goods Administration.
Constitution	the constitution of Anatara.	Us or we	the Company.
Corporations	Corporations Act 2001 (Cth).	weaners	just weaned piglets
Act		WHO	the World Health Organisation.
CRC	Cooperative Research Centre.	You	the investors under this Prospectus.
CVM	Committee for Veterinary Medicines.	ZnO	zinc oxide.
DEPI	Department of Environment and		

Primary Industries.



**Anatara Lifesciences Limited** ABN 41 145 239 872



# **Application Form**

#### Offer closes 5.00pm (AEST) on 3rd October 2014

prospectus ("Prospectus") lodged with the Australian Securities and Investments Commission on 4th September 2014 (or any supplementary or replacement propsectus).

This Application Form relates to the Offer by Anatara Lifesciences Limited (the "Company") of fully paid ordinary shares ("Shares") in the Company, made under the

This Application Form is important. If you are in doubt as to how to deal with it, please contact your financial or other professional adviser. You should read the entire Prospectus carefully before completing this Application Form. To meet the requirements of the Corporations Act, this Application Form must not be distributed unless included in, or accompanied by, the Prospectus. Capitalised terms have the meaning given to them in the Prospectus.

#### STEP 1

#### Shares applied for

Enter the number of Shares you wish to apply for. The Application must be for a minimum of 4,000 Shares (A\$2,000). Applications for greater than 4,000 Shares must be in multiples of 1,000 Shares (A\$500). Enter the amount of the Application Monies. To calculate this amount, multiply the number of Shares applied for by the offer price which is A\$0.50.

#### STEP 2 Applicant name(s) and postal address

Enter the full name you wish to appear on the confirmation statement. This must be either your own name or the name of a company. Up to three joint applicants may register. You should refer to the table overleaf for the correct forms of registrable title(s). Applications using the wrong form of names may be rejected. CHESS participants should complete their name identically to that presently registered in CHESS. Enter your postal address for all correspondence. All communications to you from the Share Registry will be mailed to the person(s) and address as shown. For joint applicants, only one address can be entered. Enter your contact name and telephone number. This information may be used to communicate other matters to you subject to the Company's privacy statement. This is not compulsory but will assist us if we need to contact you.

#### STEP 3 **CHESS holdings only**

The Company will apply to ASX for Shares to participate in CHESS, operated by ASX Settlement Pty Limited, a wholly owned subsidiary of ASX. In CHESS, the Company will operate an electronic CHESS subregister of shareholdings and an electronic issuer sponsored subregister of shareholdings.

Together, the two subregisters will make up the Company's principal register of Shares. The Company will not be issuing certificates to applicants in respect of

If you are a CHESS participant (or are sponsored by a CHESS participant) and you wish to hold Shares allotted to you under this Application on the CHESS subregister, enter your CHESS HIN.

Otherwise, leave the section blank and on allotment you will be sponsored by the Company and a "Securityholder Reference Number" ("SRN") will be allocated to

Please note that if you supply a CHESS HIN but the name and address details on your Application Form do not correspond exactly with the registration details held at CHESS, your Application will be deemed to be made without the CHESS HIN, and any Shares issued will be held on the issuer sponsored subregister.

#### STEP 4 **Application payment**

Need assistance?

1300 850 505

Please return your completed form to:

Computershare Investor Services Pty Limited

+61 3 9415 4000

Applicants who received this Offer from their broker

must return their Application Form and Application

**Phone** 

(within Australia)

GPO Box 52

(outside Australia)

Melbourne Victoria 3001

Monies back to their broker.

Unless received from their broker, Applicants under the Offer must lodge their Application Form and Application Monies with the Share Registry. Any cheque must be made payable to "Anatara - Share Offer".

Applicants who received this Offer from their broker must return their Application Form and Application Monies back to their broker. Any cheque must be made payable to the broker.

Cheque(s) or bank draft(s) must be in Australian dollars, drawn on an Australian branch of an Australian bank, and must be crossed 'Not Negotiable'.

#### Lodgement instructions

There is no maximum value of Shares that may be applied for under the Offer. The Company may determine a person to be eligible to participate in the Offer.

The Offer opens at 9.00 am (AEST) on 18 September 2014 and is expected to close at 5.00 pm (AEST) on 3 October 2014. The Company and the Lead Manager may elect to extend the Offer or any part of it, or accept late Applications either generally or in particular cases. The Offer, or any part of it, may be closed at any earlier date and time, without further notice. Applicants are therefore encouraged to submit their Applications as early as possible.

#### **Privacy Statement**

Personal information is collected on this form by Computershare Investor Services Pty Limited (CIS), as Share Registry for the Company for the purpose of maintaining registers of Shares and facilitating payments and other corporate actions and communications. Your personal information may be disclosed to related bodies corporate of CIS, to external service companies such as print or mail service providers, or as otherwise required or permitted by law. If you would like details of your personal information held by CIS, or you would like to correct information that is inaccurate, incorrect or out of date, please contact CIS. In accordance with the Corporations Act, you may be sent material (including marketing material) approved by the Company in addition to general corporate communications. You may elect not to receive marketing material by contacting CIS. You can contact CIS using the details provided on the front of this Application Form or e-mail privacy@computershare.com.au.

# Offer Application Form

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Acceptance of By returning this Application - you declare that this Application - you declare - you de	on Form with you	r Applicatio			the Prospec	ctus and ti	he declara	ations/state	ments																rospectus) is

- you represent and warrant that you have read and understood the Prospectus and that you acknowledge the matters, and make the warranties and representations, contained in the Prospectus and this Application Form;
- you declare that all details and statements made are complete and accurate;
- you declare that each applicant, if a natural person, is at least 18 years old;
   you declare that you are located in Australia or New Zealand and are not acting for the account or benefit of any person
- you represent and warrant that the law of any other place does not prohibit you from being given the Prospectus and any supplementary or replacement prospectus or making an Application on this Application Form;
- you provide authorisation to be registered as the holder of Shares issued to you and agree to be bound by the Constitution and the Prospectus:
- you apply for the number of Shares set out on or determined in accordance with this Application Form and agree to be issued or transferred such number of Shares, a lesser number or none;
- situation or particular needs and that the investment performance of shares is not guaranteed by the Company;
- your Application to acquire Shares is irrevocable and may not be varied or withdrawn except as allowed by law,
   you acknowledge that an Application may be rejected without giving any reason, including where this Application Form is not properly completed or where a cheque submitted with this Application Form is dishonoured or for the wrong amount
- and you authorise the Company to complete or correct this Application Form; and you acknowledge that if you are not issued any Shares or you are issued fewer Shares than the number that you applied and paid for as a result of a scale back, all or some of your Application Monies (as applicable) will be refunded to you (without interest) in accordance with the Corporations Act.

#### Correct forms of registrable titles

Applications must be made in the name(s) of natural persons, companies or other legal entities in accordance with the Corporations Act. At least one full given name and surname is required for each natural person. The name of the beneficial owner or any other registrable name may be included by way of an account designation or completed as described in the correct forms of registrable title(s) below.

Type of investor	Correct form of registration	Incorrect form of registration
Individual - Use given name(s) in full, not initials	Mr John Alfred Smith	J.A Smith
Joint - Use given name(s) in full, not initials	Mr John Alfred Smith & Mrs Janet Marie Smith	John Alfred & Janet Marie Smith
Company - Use company title, not abbreviations	ABC Pty Ltd	ABC P/L; ABC Co
Trusts - Use trustee(s) personal name(s)	Ms Penny Smith < Penny Smith Family A/C>	Penny Smith Family Trust
- Do not use the name of the trust		
Deceased Estates - Use executor(s) personal name(s)	Mr William Smith < Est John Smith A/C>	Estate of Late John Smith
- Do not use the name of the deceased		
Minor (a person under the age of 18)	Mr John Alfred Smith <peter a="" c="" smith=""></peter>	Peter Smith
- Use the name of a responsible adult with an appropriate designation		
Partnerships - Use partners personal name(s)	Mr John Smith & Mr William Smith	John Smith & Son
- Do not use the name of the partnership	<john &="" a="" c="" smith="" son=""></john>	
Clubs/Unincorporated Bodies/Business Names - Use office bearer(s) personal name(s)	Mrs Janet Smith	ABC Tennis Association
- Do not use the name of the club etc	<abc a="" association="" c="" tennis=""></abc>	
Superannuation Funds - Use the name of trustee of the fund	John Smith Pty Ltd <super a="" c="" fund=""></super>	John Smith Pty Ltd
- Do not use the name of the fund		Superannuation Fund



# Corporate directory

#### Company

Anatara Lifeciences Limited

433 Logan Road Stones Corner Brisbane, QLD 4120

www.anataralifesciences.com

#### **Directors**

Dr Mel Bridges

(Non-Executive Chairman)

**Dr David Venables**(Managing Director)

Mr Iain Ross

(Non-Executive Director)

Dr Tracie Ramsdale

(Non-Executive Director)

Dr Jay Hetzel

(Non-Executive Director)

#### **Company Secretary**

Mr Stephen Denaro

#### **Executives**

Dr David Venables

(Chief Executive Officer)

Dr Tracey Mynott

(Chief Scientific Officer)

Alan Dowling

(Group Accountant)

Hayley van der Meer

(Commercial Manager)

#### Share registry

Computershare Investor Services Pty

Limited

117 Victoria Street West End. QLD 4101

West End, QLD 4101

Tel: 1300 850 505 (within Australia) or +61 3 9415 4000 (outside Australia)

www.computershare.com.au

Lead Manager and Underwriter to the Offer

Wilson HTM Corporate Finance Ltd

Level 16, 357 Collins Street Melbourne, VIC 3000

www.wilsonhtm.com.au

#### Auditor

Grant Thornton Audit Pty Ltd

The Rialto, Level 30 525 Collins Street Melbourne, VIC 3000

www.grantthornton.com.au

#### **Investigating Accountant**

Grant Thornton Corporate Finance Pty Ltd

The Rialto, Level 30 525 Collins Street Melbourne, VIC 3000

www.grantthornton.com.au

#### Patent attorneys

Pharmaceutical Patent Attorneys, LLC

55 Madison Avenue, 4th floor Morristown, NJ 07960-7397 USA

www.LicensingLaw.Net

Dr Mark Egerton

Fisher Adams Kelly Level 29, 12 Creek Street Brisbane, QLD 4000

www. fisher a damskelly. com. au

#### Lawyers to the Offer

McCullough Robertson

Level 11, Central Plaza Two

66 Eagle Street

Brisbane, QLD 4000

www.mccullough.com.au



